DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 413, 495, and 512

[CMS–1833–P]

RIN 0938–AV45

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2026 Rates; Requirements for Quality Programs; and Other Policy Changes

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); update and make changes to requirements for certain quality programs; and make other policy-related changes.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 10, 2025.

ADDRESSES: In commenting, please refer to file code CMS–1833–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *https://www.regulations.gov*. Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1833–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1833–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov*, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Inpatient Critical Access Hospital (CAH) Issues.

Emily Lipkin, Jim Mildenberger and Hyeyoung Kim, *DAC@cms.hhs.gov*, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Lily Yuan, *NewTech@cms.hhs.gov*, New Technology Add-On Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov*, and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov*, MS–DRG Classifications Issues.

Radhika Puri, *Radhika.puri@cms.hhs.gov*, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov*, Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, *lang.le@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*, Hospital Readmissions Reduction Program—Measures Issues.

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Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov*, and Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, *elizabeth.goldstein@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Kristina Rabarison, *Kristina.Rabarison@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues.

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Jessica Warren, *jessica.warren@cms.hhs.gov*, and Lisa Marie Gomez, *LisaMarie.Gomez1@cms.hhs.gov*, Medicare Promoting Interoperability Program.

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CMMI_TEAM@cms.hhs.gov, Transforming Episode Accountability Model (TEAM).

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov*. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the commenter will take actions to harm an individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a

plain language summary of this proposed rule may be found at *https://www.regulations.gov/*.

Deregulation Request for Information (RFI): On January 31, 2025, President Trump issued Executive Order (E.O.) 14192 ''Unleashing Prosperity Through Deregulation,'' which states the Administration policy to significantly reduce the private expenditures required to comply with Federal regulations to secure America's economic prosperity and national security and the highest possible quality of life for each citizen. We would like public input on approaches and opportunities to streamline regulations and reduce administrative burdens on providers, suppliers, beneficiaries, and other interested parties participating in the Medicare program. CMS has made available an RFI at *https://www.cms.gov/medicare-regulatory-relief-rfi.* Please submit all comments in response to this RFI through the provided weblink.

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2026 proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2026 proposed rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1833–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact *Michael Treitel, DAC@cms.hhs.gov*.

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2026 IPPS/LTCH PPS proposed rule would make payment and policy changes under the Medicare inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it would make payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This proposed rule also would make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. We are also proposing changes relating to Medicare graduate medical education (GME) for teaching hospitals.

We are proposing several changes across pay for performance programs. In the Hospital Value-Based Purchasing (VBP) Program, we are proposing modifications to the Hospital-Level Total Hip Arthroplasty/Total Knee Arthroplasty (THA/TKA) Complications measure beginning with the FY 2033 program year. We are also providing notice of the technical update to the five National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) measures beginning with the FY 2028 program year, and the technical update to remove the COVID–19 exclusion from the six measures in the Clinical Outcomes domain beginning with the FY 2027 program year. Lastly, we provide previously and newly established performance standards for the FY 2028 through FY 2031 program years for the Hospital VBP Program. In the Hospital Acquired-Conditions (HAC) Reduction Program, we are also providing notice of the technical update to the five Centers for Disease Control National Control (CDC) NHSN healthcare-associated infection (HAI) measures. In the Hospital Readmissions Reduction Program, we are proposing to add Medicare Advantage (MA) beneficiaries to the six Hospital Readmissions Reduction Program (HRRP) measures and make corresponding administrative updates.

In the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), we are proposing to modify the public reporting requirements and remove three existing measures.

In the Hospital Inpatient Quality Reporting (IQR) Program, we are proposing to modify four existing quality measures and remove four existing measures.

We also are proposing to update and codify the Extraordinary Circumstances Exception (ECE) policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital in the Hospital IQR, Hospital Readmissions Reduction, PCHQR, HAC Reduction, and Hospital VBP Programs.

In the Medicare Promoting Interoperability Program, we are proposing to define the electronic health record (EHR) reporting period in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that calendar year for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program and to make corresponding revisions at 42 CFR 495.4. We are proposing to modify the Security Risk Analysis measure beginning with the EHR reporting period in CY 2026. We are proposing to modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides measure beginning with the EHR reporting period in CY 2026. We are proposing to add an optional bonus measure under the Public Health and Clinical Data Exchange objective for reporting data to a public health agency (PHA) using the Trusted Exchange Framework and Common Agreement (TEFCA) beginning with the EHR reporting period in CY 2026.

In the LTCH Quality Reporting Program (QRP), we are proposing to remove one item from the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) with respect to patients who have expired in the LTCH. We are also proposing to remove four Social Determinant of Health (SDOH) standardized patient assessment data elements from the LCDS. Next, we are proposing to amend the reconsideration request process in the LTCH QRP. Finally, we include Requests for Information (RFIs) on: (1) future measure concepts for the LTCH QRP; (2) revisions to the data submission deadlines for assessment data collected for the LTCH QRP; and (3) advancing digital quality measurement (dQM) in the LTCH QRP.

The Transforming Episode Accountability Model (TEAM), a mandatory alternative payment model that was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), aims to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft (CABG), lower extremity joint replacement (LEJR), major bowel procedure, surgical hip/femur fracture treatment (SHFFT), and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. In this proposed rule, we are proposing updates to TEAM that would modify policies affecting participation of new hospitals, quality measure and assessment, the construction of target prices, the removal of certain health reporting elements, the expansion of the Skilled

Nursing Facility (SNF) 3-Day Rule, and the removal of the Decarbonization and Resilience Initiative (DRI). Additionally, the policies in this proposed rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

Under various statutory authorities, we either discuss continued program implementation or propose to make changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2026 and subsequent fiscal years, and other policies and provisions included in this proposed rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Section 1814(l)(4) of the Act requires, beginning with FY 2015, that CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an EHR reporting period for a cost reporting period shall be paid 100 percent of reasonable costs rather than 101 percent of reasonable costs.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. Hospitals paid under the IPPS with approved GME programs are paid for the indirect costs of training residents in accordance with section 1886(d)(5)(B) of the Act.
- Section 1886(d)(5)(F) of the Act provides for additional Medicare IPPS payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. These payments are known as the Medicare disproportionate share hospital (DSH) adjustment. Section 1886(d)(5)(F) of the Act specifies the methods under which a hospital may qualify for the DSH payment adjustment.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(b)(3)(B)(ix) of the Act, which requires downward adjustments to the applicable percentage increase, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(n) of the Act, which establishes the requirements for an eligible hospital to be treated as a meaningful EHR user for an EHR reporting period for a payment year or, for purposes of subsection (b)(3)(B)(ix) of the Act, for a fiscal year.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value-Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for an additional uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act if subsection (r) did not apply (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act, in the absence of section 1886(r) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) the hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.
- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by 2 percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data on quality measures in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub.

L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.

- Section 1899B of the Act, which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program (CHIP) beneficiaries while reducing program expenditures.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this proposed rule. In general, these major provisions are being proposed as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this proposed rule is presented in section I.D. of the preamble of this proposed rule.

a. Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy

To help mitigate growing wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We also stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301 through 69308), we adopted an extension of the low wage index hospital policy and the related budget neutrality adjustment effective for at least three more years, beginning in FY 2025, in order for sufficient wage data from after the end of the COVID–19 Public Health Emergency to become available.

As discussed in section III.F.5. of the preamble of this proposed rule, on July 23, 2024, the Court of Appeals for the D.C. Circuit held that the Secretary lacked authority under section 1886(d)(3)(E) of the Act or under the ''adjustments'' language of section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020, and that the policy and related budget neutrality adjustment must be vacated. *Bridgeport Hosp.* v. *Becerra,* 108 F.4th 882, 887–91 & n.6 (D.C. Cir. 2024). After considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* in the FY 2025 IFC (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. In addition, we established an interim transition policy for hospitals significantly impacted by the removal of the FY 2025 low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act.

For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy and would no longer apply a low wage index budget neutrality factor to the standardized amounts. As discussed in section III.F.7. of the preamble of this proposed rule, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act to adopt a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy, that would be implemented in a budget neutral manner. This proposed transitional exception policy would apply to hospitals that benefitted from the FY 2024 low wage index hospital policy and would compare the hospital's proposed FY 2026 wage index to the hospital's FY 2024 wage index. If the hospital's proposed FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index, then the proposed transitional payment exception for FY 2026 for that hospital would be equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index. We proposed to make this policy budget neutral through an adjustment applied to the standardized amounts for all hospitals.

b. Proposed Update to the IPPS Labor-Related Share

As discussed in section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the 2018-based IPPS market basket to reflect a 2023 base year. In addition, using the cost category weights from the proposed 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we are proposing to use for discharges occurring on or after October 1, 2025. The proposed labor-related share of 66.0 percent is 1.6 percentage points lower than the current labor-related share of 67.6 percent. As discussed in section IVB.3. of the preamble of this proposed rule, this downward revision to the labor-related share is primarily the result of incorporating the more recent 2023 Medicare cost report data for Wages and Salaries, Employee Benefits, and Contract Labor costs. This is partially offset by an increase in the Professional Fees: Labor-Related cost weight.

c. Hospital Readmission Reduction Program

We are proposing to make changes to policies for the Hospital Readmissions Reduction Program, which was established under section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions. In this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing the following policies: (1) Refine all six readmission measures to add Medicare Advantage patient cohort data; (2) remove the COVID–19 diagnosed patients measure denominator exclusion from the all six readmission measures, beginning with the FY 2026 program year; (3) reduce the applicable period from 3-years to 2-years and update codified regulation language; (4) modify the diagnosis-related group (DRG) payment ratios in the payment adjustment formula to include MA beneficiaries; and (5) update and codify the ECE policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital.

d. Hospital Acquired Condition (HAC) Reduction Program

Section 1886(p) of the Act establishes the HAC Reduction Program under which payments to applicable hospitals are adjusted to provide an incentive to

reduce hospital-acquired conditions. In this FY 2026 IPPS/LTCH PPS proposed rule, we are making a technical update to the NHSN Healthcare Associated Infection (HAI) measures baseline. We are also proposing to update and codify the ECE policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital.

e. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing modifications to the THA/TKA Complications measure beginning with the FY 2033 program year. We are also providing notice of the technical update to remove the COVID–19 exclusion from the six measures in the Clinical Outcomes domain beginning with the FY 2027 program year and the technical update to the five NHSN Healthcare Associated Infection (HAI) measures beginning with the FY 2028 program year. We also are proposing to update and codify the ECE policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital. We are also proposing to remove the Program's Health Equity Adjustment. Lastly, we provide previously and newly established performance standards for the FY 2028 through FY 2031 program years for the Hospital VBP Program.

e. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase. In this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing several changes to the Hospital IQR Program. We are proposing refinements to four measures currently in the Hospital IQR Program measure set: (1) Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) beginning with the April 1, 2023–March 30, 2025 Reporting Period/2027 Payment Determination; (2) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity beginning with the July 1, 2023–June 30, 2025 Reporting Period/2027 Payment Determination; (3) the Hybrid Hospital-Wide Readmission (HWR) measure beginning with the July 1, 2025, through June 30, 2026 Reporting Period/FY 2028 Payment Determination; and (4) the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the July 1, 2025, through June 30, 2026 Reporting Period/FY 2028 Payment Determination. We are also proposing to remove four measures: (1) the Hospital Commitment to Health Equity measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) the COVID–19 Vaccination Coverage among HCP measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) the Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination; and (4) the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. We are proposing to update and codify the ECE policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital. Additionally, we seek comments regarding measure concepts related to well-being and nutrition for future consideration. We also seek comments on the path forward for digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR).

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

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. In the FY 2026 IPPS/LTCH PPS proposed rule, we are proposing to publicly report PCH data on both the Provider Data Catalog and on Care Compare and to make corresponding changes to regulatory text to replace references to ''Provider Data Catalog'' with ''CMS website''. We are also proposing to remove the (1) Hospital Commitment to Health Equity, (2) the Screening for Social Drivers of Health measure; and (3) the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. Lastly, we are proposing to update and codify the ECE policy to clarify that CMS has the discretion to grant an extension in response to an ECE request from a hospital.

g. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In the LTCH QRP, we are proposing to remove five items from the LCDS. We are also proposing to amend the reconsideration request process in the LTCH QRP. Finally, we include Requests for Information (RFIs) on: (1) future measure concepts for the LTCH QRP; (2) revisions to the data submission deadlines for assessment data collected for the LTCH QRP; and (3) advancing digital quality measurement (dQM) in the LTCH QRP.

h. Medicare Promoting Interoperability Program

Under sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act, respectively, eligible hospitals and CAHs are required to submit data in accordance with section 1886(n) to successfully demonstrate meaningful use of CEHRT for an EHR reporting period to avoid a downward payment adjustment under Medicare for the associated fiscal year. We are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing: (1) to amend the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4 for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program to define the EHR reporting period in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that calendar year; (2) to modify the Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management in addition to the existing measure requirement to attest ''yes'' to having conducted security risk analysis, beginning with the EHR reporting period in CY 2026; (3) to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using the eight SAFER Guides published in January 2025, beginning with the EHR reporting period in CY 2026; and (4) to add an optional bonus measure to the Public Health and Clinical Data Exchange objective for eligible hospitals and CAHs that submit health information to a public health agency (PHA) using the Trusted Exchange Framework and Common Agreement™ (TEFCA), and consistent with other measure requirements, beginning with the EHR reporting period in CY 2026.

i. Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this proposed rule, we propose changes to the Transforming Episode Accountability Model (TEAM). TEAM is a 5-year mandatory model that will be tested under the authority of section 1115A of the Act, beginning on January 1, 2026, and ending on December 31, 2030. We are proposing changes to multiple areas of the model, including: (1) a limited deferment period for certain hospitals; (2) addressing the expiration of the Medicare Dependent Hospital program; (3) adding the Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO–PM); (4) applying a neutral quality measure score for TEAM participants with insufficient quality data; (5) a methodology to construct target prices when there are coding changes; (6) reconstructing the normalization factor and prospective trend factor; (7) replacing the Area Deprivation Index (ADI) with the Community Deprivation Index (CDI); (8) using a 180-day lookback period and Hierarchical Condition Categories (HCC) version 28 for beneficiary risk adjustment; (9) aligning the date range used for episode attribution; (10) removing health equity plans and health related social needs data reporting; (11) expanding the Skilled Nursing Facility (SNF) 3-day rule waiver; and (12) removing the Decarbonization and Resilience Initiative (DRI).

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major provisions described in section I.A.2. of the preamble of this proposed rule.

Provision description	Description of costs, transfers, savings, and benefits
Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy.	As discussed in section III.F.7. of the preamble of this proposed rule, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act to adopt a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy, that would be implemented in a budget neutral manner. We proposed to make this policy budget neutral through an adjustment applied to the standardized amounts for all hospitals.
Proposed Update to the IPPS Labor-Related Share.	As discussed in section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the 2018-based IPPS market basket to reflect a 2023 base year. In addition, using the cost category weights from the proposed 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we are proposing to use for discharges occurring on or after October 1, 2025. The proposed labor-related share of 66.0 percent is 1.6 percentage points lower than the current labor-related share of 67.6 percent. This proposed change is budget neutral.
Proposed Update to the IPPS Payment Rates and Other Payment Policies.	As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience an increase of approximately $4.0 billion in FY 2026, primarily driven by the changes in FY 2026 operating payments, uncompensated care 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 October 1, 2025.
Proposed Update to the LTCH PPS Payment Rates and Other Payment Policies.	As discussed in Appendix A of this proposed rule, based on the best available data for the 328 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present 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 2026, would result in an estimated increase in payments in FY 2026 of approximately $61 million.
Changes to the Hospital Readmission Reduction Program.	We estimated that our changes for the Hospital Readmissions Reduction Program will result in no financial impact for the FY 2027 payment determination or subsequent years.
Changes to the Value-Based Incentive Payments under the Hospital VBP Program.	We estimated that there will be no net financial impact to the Hospital VBP Program for the FY 2026 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 the FY 2026 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2026 discharges is approximately $1.7 billion.
Proposed Changes to the HAC Reduction Program.	We estimated that our changes for the HAC Reduction Program will result in no financial impact for the FY 2027 payment determination or subsequent years.
Changes to the Hospital IQR Program.	Across 3,050 IPPS hospitals, we estimated that our changes for the Hospital IQR Program will result in a maximum decrease of 660,577 hours and $18,008,959 to the information collection burden for the FY 2026 payment determination or subsequent years.
Proposed Changes to the PCHQR Program.	Across 11 PCHs, we estimated that our changes for the PCHQR Program will result in a maximum decrease of 153 hours and $7,765 to the information collection burden for the FY 2026 program year or subsequent years.
Changes to the LTCH QRP	Across 330 LTCHs, we estimated that our proposed changes for the FY 2026 LTCH QRP would result in a total information collection burden increase of 4 hours and $187.60 associated with updates to our reconsideration policy. We estimated that our proposed changes for the FY 2028 LTCH QRP would result in a decrease of 2,633.51 hours associated with our policies and updated burden estimates and a total cost decrease of approximately $180,016.80.
Changes to the Medicare Promoting Interoperability Program.	Across 4,550 eligible hospitals and CAHs, we estimated that our changes for the Medicare Promoting Interoperability Program will not result in a change to the information collection burden for the EHR reporting period in CY 2026 and subsequent years.
Transforming Episode Accountability Model (TEAM).	We estimate for the TEAM proposals included in this proposed rule that there would be no significant change from the savings estimate in the FY 2025 IPPS/LTCH PPS final rule. Therefore, we estimate testing TEAM would result in saving the Medicare program $481 million across the 5 performance years.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment (COLA) factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income

patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for an additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

With the recent enactment of section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025, under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through September 30, 2025. For discharges occurring on or after October 1, 2007, but before October 1, 2025, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years). As section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025 only, beginning on October 1, 2025, the MDH program will no longer be in effect absent a change in law. Because the MDH program is not authorized by statute beyond September 30, 2025, beginning October 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.

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); Inpatient psychiatric hospitals (IPF) and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

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

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals. The additional payment is based on the indirect medical education (IME) adjustment factor, which is calculated using a hospital's ratio of residents to beds and a multiplier, which is set by Congress. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. The regulations regarding the indirect medical education (IME) adjustment are located at 42 CFR 412.105.

C. Summary of Provisions of Recent Legislation That Would Be Implemented in This Proposed Rule

1. The Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4)

Section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended through FY 2025 the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals that had been in effect for FYs 2019 through 2024. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2025, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through September 30, 2025, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through FY 2025 (that is, through September 30, 2025).

D. Summary of the Proposed Provisions

In this proposed rule, we set forth proposed payment and policy changes to the Medicare IPPS for FY 2026 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2026.

The following is a general summary of the changes that we are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2026.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2026 status of new technologies approved for add-on payments for FY 2025, a presentation of our evaluation and analysis of the FY 2026 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) Public Law 108–173, obtained in a town hall meeting for applications not submitted under an alternative pathway), and a discussion of the proposed status of FY 2026 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule, we propose revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2026 wage index update using wage data from cost reporting periods beginning in FY 2022.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2026 based on the 2022 Occupational Mix Survey.
- Proposed application of the rural, imputed and frontier State floors, and proposed transition for the discontinuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2026 based on commuting patterns of

hospital employees who reside in a county and work in a different area with a higher wage index.

- Proposed labor-related share for applying the FY 2026 wage index.

3. Proposed Rebasing and Revising of the IPPS Market Baskets

In section IV. of the preamble of this proposed rule, we propose to rebase and revise the IPPS market baskets to reflect a 2023 base year. In section IV.B.3. of the preamble of this proposed rule, using the cost category weights from the proposed 2023-based IPPS market basket, we propose to use a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000.

4. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2026

In section V. of the preamble of this proposed rule, we discuss the following:

- Proposed calculation of Factor 1 and Factor 2 of the uncompensated care payment methodology.
- Proposed methodological approach for determining Factor 3 of the uncompensated care payment for FY 2026, which is the same methodology that was used for FY 2025.
- Proposed methodological approach for determining the amount of interim uncompensated care payments using the average of the most recent 3 years of discharge data.

5. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section VI. of the preamble of this proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital market basket update for FY 2026.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed conforming amendments to reflect the statutory extension of the temporary changes to the low-volume hospital payment adjustment through September 30, 2025.
- Proposed conforming amendments to reflect the statutory extension of the MDH program through September 30, 2025.
- A direct graduate medical education (GME) and indirect medical education (IME) policy proposal for calculating full-time equivalent counts and caps for cost reporting periods other than 12 months; and a notice of closure of two teaching hospitals and opportunities to apply for available slots.
- Proposed nursing and allied health education (NAHE) program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CY 2024; and proposed regulatory changes regarding the calculation of net cost of NAHE.
- Proposed update to and revision to the payment adjustment for certain immunotherapy cases.
- Proposed changes to the requirements of the Hospital Readmissions Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2026 Hospital Readmissions Reduction Program.
- Proposed changes to the requirements of the Hospital Value-Based Purchasing Program—Updating the proposed estimate of the financial impacts for the FY 2026 Hospital Value-Based Purchasing Program.
- Proposed changes to the requirements of the Hospital-Acquired Conditions Reduction Program—Updating the proposed estimate of the financial impacts for the FY 2026 Hospital-Acquired Conditions Reduction Program.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2025.

6. Proposed FY 2026 Policy Governing the IPPS for Capital-Related Costs

In section VII. of the preamble of the proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2025.

7. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VIII. of the preamble of the proposed rule, we discuss the following:

- Proposed changes to payments to certain excluded hospitals for FY 2026.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

8. Proposed Changes to the LTCH PPS

In section IX. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2026.

9. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section X. of the preamble of the proposed rule, we addressed the following:

- Solicitation of comment on adopting measures across the hospital quality reporting and value-based purchasing programs which capture more forms of unplanned post-acute care and encourage hospitals to improve discharge processes.
- Proposed changes to the requirements for the Hospital IQR Program.
- Proposed changes to the requirements for the PCHQR Program.
- Proposed changes to the requirements for the LTCH QRP, and requests for information on future measure concepts, revisions to the data submission deadlines for assessment data collection, and advancing digital quality measurement (dQM) in the LTCH QRP.
- Proposed changes to requirements pertaining to eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

10. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section XI. of the preamble of the proposed rule includes proposed changes to TEAM that would affect participation, quality measure and assessment, pricing methodology, health data reporting, waivers of Medicare Program requirements, and the Decarbonization and Resilience Initiative.

11. Other Provisions of the Proposed Rule

Section XII.A. of the preamble of the proposed rule includes our discussion of the MedPAC Recommendations.

Section XII.B. of the preamble of the proposed rule includes a descriptive listing of the public use files associated with this proposed rule.

Section XIII. of the preamble of the proposed rule includes the collection of information requirements for entities based on our proposals.

Section XIV. of the preamble of the proposed rule includes information regarding our responses to public comments.

12. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the

proposed FY 2026 prospective payment rates for operating costs and capital-related costs for acute care hospitals, including cost-of-living adjustment (COLA) factors for IPPS hospitals located in Alaska and Hawaii. We are proposing to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum of the proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2026 for certain hospitals excluded from the IPPS.

13. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2026 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2026. We are proposing to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

14. Impact Analysis

In Appendix A of this proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, LTCHs, and other entities.

15. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2026 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

16. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2025 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in Appendix B of this proposed rule. For further information relating specifically to the MedPAC March 2024 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov*.

II. Proposed Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2025 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085; 83 FR 41158 through 41258; 84 FR 42058 through 42165; 85 FR 58445 through 58596; 86 FR 44795 through 44961; 87 FR 48800 through 48891; 88 FR 58654 through 58787; and 89 FR 69000 through 69109, respectively).

For discussion regarding our previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48799 through 48800).

C. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed FY 2026 MS–DRG Updates

a. International Classification of Diseases, 10th Revision (ICD–10)

Providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting.

b. Basis for Proposed FY 2026 MS–DRG Updates

The deadline for interested parties to submit MS–DRG classification change requests for FY 2026 was October 20, 2024. All requests are submitted to CMS via Medicare Electronic Application Request Information System™ (MEARIS™), accessed at *https://mearis.cms.gov.* Specifically, as indicated on the MEARIS™ site, the MS–DRG classification change request process may be used for requests to create, modify, or delete MS–DRGs,

change ICD–10–CM diagnosis code(s) severity level designations, change ICD–10–PCS procedure code(s) Operating Room (O.R.) designations, or to review the CC Exclusions List or the surgical hierarchy.

Within MEARIS™, we have built in several resources to support users, including a ''Resources'' section available at *https://mearis.cms.gov/public/resources* with technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'', also at the bottom of the MEARIS™ site.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the request for MS–DRG classification changes to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA) of 1995 and approved under OMB control number 0938–1431 and has an expiration date of 09/30/2025.

Interested parties should submit any MS–DRG classification change requests, including any comments and suggestions for FY 2027 consideration by October 20, 2025 via MEARIS™ at: *https://mearis.cms.gov/public/home.*

As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. We further note that we also received recommendations and feedback that did not involve requests to create, modify, or delete MS–DRGs, change code designations, or to review the CC Exclusions List or the surgical hierarchy, which therefore are not summarized or addressed in this discussion of the MS–DRG classification change requests received for FY 2026.

We received requests to modify the GROUPER logic in several MS–DRGs under MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) and a request to modify the GROUPER logic for MS–DRG 794 (Neonate with Other Significant Problems) under MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period). Specifically, we received requests to—

- Modify the GROUPER logic of new MS–DRG 426 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device), new MS–DRG 427 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical with CC), and new MS–DRG 428 (Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical without CC/MCC); new MS–DRG 447 (Multiple Level Spinal Fusion Except Cervical with MCC or Custom-Made Anatomically Designed Interbody Fusion Device) and new MS–DRG 448 (Multiple Level Spinal Fusion Except Cervical without MCC); and MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with an ICD–10–PCS code that describes fusion of a sacroiliac joint using an internal fixation device with tulip connector or insertion of an internal fixation device with tulip connector into a pelvic bone with another spinal fusion procedure code that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG.
- Modify the GROUPER logic of MS–DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively); and MS–DRGs 492, 493, and 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with MCC, with CC, and without CC/MCC, respectively) by reassigning cases with ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) that currently map to the lower severity level MS–DRG to the highest severity level (with MCC) MS–DRG.
- Modify the GROUPER logic of MS–DRG 794. The requestor recommended that ICD–10–CM diagnosis codes P09.6 (Abnormal findings on neonatal screening for neonatal hearing loss), Z13.0 (Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism), Z82.5 (Family history of asthma and other chronic lower respiratory diseases) and Z82.79 (Family history of other congenital malformations, deformations and chromosomal abnormalities), be added to the MS–DRG 795 (Normal Newborn) ''only secondary diagnosis'' list so that they would result in assignment to MS–DRG 795 when coded with a principal diagnosis code from ICD–10–CM category Z38 (Liveborn infants according to place of birth and type of delivery) instead of MS–DRG 794.

We appreciate the submissions and related analyses provided by the requestors for our consideration as we review MS–DRG classification change requests for FY 2026; however, we note the complexity of the GROUPER logic for these MS–DRGs in connection with these requests requires more extensive analyses to identify and evaluate all the data relevant to assessing these potential modifications. Specifically, we note that MS–DRGs 426, 427, 428, 447, and 448 recently became effective October 1, 2024 (FY 2025) and as discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 35982 through 35983) and final rule (89 FR 69049 through 69053) in consideration of any future modifications to the current structure of the logic for case assignment to MS–DRGs 456, 457, and 458 we noted that additional analysis would be needed because the logic is also defined by diagnosis code logic as well as extensive fusions. We also note that, as discussed further in section II.C.5.c. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we identified additional inconsistencies related to the diagnosis code logic for MS–DRGs 456, 457, and 458 for which we are proposing modifications. In addition, analyzing the impact of restructuring the logic in these MS–DRGs with respect to procedure codes describing fusion of a sacroiliac joint using an internal fixation device with tulip connector necessitates evaluating the impact across numerous other MS–DRGs in MDC 08, as well as MS–DRG 028 (Spinal Procedures with MCC), MS–DRG 029 (Spinal Procedures with CC or Spinal Neurostimulators), and MS–DRG 030 (Spinal Procedures without CC/MCC) under MDC 01 (Diseases and Disorders of the Nervous System) since the procedure codes describing fusion of a sacroiliac joint using an internal fixation device with tulip connector also map to these MS–DRGs.

With respect to the request to reassign cases reporting procedure code XW0V0P7 from the lower severity level to the highest (with MCC) severity level in the previously listed MS–DRGs, we note that the procedure to insert a bone void filler is designated as a non-operating room (Non-O.R.) procedure and believe that the key factor that

would contribute to resource utilization in these cases is the fact that the patients have an infection(s) which require additional resources. As discussed in section II.C.5.a. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we also received an MS–DRG request related to cases reporting a hip or knee procedure with a diagnosis of periprosthetic joint infection (PJI) in MS–DRGs 463, 464, and 465. In our review of the claims data to address that request we noted that a subset of the cases also reported procedure code XW0V0P7. Consistent with our established process, we must also consider if there are additional factors, such as the severity of illness with other secondary CC/MCC conditions reported and any other O.R. procedures or services provided, such as mechanical ventilation, that may be contributing to the consumption of resources for these cases. For these reasons and those previously described, we believe additional time is needed to review and evaluate potential extensive modifications to the structure of these MS–DRGs.

With respect to the request to modify the GROUPER logic of MS–DRG 794, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69061 through 69065), we acknowledged that MS–DRG 794 utilizes ''fall-through'' logic, meaning if a diagnosis code is not assigned to any of the other MS–DRGs, then assignment ''falls-through'' to MS–DRG 794. As discussed in the FY 2025 IPPS/LTCH PPS rule, we stated we have started to examine the GROUPER logic that would determine the assignment of cases to the MS–DRGs in MDC 15, including MS–DRGs 794 and 795, to determine where further refinements could potentially be made to better account for differences in clinical complexity and resource utilization. However, as we have noted in prior rulemaking (72 FR 47152), we stated we cannot adopt the same approach to refine the newborn MS–DRGs because of the extremely low volume of Medicare patients there are in these MS–DRGs. We believe it is appropriate to consider the request to add ICD–10–CM diagnosis codes P09.6 (Abnormal findings on neonatal screening for neonatal hearing loss), Z13.0 (Encounter for screening for diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism), Z82.5 (Family history of asthma and other chronic lower respiratory diseases) and Z82.79 (Family history of other congenital malformations, deformations and chromosomal abnormalities) to the MS–DRG 795 (Normal Newborn) ''only secondary diagnosis'' list in connection with our continued examination of the GROUPER logic that would determine the assignment of cases to the MS–DRGs in MDC 15 in future rulemaking, rather than proposing to change the MS–DRG assignment of individual ICD–10–CM diagnosis codes at this time. Additional time is needed to fully and accurately evaluate cases currently grouping to the MS–DRGs in MDC 15 to consider if restructuring the current MS–DRGs would better recognize the clinical distinctions of these patient populations.

We will continue to monitor the data as we consider these issues in connection with future rulemaking. As we continue the analysis of the claims data with respect to MS–DRGs in MDC 08, MDC 01, and MDC 15, we welcome public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs. Feedback and other suggestions may be directed to MEARIS™ at: *https://mearis.cms.gov/public/home.* As noted, interested parties should submit any MS–DRG classification change requests, including any comments and suggestions for FY 2027 consideration by October 20, 2025 via MEARIS™ at: *https://mearis.cms.gov/public/home.*

As we did for the FY 2025 IPPS/LTCH PPS proposed rule, for this FY 2026 IPPS/LTCH PPS proposed rule we are providing a test version of the ICD–10 MS–DRG GROUPER Software, Version 43, so that the public can better analyze and understand the impact of the proposals included in this FY 2026 IPPS/LTCH PPS proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2026. Therefore, it includes the new diagnosis and procedure codes that are effective for FY 2026 as reflected in Table 6A.—New Diagnosis Codes—FY 2026 and Table 6B.—New Procedure Codes—FY 2026 associated with this FY 2026 IPPS/LTCH PPS proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2026 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2026 and Table 6D.—Invalid Procedure Codes—FY 2026 associated with this FY 2026 IPPS/LTCH PPS proposed rule. These tables are not published in the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule. Because the diagnosis and procedure codes no longer valid for FY 2026 are not reflected in the test software, we are making available a supplemental file in Table 6P.1a that includes the mapped Version 43 FY 2026 ICD–10–CM codes and the deleted Version 42 FY 2025 ICD–10–CM codes and Table 6P.1b that includes the mapped Version 43 FY 2026 ICD–10–PCS codes and the deleted Version 42.1 FY 2025 ICD–10–PCS codes that should be used for testing purposes with users' available claims data. Therefore, users will have access to the test software allowing them to build case examples that reflect the proposals included in this FY 2026 IPPS/LTCH PPS proposed rule. In addition, users will be able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 43 that contains the documentation for proposed FY 2026 ICD–10 MS–DRG GROUPER Version 43 logic changes and will also be able to view a draft version of the Definitions of Medicare Code Edits (MCE) Manual to review any changes that will become effective October 1 for FY 2026. As a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, any further changes to the MCE will be reflected in the finalized Definitions of Medicare Code Edits (MCE) Manual, made available in association with the annual IPPS/LTCH PPS final rule. We are making available the draft FY 2026 ICD–10 MCE Version 43 Manual file on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

The MCE manual is comprised of two chapters: *Chapter 1: Edit code lists* provides a listing of each edit, an explanation of each edit, and as applicable, the diagnosis and/or procedure codes for each edit, and *Chapter 2: Code list changes* summarizes the changes in the edit code lists (for example, additions and deletions) from the prior release of the MCE software. The public may submit any questions, comments, concerns, or recommendations regarding the MCE to the CMS mailbox at *MSDRGClassificationChange@cms.hhs.gov* for our review and consideration.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 43, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 43, the draft version of the Definitions of Medicare Code Edits Manual, Version 43, and the supplemental mapping files in Tables 6P.1a and 6P.1b of the FY 2025 and FY 2026 ICD–10–CM

diagnosis codes and ICD–10–PCS procedure codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

The following are the changes that we are proposing to the MS–DRGs for FY 2026. We are inviting public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in this FY 2026 IPPS/LTCH PPS proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. For this FY 2026 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2024 update of the FY 2024 MedPAR file, which contains hospital bills received from October 1, 2023 through September 30, 2024. In our discussion of the proposed MS–DRG reclassification changes, we refer to these claims data as the ''September 2024 update of the FY 2024 MedPAR file.''

In deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661), we continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of MS–DRG classification requests, consistent with our approach since FY 2021 when we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. Accordingly, in our analysis of the MS–DRG classification requests for FY 2026 that we received by October 20, 2024, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

Criteria No.	Three-way split 123 (MCC vs CC vs NonCC)	Two-way split 1_23 MCC vs (CC+NonCC)	Two-way split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group.	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group.	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group.	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group.
2. At least 5% of the patients are in the MCC/CC/NonCC group.	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group.	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group.	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group.
3. There is at least a 20% difference in average cost between subgroups.	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group.	20%+ difference in average cost between MCC group and (CC+NonCC) group.	20%+ difference in average cost between (MCC+CC) group and NonCC group.
4. There is at least a $2,000 difference in average cost between subgroups.	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group.	$2,000+ difference in average cost between MCC group and (CC+NonCC) group.	$2,000+ difference in average cost between (MCC+CC) group and NonCC group.
5. The R2 of the split groups is greater than or equal to 3.	R2 >3.0 for the three-way split within the base MS–DRG	R2 >3.0 for the two-way 1_23 split within the base MS–DRG.	R2 >3.0 for the two-way 12_3 split within the base MS–DRG.

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for this FY 2026 IPPS/LTCH PPS proposed rule, our MS–DRG analysis was based on ICD–10 claims data from the September 2024 update of the FY 2024 MedPAR file. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes two years of MedPAR claims data to compare the data results from one year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three-way split. In applying the criteria for a three-way split, a base MS–DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each

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

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

We received a request to review the recent MS–DRG assignments to Pre-MDC MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies) and to clarify how decisions for the assignment of cell and gene therapies will be made moving forward. According to the requestor, for FY 2025, CMS did not assign prademagene zamikeracel (PZ), an autologous genetically engineered cell-based gene therapy, to MS–DRGs that would create clinical homogeneity and therefore, the mapping of these cases to MS–DRG 018 instead implied that estimated post-approval product pricing takes precedent for cell and gene therapies over clinical homogeneity principles. The requestor acknowledged that CMS has previously clarified that therapies mapped to Pre-MDC MS–DRG 018 do not need to be CAR T-cell products or utilized in the treatment of cancer and stated it concurs with that approach. However, the requestor indicated that the mapping of PZ to Pre-MDC MS–DRG 018 for FY 2025 also raised the following questions:

- Why was PZ mapped to Pre-MDC MS–DRG 018 when a different product (eladocagene exuparvovec) that is also delivered via operating room administration methods was mapped to other non-pre-MDC MS–DRGs?
- Why did CMS indicate that Lantidra, a recently approved cellular therapy, would map to the same MS–DRGs as existing insulin delivery therapies and technologies used to treat the subset of patients with hard-to-control Type 1 diabetes complicated by severe hypoglycemia who cannot receive a whole pancreas transplant instead of to Pre-MDC MS–DRG 018?
- Does CMS intend a future split of Pre-MDC MS–DRG 018 between medical and surgical cell and gene therapies to recognize the clinical resource differential between the two modalities, even if the 500 case volume threshold is not reached?
- Why was a product delivered via allogeneic stem cell transplant procedure (Orca-T) mapped to Pre-MDC MS–DRG 018 instead of Pre-MDC MS–DRG 014 (Allogeneic Bone Marrow Transplant)?
- If products delivered via stem cell transplant should be mapped to Pre-MDC MS–DRG 018 based on resource use, per the Orca-T example, why are multiple gene therapy products delivered via stem cell transplant instead mapped to Pre-MDC MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC and without CC/MCC, respectively)?

The requestor stated the previously listed questions illustrate examples of inconsistencies with the MS–DRG mappings of cell and gene therapy products in recent years. The requestor recommended that CMS review recent MS–DRG assignments for these products and consider refinements to the approach. The requestor also urged CMS to clarify how decisions for cell and gene therapies will be made in the future. The requestor stated that if the intent of CMS is for Pre-MDC MS–DRG 018 to be a broad cell and gene therapy MS–DRG then a modification to the title of Pre-MDC MS–DRG 018 should be proposed and therapies currently assigned to other MS–DRGs should be re-mapped.

The requestor also suggested that CMS clarify the process by which interested parties can submit comments on potential or proposed procedure code mappings to the MS–DRGs for code proposals discussed at the Spring ICD–10 Coordination and Maintenance (C&M) Committee meeting since, given the timing, proposed code assignments are not published in association with the annual IPPS/LTCH PPS proposed rule. Specifically, the requestor stated there is no opportunity for interested parties to provide feedback to CMS about the assignment of new codes to Pre-MDC MS–DRG 018. The requestor stated that because MS–DRG 018 is a Pre-MDC MS–DRG with a limited number of procedure codes mapping to it, it is important for interested parties to have the ability to preview potential assignments to this MS–DRG and provide feedback to CMS prior to any final mapping decisions being made. The requestor acknowledged that CMS previously responded to prior comments regarding the process of commenting on the assignment of newly created codes; however, the requestor suggested that CMS provide additional clarification. Specifically, the requestor stated that the primary comment period with respect to the Spring procedure code requests is the timeframe following the ICD–10 C&M Committee meeting and that the materials provided in association with the meeting do not contain mapping requests submitted by the code requestor. The requestor indicated that if it is to assume any new procedure code request could potentially be mapped to Pre-MDC MS–DRG 018 and submits comments accordingly, that would create an undue burden. The requestor submitted the following questions regarding the process by which interested parties may submit comments on potential procedure code mappings to MS–DRGs:

- Can mapping requests be submitted as part of the request for a new ICD–10–PCS procedure code or do mapping requests need to go through the MS–DRG modification process with an annual October deadline?
- Can CMS provide information on mapping requests as part of the ICD–10 C&M Committee meeting materials?
- Will comments submitted to the ICD–10 C&M Committee about potential mappings be shared with the CMS teams associated with MS–DRG mapping decisions?
- Should interested parties include the same comments that are submitted to the ICD–10 C&M Committee in their proposed rule comments?
- Will comments submitted as part of the proposed rule be considered within scope for proposed codes presented during the spring meeting that are subsequently finalized but not listed in Table 6A.—New Diagnosis codes and Table 6B.—New Procedure Codes with proposed mappings?
- Do CMS' prior responses indicate that interested parties who submit comments on procedure code mappings should request code proposals presented at the spring meeting be delayed until the fall meeting?

The requestor recommended that CMS address the previously listed

questions and seek input on the process by which interested parties may submit comments on potential procedure code mappings.

We appreciate the requestor's feedback and suggestions regarding the classification of therapies to Pre-MDC MS–DRG 018 and the broader topic of MS–DRG mappings of cell and gene therapy products for the future. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69008 through 69010), we summarized and responded to comments regarding the mapping of procedure codes describing the application of PZ and other newly established procedure codes to Pre-MDC MS–DRG 018. We note that we previously addressed similar comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48806 through 48807), and we also noted that we provided detailed summaries and responses to these same or similar comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798 through 44806). We also refer the reader to the discussion in section II.D. of this FY 2026 IPPS/LTCH PPS proposed rule, regarding the proposed relative weight methodology for cases mapping to Pre-MDC MS–DRG 018 effective October 1, 2025, for FY 2026.

With respect to the requestor's suggestion that a modification to the title of Pre-MDC MS–DRG 018 be proposed, we note that the requestor did not provide a specific recommendation for FY 2026 consideration; however, we acknowledge that there has been discussion related to requests to revise the title to Pre-MDC MS–DRG 018 in prior rulemaking, most recently in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69008 through 69010), and we continue to be interested in obtaining input from members of the public on options to consider, recognizing there are additional types of cell and gene therapies now mapping to Pre-MDC MS–DRG 018. We will continue to review additional feedback and suggestions in connection with future rulemaking.

In response to the requestor's assertion that there is no opportunity for interested parties to submit feedback about MS–DRG assignments, as we have discussed in prior rulemaking (87 FR 48807 through 48808) and as noted in the request, interested parties may use current coding information as shown in the ICD–10 C&M Committee meeting materials to consider the potential MS–DRG assignments for any procedure codes that may be finalized after the Spring meeting and submit public comments for consideration. As we have noted in prior rulemaking, because the diagnosis and procedure code proposals that are presented at the Spring ICD–10–CM C&M Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the proposed rule, we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code. In response to the question regarding the inclusion of information on mapping requests as part of the ICD–10 C&M Committee meeting materials, we note that, as announced at each ICD–10 C&M Committee meeting, there is no discussion of MS–DRGs, payment, coverage, or billing at the ICD–10 C&M Committee meetings; therefore, we do not include such information in the meeting materials made publicly available in association with the meeting. Rather, we state that any issues related to MS–DRGs or payment are addressed through IPPS rulemaking. The purpose of the ICD–10 C&M Committee meeting is to present code proposals based on requests received regarding coding updates (that is, additions, deletions, or revisions). Therefore, while mapping requests may be included in the submission of an ICD–10–PCS procedure code request, that information is not included in the meeting materials, nor is there any discussion about any mapping request(s) during the meeting.

In response to the requestor's question regarding whether comments submitted to the ICD–10 C&M Committee about potential mappings are shared with the CMS staff associated with MS–DRG mapping decisions, we note that the comments are shared. With respect to whether interested parties should include the same comments submitted to the ICD–10 C&M Committee in the comments submitted in response to the proposed rule, we note that what comments to include and submit for each process is up to the commenter. In response to the question of whether comments submitted in response to the proposed rule would be considered within scope for proposed codes presented during the Spring meeting that are subsequently finalized but not listed in Table 6A.—New Diagnosis codes and Table 6B.—New Procedure Codes with proposed mappings, we note that the procedure code update files reflecting the newly finalized codes are made publicly available following the receipt and review of public comments received by the established deadline for the Spring coding topics, and that interested parties may choose to submit public comments on MS–DRG assignment for the agency's consideration. Lastly, in response to the question of whether interested parties considering submitting comments on procedure code mappings should request code proposals associated with the Spring meeting be delayed until the Fall meeting, we similarly note that the decision on what comments a commenter decides to include and submit in response to a code proposal is up to the commenter. We refer the reader to section II.C.11. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule for additional information regarding the ICD–10 C&M Committee meeting process.

In connection with the comments and questions about how products are grouped under the IPPS MS–DRGs, specifically with respect to cell and gene therapies under Pre-MDC MS–DRG 018, for FY 2026, we also received a request to create a new neurosurgical gene therapy MS–DRG to more accurately reflect the clinical characteristics and resource intensity required for the administration of neurosurgical gene therapies, including eladocagene exuparvovec, for patients diagnosed with Aromatic L-amino acid decarboxylase (AADC) deficiency. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44895) and the FY 2023 IPPS/LTCH PPS final rule (87 FR 48853 through 48854) for discussion regarding eladocagene exuparvovec.

The requestor (the manufacturer), expressed its appreciation for CMS' efforts to reassign cases reporting procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) to a surgical MS–DRG as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44895). According to the requestor, the decision appropriately reclassified cases involving eladocagene exuparvovec from a Non-O.R. procedure to an operating room (O.R.) procedure due to

the requirement for intraputaminal administration via a burr hole in the skull. However, the requestor did not agree with the current assignment to MS–DRGs 628, 629, and 630 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 10, or MS–DRGs 987, 988, and 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without MCC/CC, respectively). According to the requestor, the clinical characteristics and average costs of the cases currently assigned to MS–DRGs 628, 629, and 630 are significantly different from those associated with eladocagene exuparvovec neurosurgical gene therapy for rare disease.

The requestor stated that CMS denied the request to create a new MS–DRG for FY 2023, stating that it would continue to explore appropriate mechanisms to address low volume MS–DRGs indicated for rare diseases; however, after receiving responses to the Request for Information (RFI), the requestor stated that there have not been any changes proposed to the IPPS. The requestor stated its belief that assigning cases for this gene therapy and the rare disease indicated to a new MS–DRG is both appropriate and warranted. According to the requestor, the current MS–DRGs that eladocagene exuparvovec cases group to do not adequately reflect the clinical characteristics or resource needs associated with treatment which may deter hospitals from providing this therapy.

The requestor also stated there are approximately 68 gene therapy trials in the U.S. for central nervous system disorders for which over 30 of the 68 trials involve the gene therapy being administered directly into the brain parenchyma. According to the requestor, gene therapies administered surgically, including with neurosurgery, are extremely complicated, resource-intensive procedures for hospitals to undertake. These procedures require highly specialized surgeons, surgical equipment, and staff. Patients undergoing these procedures may also require continuous monitoring and longer hospital stays. The requestor stated the more intensive needs of these patients are not adequately captured in existing MS–DRGs and the creation of a new MS–DRG for neurosurgical gene therapy would help CMS proactively shape payment policy for this evolving class of therapies, thus allowing appropriate payment to support patient access to these treatments.

Our analysis of the September 2024 update of the FY 2024 MedPAR file yielded zero cases reporting the administration of eladocagene exuparvovec, therefore, we believe it would be premature to consider the creation of a new neurosurgical gene therapy MS–DRG at this time. We appreciate the detailed clinical information that the requestor provided and acknowledge that cases involving neurosurgery are technically complex and that patients undergoing these procedures tend to be critically ill, many with rare diseases.

We note that we did receive a new procedure code request to identify and describe the Smartflow® Neuro Cannula as the delivery mechanism to administer eladocagene exuparvovec that was included as a topic in the Spring 2025 ICD–10 Coordination and Maintenance Committee Update materials. We refer the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, and the related materials.

We continue to welcome additional feedback and comments on other options to consider on how to appropriately address low volume, high-cost treatments for rare diseases.

We also note, as discussed in prior rulemaking, that this category of therapies continues to evolve, and we are in the process of carefully considering the feedback we have previously received about ways in which we can continue to appropriately reflect resource utilization while maintaining clinical coherence and stability in the relative weights under the IPPS MS–DRGs. We appreciate the recommendations and suggestions for consideration we have received and will continue to examine these complex issues in connection with future rulemaking. We acknowledge that there may be distinctions to account for as we continue to gain more experience in the use of these therapies and have additional claims data to analyze.

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

a. Logic for MS–DRGs 023 Through 027

For this FY 2026 IPPS/LTCH PPS proposed rule, we received three separate but related requests to review the MS–DRG assignments for a subset of procedures assigned to MS–DRGs 023 through 027. In this section of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we discuss each of these separate, but related requests.

The first request was to create a new MS–DRG for cases involving ''chemotherapy implants'' and cases involving ''epilepsy with neurostimulator.'' The requestor noted chemotherapy implants are used to treat patients with brain tumors. They are implanted into the brain during the craniotomy procedure at the time of tumor resection. Upon implantation, these devices immediately release radiation or chemotherapeutic agents. This approach enables treatment to be initiated at the time of tumor resection without undue delay. ''Epilepsy with neurostimulator'' cases involve devices used in the treatment of medically intractable epilepsy. The neurostimulator is implanted in the skull via a craniotomy and is connected to electrodes that are implanted on the surface of the brain or in the brain through either a craniotomy or a burr hole(s). According to the requestor, like the procedure to insert a chemotherapy implant, the craniotomy procedure to insert the neurostimulator lead is performed under general anesthesia and the procedure typically takes four hours.

The requestor performed their own analysis of Medicare claims data and stated they found that the average costs of cases involving chemotherapy implants and cases involving epilepsy with neurostimulators are significantly higher than the average costs of other procedures currently grouped within MS–DRG 023. The requestor asserted that as a result, these cases are not being adequately paid under the current MS–DRG. Therefore, given the limited options within the existing MS–DRG structure, the requestor recommended that CMS extract cases reporting the insertion of a chemotherapy implant and cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain, and a principal diagnosis of epilepsy from MS–DRG 023 and create a new MS–DRG for these cases with a payment rate that better aligns with the resource utilization associated with these procedures. The requestor stated that this recommendation appeared to be reasonable, given that CMS has already determined that these two subsets of cases are clinically coherent by virtue of them being currently assigned to the same MS–DRG.

To begin our analysis, we reviewed the GROUPER logic for MS–DRGs 023 and 024. The requestor is correct that currently, cases involving ''chemotherapy implants'' and cases involving ''epilepsy with neurostimulator'' are assigned to the higher severity level MS–DRG 023. MS–

DRGs 023 and 024 contain a logic list referred to as ''Chemotherapy Implant.'' This logic list includes the following four ICD–10–PCS codes:

ICD–10–PCS code	Description
00H004Z	Insertion of radioactive element, cesium-131 collagen implant into brain, open approach.
3E0Q005	Introduction of other antineoplastic into cranial cavity and brain, open approach.
3E0Q305	Introduction of other antineoplastic into cranial cavity and brain, percutaneous approach.
3E0Q705	Introduction of other antineoplastic into cranial cavity and brain, via natural or artificial opening.

The ''Chemotherapy Implant'' logic list was created for cases reporting the implantation of a chemotherapeutic agent and devices implanted in the brain, such as implantable chemotherapeutic wafers. Additionally, MS–DRGs 023 and 024 contain a logic list referred to as ''Epilepsy Principal Diagnosis'' that includes 58 ICD–10–CM diagnosis codes that describe epilepsy, and a logic list referred to as ''Neurostimulator'' that includes the following three ICD–10–PCS procedure code combinations:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

These two logic lists were created to capture cases involving the use of the RNS® neurostimulator, a treatment option for persons diagnosed with medically intractable epilepsy. The RNS® neurostimulator includes a cranially implanted programmable neurostimulator connected to one or two depth and/or subdural cortical strip leads that are surgically placed in or on the brain at the seizure focus. The implanted neurostimulator continuously monitors brain electrical activity and is programmed by a physician to detect abnormal patterns of electrical activity that the physician believes may lead to seizures (epileptiform activity).

We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 023 and 024.

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for all cases in MS–DRG 023 and compared the results to cases reporting one of the four procedure codes that appear under the logic list referred to as ''Chemotherapy Implant'' in MS–DRG 023 and for all cases reporting 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), and a principal diagnosis of epilepsy. The following table shows our findings:

MS–DRG 023—All Cases Compared to Cases Reporting the Insertion of a Chemotherapy Implant and Cases Reporting a Neurostimulator Generator Inserted Into the Skull With the Insertion of a Neurostimulator Lead Into the Brain and a Principal Diagnosis of Epilepsy

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	12,136	10	$51,132
Cases reporting the insertion of a chemotherapy implant	176	6.4	49,743
Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	68	2.4	66,303

As shown in the table, for MS–DRG 023, we identified a total of 12,136 cases, with an average length of stay of 10 days and average costs of $51,132. Of the 12,136 cases in MS–DRG 023, there were 176 cases reporting the insertion of a chemotherapy implant with an average length of stay of 6.4 days and average costs of $49,743. Additionally, there were 68 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) that had a principal diagnosis of epilepsy with an average length of stay of 2.4 days and average costs of $66,303.

As the data show, the 68 cases in MS–DRG 023 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) and a principal diagnosis of epilepsy have average costs that are higher than the average costs of all cases in MS–DRG 023 ($66,303 compared to $51,132), and they have an average length of stay that is shorter (2.4 days compared to 10 days). The 176 cases in MS–DRG 023 reporting the insertion of a chemotherapy implant have average costs that are lower than the average costs of all cases in MS–DRG 023 ($49,743 compared to $51,132), and they have an average length of stay that is shorter (6.4 days compared to 10 days).

We reviewed the claims data, and do not believe the data support creating a new MS–DRG for cases reporting the insertion of a chemotherapy implant and cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy. The results of the claims analysis as

previously summarized indicate the cases reporting the insertion of a chemotherapy implant demonstrate comparable resource utilization with other cases in their currently assigned MS–DRG. Further, the claims data analysis indicates that these two subsets of cases, that is cases reporting the insertion of a chemotherapy implant and 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) and a principal diagnosis of epilepsy and cases reporting the insertion of a chemotherapy implant, do not demonstrate comparable resource utilization. The cases in MS–DRG 023 reporting the insertion of a chemotherapy implant have average costs that are lower than the average costs of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain and a principal diagnosis of epilepsy ($49,743 compared to $66,303), and they have an average length of stay that is longer (6.4 days compared to 2.4 days).

Therefore, based on review of the claims data, we are not proposing to create a new-MS–DRG for cases reporting the insertion of a chemotherapy implant and cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy for FY 2026. However, while our analysis of the claims data does not support creating a new MS–DRG for cases reporting the insertion of a chemotherapy implant and cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy, as discussed, 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) and a principal diagnosis of epilepsy have average costs that are higher than the average costs of all cases in MS–DRG 023, with a shorter average length of stay. Accordingly, we determined that further analysis of cases reporting 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), and a principal diagnosis of epilepsy is needed in conjunction with the separate but related requests we received to review the MS–DRG assignments for a subset of procedures also assigned to MS–DRGs 023 through 027 for this FY 2026 IPPS/LTCH PPS proposed rule to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped, as discussed later in this section.

As noted previously, MS–DRGs 023 and 024 contain a logic list referred to as ''Chemotherapy Implant'' that includes the following four ICD–10–PCS codes:

ICD–10–PCS code	Description
00H004Z	Insertion of radioactive element, cesium-131 collagen implant into brain, open approach.
3E0Q005	Introduction of other antineoplastic into cranial cavity and brain, open approach.
3E0Q305	Introduction of other antineoplastic into cranial cavity and brain, percutaneous approach.
3E0Q705	Introduction of other antineoplastic into cranial cavity and brain, via natural or artificial opening.

During our review of the GROUPER logic for MS–DRGs 023 and 024, we identified that the following four ICD–10–PCS procedure codes describing the insertion of a radioactive element were inadvertently excluded from the ''Chemotherapy Implant'' logic list:

ICD–10–PCS code	Description
00H001Z	Insertion of radioactive element into brain, open approach.
00H005Z	Insertion of radioactive element, palladium-103 collagen implant into brain, open approach.
00H031Z	Insertion of radioactive element into brain, percutaneous approach.
00H041Z	Insertion of radioactive element into brain, percutaneous endoscopic approach.

In review of this finding, we analyzed claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 023, 024, 025, 026, and 027 for all cases and for cases reporting procedure codes 00H001Z, 00H005Z, 00H031Z, or 00H041Z. The findings from our analysis are shown in the following table.

MS–DRG		Number of cases	Average length of stay	Average costs
023	All cases	12,136	10	$51,132
	Cases reporting 00H001Z, 00H005Z, 00H031Z, or 00H041Z	0	0	0
024	All cases	4,624	5	35,516
	Cases reporting 00H001Z, 00H005Z, 00H031Z, or 00H041Z	0		0
025	All cases	21,059	8.6	40,215
	Cases reporting 00H001Z, 00H005Z, 00H031Z, or 00H041Z	4	3.8	40,199
026	All cases	5,833	4.1	28,404
	Cases reporting 00H001Z, 00H005Z, 00H031Z, or 00H041Z	0	0	0
027	All cases	7,049	1.9	23,059
	Cases reporting 00H001Z, 00H005Z, 00H031Z, or 00H041Z	0	0	0

As the data show, we found four cases reporting procedure code 00H001Z, 00H005Z, 00H031Z, or 00H041Z in MS–DRG 025, with average costs of $40,199 and an average length of stay of 3.8 days. We reviewed this issue and note radioactive elements are inserted into the brain to deliver a targeted concentrated dose of radiation directly to a brain tumor or tumor bed. They are primarily used to treat recurrent brain metastases or other aggressive brain cancers, as it allows for high-dose radiation delivery specifically to the tumor site while minimizing damage to surrounding healthy brain tissue. Although we did not identify many cases, we believe the four procedure codes describing the insertion of a radioactive element into the brain are clinically aligned with the procedure codes currently included in the ''Chemotherapy Implant'' logic list in MS–DRGs 023 and 024.

Therefore, for clinical consistency we are proposing to add procedure codes 00H001Z, 00H005Z, 00H031Z, and 00H041Z to the ''Chemotherapy Implant'' logic list in MS–DRGs 023 and 024, effective October 1, 2025, for FY 2026. We are also proposing to change the description of the logic list in MS–DRGs 023 and 024 from ''Chemotherapy Implant'' to ''Antineoplastic Implant'' to better reflect the GROUPER logic that includes ICD–10–PCS procedure codes describing antineoplastic agents implanted in the brain.

As mentioned previously, for this FY 2026 IPPS/LTCH PPS proposed rule, we received three separate but related requests to review and reconsider the MS–DRG assignments for a subset of procedures assigned to MS–DRGs 023 through 027. The second and third request involve the MS–DRG assignment of cases reporting procedure codes describing the insertion of deep brain stimulators (DBS). Deep brain stimulation is a surgical treatment that involves the implantation of a neurostimulator, used in the treatment of essential tremor, Parkinson's disease, dystonia, epilepsy, obsessive-compulsive disorder and chronic pain. A DBS system consists of one or two leads that are placed stereotactically at defined targets deep within the brain via one or two burr holes created in the skull. The lead is then connected to an extension that is tunneled under the skin, down the neck, and connected to a programmable neurostimulator generator that is placed under the skin.

The second request we received was to reassign cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (MCC) severity level MS–DRG 023, even if there is no MCC reported. The requestor suggested that if finalized, the title for MS–DRG 023 should be revised to reflect ''Craniotomy with Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant or Major Device Implant or Epilepsy with Neurostimulator.''

The requestor performed their own analysis and stated they found that the majority of cases reporting the implantation of a DBS system are assigned to the lower severity level MS–DRG 024. The requestor also stated that in their analysis, the cases reporting the implantation of a DBS system assigned to MS–DRG 024 have average costs that are 20% greater than all cases in MS–DRG 024. The requestor asserted that reassigning cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (with MCC) severity level MS–DRG 023, even if there is no MCC reported, would better recognize hospital resource utilization when the DBS systems are inserted.

The requestor identified cases reporting the implantation of a DBS system by the presence of the following procedure code combinations:

- 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach);
- 0JH60EZ (Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach); and
- 0JH60EZ (Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach).

To begin our analysis, we again reviewed the GROUPER logic for MS–DRGs 023 and 024. The GROUPER logic for MS–DRGs 023 and 024 also contains 78 procedure code combinations representing the insertion of neurostimulator generator and a neurostimulator lead that are captured under a list referred to as ''Major Device Implant.'' The procedure codes describing the insertion of a neurostimulator generator on this list describe insertion of the neurostimulator generator into the subcutaneous areas of the chest, back, or abdomen, as well as into the skull. The procedure codes describing the insertion of a neurostimulator lead describe the insertion of the lead into the brain or the cerebral ventricle. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 023 and 024.

In our analysis of this issue, we agree that the four procedure code combinations discussed previously that were identified by this requestor are included in the ''Major Device Implant'' logic list of MS–DRGs 023 and 024, but we note that 32 additional procedure code combinations exist on the ''Major Device Implant'' logic list that also describe the implantation of a DBS system by describing the insertion of a neurostimulator generator into the subcutaneous areas of the chest, back, or abdomen in combination with a code describing the insertion of a neurostimulator lead into the brain. We refer the reader to Table 6P.2a associated with this FY 2026 IPPS/LTCH PPS proposed rule (and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for the list of the 36 ICD–10–PCS procedure code combinations in the logic of MS–DRGs 023 and 024 in the ''Major Device Implant'' logic list that we identified that describe the implantation of a DBS system and therefore were included in our analysis.

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for all cases in MS–DRGs 023 and 024 and compared the results to cases reporting the implantation of a DBS system by reporting a procedure code combination that describes the insertion of a neurostimulator generator into the subcutaneous areas of the chest, back, or abdomen in combination with a code describing the insertion of a neurostimulator lead into the brain. The following table shows our findings:

MS–DRGs 023 and 024—All Cases Compared to Cases Reporting the Insertion of a Deep Brain Stimulation System

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	12,136	10	$51,132
Cases reporting the implantation of a DBS system	26	8.3	81,947
MS–DRG 024—All cases	4,624	5	35,516
Cases reporting the implantation of a DBS system	432	1.7	43,032

As shown in the table, for MS–DRG 023, we identified a total of 12,136 cases, with an average length of stay of 10 days and average costs of $51,132. Of the 12,136 cases in MS–DRG 023, there were 26 cases reporting the implantation of a DBS system with an average length of stay of 8.3 days and average costs of $81,947. For MS–DRG 024, we identified a total of 4,624 cases, with an average length of stay of 5 days and average costs of $35,516. Of the 4,624 cases in MS–DRG 024, there were 432 cases reporting the implantation of a DBS system with an average length of stay of 1.7 days and average costs of $43,032.

We reviewed the claims data, and the data do not support reassignment of the cases reporting the implantation of a DBS system from MS–DRG 024 to MS–DRG 023 even if there is no MCC reported. The results of the claims analysis as previously summarized indicate the cases reporting the implantation of a DBS system, without reporting a secondary diagnosis designated as an MCC, that are currently assigned to MS–DRG 024, have average costs that are lower than the average costs of all cases in MS–DRG 023 ($43,032 compared to $51,132), and they have an average length of stay that is shorter (1.7 days compared to 10 days). While the average costs of these cases are higher than the average costs of all cases in MS–DRG 024 ($43,032 compared to $35,516), we believe it would not be appropriate to reassign these cases into the higher severity level MS–DRG 023, even if there is no MCC reported, because the cases would not be coherent with regard to resource utilization. The cases reporting the implantation of a DBS system, without reporting a secondary diagnosis designated as an MCC, that are currently assigned to MS–DRG 024 have average costs that are $8,100 lower than the average costs of all cases in MS–DRG 023. Therefore, we are not proposing to reassign cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (with MCC) severity level MS–DRG 023, even if there is no MCC reported. However, while the analysis of the claims data does not support reassigning the cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (MCC) severity level MS–DRG 023 even if there is no MCC reported, as discussed, our analysis of the claims data found the average costs of the cases reporting the implantation of a DBS system are higher than all cases in their respective MS–DRGs, while the average lengths of stay are shorter. Accordingly, and as discussed later in this section, we determined that further analysis of cases reporting the implantation of a DBS system is needed in conjunction with the separate but related requests we received to review the MS–DRG assignments for a subset of procedures also assigned to MS–DRGs 023 through 027 for this FY 2026 IPPS/LTCH PPS proposed rule to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped.

The third request we received was to have all cases reporting the concomitant insertion of a DBS generator and lead assigned to MS–DRGs 023 and 024. This requestor performed their own analysis and stated they found 76 claims reporting procedure codes describing the insertion of a DBS generator and a lead assigned to MS–DRGs 026 and 027 (Craniotomy and Endovascular Intracranial Procedures with CC, and without CC/MCC, respectively) and found that the average costs of these cases were 54% and 63% higher than the average of all cases in MS–DRGs 026 and 027, respectively. The requestor stated that placement of a complete DBS system, which requires placement of both the generator and the lead, during a single procedure, appears to be an efficacious and well-tolerated procedure. The requestor asserted that the relatively low reimbursement in MS–DRGs 026 and 027 can limit patient access to a single stage procedure.

This requestor identified cases reporting the implantation of a DBS system by the presence of the following procedure code combinations:

- 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0JH60DZ (Insertion of multiple array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach);
- 0JH60EZ (Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach); and
- 0JH60EZ (Insertion of multiple array rechargeable stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach);
- 0JH60BZ (Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach); and
- 0JH60BZ (Insertion of single array stimulator generator into chest subcutaneous tissue and fascia, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach).

To begin our analysis, we again reviewed the GROUPER logic for MS–DRG 023 and 024. As mentioned previously, the GROUPER logic for MS–DRGs 023 and 024 contains 78 procedure code combinations representing the insertion of neurostimulator generator and a neurostimulator lead that are captured under a list referred to as ''Major Device Implant.'' The procedure codes describing the insertion of a neurostimulator generator on this list describe insertion of the neurostimulator generator into the subcutaneous areas of the chest, back, or abdomen, as well as into the skull.

In reviewing this request, we noted that the procedure code combinations in MS–DRG 023 and 024 captured under the ''Major Device Implant'' logic list that describe the insertion of a neurostimulator generator into the subcutaneous areas of the chest, back, or abdomen, all describe the insertion of a multiple array stimulator generator or a rechargeable multiple array stimulator generator. Procedure code combinations describing the insertion of a single array stimulator generator or a rechargeable single array stimulator generator into the subcutaneous areas of the chest, back, or abdomen and a neurostimulator lead are not captured under the ''Major Device Implant'' logic list, therefore MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively) are assigned based on the reporting of the ICD–10–PCS procedure code describing the insertion of the neurostimulator into the brain. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 023, 024, 025, 026, and 027.

We identified 36 ICD–10–PCS procedure code combinations that would describe the implantation of a DBS system with a single array stimulator generator or a rechargeable single array stimulator generator and the insertion of a neurostimulator lead into the brain. We refer the reader to Table 6P.2b associated with this FY 2026 IPPS/LTCH PPS proposed rule (and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for the list of the 36 ICD–10–PCS procedure code combinations we identified that describe the implantation of a DBS system with a single array stimulator generator or a rechargeable single array stimulator generator and the insertion of a neurostimulator lead into the brain.

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for all cases in MS–DRGs 025, 026, and 027 and compared the results to cases reporting a procedure code combination that describes the insertion of a single array stimulator generator or a rechargeable single array stimulator generator into the subcutaneous areas of the chest, back, or abdomen in combination with a code describing the insertion of a neurostimulator lead into the brain. The following table shows our findings:

MS–DRGs 025, 026, and 027—All Cases Compared to Cases Reporting the Insertion of a Single Array Generator and Insertion of Neurostimulator Lead Into Brain

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 025—All cases	21,059	8.6	$40,215
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain	5	5	73,168
MS–DRG 026—All cases	5,833	4.1	28,404
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain	25	2.3	42,002
MS–DRG 027—All cases	7,049	1.9	23,059
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain	78	1.4	39,381

As shown in the table, for MS–DRG 025, we identified a total of 21,059 cases, with an average length of stay of 8.6 days and average costs of $40,215. Of those 21,059 cases, there were 5 cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 025 ($73,168 compared to $40,215) and a shorter average length of stay (5 days compared to 8.6 days). In MS–DRG 026, we identified a total of 5,833 cases, with an average length of stay of 4.1 days and average costs of $28,404. Of the 5,833 cases in MS–DRG 026, there were 25 cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 026 ($42,002 compared to $28,404) and a shorter average length of stay (2.3 days compared to 4.1 days). In MS–DRG 027, we identified a total of 7,049 cases, with an average length of stay of 1.9 days and average costs of $23,059. Of the 7,049 cases in MS–DRG 027, there were 78 cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 027 ($39,381 compared to $23,059) and a shorter average length of stay (1.4 days compared to 1.9 days). As the data show, the cases in MS–DRGs 025, 026, and 027 reporting the insertion of a single array generator and insertion of neurostimulator lead into brain have average costs that are higher than the average costs of all cases in their respective MS–DRGs.

We reviewed the clinical issues and note a deep brain stimulator typically has one or two leads implanted in the brain, depending on whether one or both sides of the brain need treatment. A single array stimulator generator has one port where one lead can be connected. A multiple array stimulator generator has two or more ports where two or more leads can be connected. We believe the procedure code combinations that describe the insertion of a single array stimulator generator or a rechargeable single array stimulator generator into the subcutaneous areas of the chest, back, or abdomen in combination with a code describing the insertion of a neurostimulator lead into the brain are clinically coherent with the procedure code combinations in MS–DRG 023 and 024 captured under the ''Major Device Implant'' logic list that describe the insertion of a multiple array stimulator generator or a rechargeable multiple array stimulator generator into the subcutaneous areas of the chest, back, or abdomen in combination with a code describing the insertion of a neurostimulator lead into the brain.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 023 and 024 as a whole, we examined the average costs and length of stay for cases in MS–DRGs 023 and 024. Our findings are shown in this table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 023—All cases	12,136	10	$51,132
MS–DRG 024—All cases	4,624	5	35,516

We reviewed the data and note the cases in MS–DRGs 025, 026, and 027 reporting the insertion of a single array generator and insertion of neurostimulator lead into brain have average costs that are higher and the average length of stay is shorter than all cases in MS–DRGs 023 and 024. We agree with the requestor that cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain are more resource intensive and are clinically distinct from other cases currently assigned to MS–DRGs 025, 026, and 027. However, we do not believe proposing to reassign all cases reporting the procedure code combination describing a single array generator and insertion of neurostimulator lead into brain to MS–DRGs 023 and 024, would fully address the difference in resource utilization in these cases.

To explore other mechanisms to address this request, we then reexamined the separate but related requests discussed previously to review the MS–DRG assignments for a subset of procedures assigned to MS–DRGs 023 through 027. In examining these requests, we note that the first request was to reassign cases involving ''chemotherapy implants'' and cases involving ''epilepsy with neurostimulator'' from MS–DRG 023 and to create a new MS–DRG for these cases. While analysis of the claims data do not support creating a new MS–DRG for cases reporting the insertion of a chemotherapy implant and cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy, our analysis of that request found 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) and a principal diagnosis of epilepsy have average costs that are higher than the average costs of all cases in MS–DRG 023, with a shorter average length of stay.

The second request we received was to reassign cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (MCC) severity level MS–DRG 023 even if there is no MCC reported. While analysis of the claims data does not support reassigning the cases reporting the implantation of a DBS system from the lower (without MCC) severity level MS–DRG 024 to the higher (MCC) severity level MS–DRG 023 even if there is no MCC reported, our analysis of that request found the average costs of the cases reporting the implantation of a DBS system are higher than all cases in their respective MS–DRGs, while the average lengths of stay are shorter. Lastly, our analysis of the third request demonstrates the cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain have average costs that are higher than the average costs of all cases in their respective MS–DRGs, while the average lengths of stay are shorter.

We reviewed these issues and note intracranial neurostimulator implants, such as deep brain stimulators and RNS® neurostimulators, are similar in that these intracranial neurostimulators are implanted surgically and include placement of a neurostimulator generator and insertion of leads into specific brain regions to deliver electrical stimulation. Additionally, based on our data analysis, cases reporting the insertion of intracranial neurostimulator implants are clinically coherent in that they are similar in terms of technical complexity and hospital resource use as reflected by the similarity in average costs and average lengths of stay.

We explored creating a new base MS–DRG for cases reporting the insertion of an intracranial neurostimulator implant and compared the analysis discussed previously using the claims data from the September 2024 update of the FY 2024 MedPAR file. The following table illustrates our findings for all 654 cases reporting procedure codes describing the insertion of an intracranial neurostimulator implant.

CASES REPORTING THE INSERTION OF AN INTRACRANIAL NEUROSTIMULATOR IMPLANT

	Number of cases	Average length of stay	Average costs
Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	68	2.4	$66,303
Cases reporting the implantation of a DBS system (insertion of a multiple array generator and insertion of neurostimulator lead into brain)—with MCC	26	8.3	81,947
Cases reporting the insertion of a multiple array generator and insertion of neurostimulator lead into cerebral ventricle—with MCC	1	9	44,475
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain—with MCC	5	5	73,168
Cases reporting the insertion of a multiple array generator and insertion of neurostimulator lead into cerebral ventricle—with CC	5	2.2	81,517
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain—with CC	25	2.3	42,002
Cases reporting the implantation of a DBS system (insertion of a multiple array generator and insertion of neurostimulator lead into brain)—without MCC	432	1.7	43,032
Cases reporting the insertion of a multiple array generator and insertion of neurostimulator lead into cerebral ventricle—without CC/MCC	14	1.7	48,258

CASES REPORTING THE INSERTION OF AN INTRACRANIAL NEUROSTIMULATOR IMPLANT—Continued

	Number of cases	Average length of stay	Average costs
Cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain—without CC/MCC	78	1.4	39,381
Total	654	2.1	47,163

We reviewed these data and do not believe proposing a new base MS–DRG for these cases would better reflect hospital resource use. Because there were only 654 cases identified, the analysis demonstrates both a three-way and a two-way split of a new base MS–DRG would fail the criterion that there be at least 500 cases for each subgroup. The analysis also demonstrates the cases reporting a principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain, and cases reporting the insertion of a single or multiple array generator with a secondary diagnosis designated as an MCC, would continue to have average costs that are higher when compared to all other cases reporting the insertion of an intracranial neurostimulator implant in a new MS–DRG. We therefore explored an alternative mechanism to address these requests.

We note that in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58459 through 58462) and the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661 through 58667), we discussed requests we received to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 to MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC). While acknowledging the cases in MS–DRG 023 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® neurostimulators) and a principal diagnosis of epilepsy have average costs that are similar to the average costs of cases in MS–DRG 021, we have stated we did not support reassigning the 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® neurostimulators) and a principal diagnosis of epilepsy from MS–DRG 023 to MS–DRGs 020, 021, and 022 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage, with MCC, with CC, without CC/MCC, respectively), as the cases in MS–DRGs 020, 021, and 022 are defined by a principal diagnosis of a hemorrhage. We stated that RNS® neurostimulators are not used to treat patients with diagnosis of a hemorrhage and that we believe that it is inappropriate to reassign cases representing a principal diagnosis of epilepsy to a MS–DRG that contains cases that represent the treatment of intracranial hemorrhage.

However, after further consideration, to explore other mechanisms to address this request, we examined MS–DRGs 020, 021, and 022 to reconsider the possibility of reassigning the cases reporting the insertion of an intracranial neurostimulator implant as we have been unable to identify another MS–DRG in MDC 01 that would be a more appropriate MS–DRG assignment for these cases based on the indication for and complexity of the procedures.

The GROUPER logic for MS–DRGs 020, 021, and 022 contains a list of procedure codes describing intracranial vascular procedures that are captured under a logic list referred to as ''Intracranial Vascular Procedures'' and a list of diagnosis codes describing a diagnosis of a hemorrhage that are captured under a logic list referred to as ''Hemorrhage Principal Diagnosis.'' During our review of MS–DRGs 020, 021, and 022, we identified 57 ICD–10–PCS procedure codes describing the intracranial vascular procedures and 66 diagnosis codes describing a diagnosis of intracranial hemorrhage that were inadvertently excluded from these logic lists. We refer the reader to Table 6P.2c and Table 6P.2d associated with this FY 2026 IPPS/LTCH PPS proposed rule (and available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) for the lists of the 57 ICD–10–PCS procedure codes and 66 ICD–10–CM diagnosis codes that we identified.

As these 57 procedure codes describe the intracranial vascular procedures and the 66 diagnosis codes describe a diagnosis of intracranial hemorrhage, we believe these codes are clinically aligned with the codes currently included in the ''Intracranial Vascular Procedures'' and the ''Hemorrhage Principal Diagnosis'' logic lists, respectively in MS–DRGs 020, 021, and 022. Therefore, for clinical consistency we are proposing to add the 57 procedure codes ''Intracranial Vascular Procedures'' logic list, and the 66 diagnosis codes to the ''Hemorrhage Principal Diagnosis'' logic list of MS–DRGs 020, 021, and 022, effective October 1, 2025, for FY 2026.

In reviewing the claims data from the September 2024 update of the FY 2024 MedPAR file and examining the clinical considerations, we believe that the cases reporting the insertion of an intracranial neurostimulator implant could more suitably group to MS–DRGs 020, 021, and 022 and would lead to a grouping that is more coherent and better reflects the clinical severity and resource use involved in these cases. While we previously have stated that we believe it would be inappropriate to reassign cases representing a principal diagnosis of epilepsy to a MS–DRG that contains cases that represent the treatment of intracranial hemorrhage, after further consideration, we no longer believe maintaining a difference in assignment based on the indication is warranted in this subset of cases based on the fact that both treatments involve intracranial procedures and demonstrate comparable resource utilization.

We also believe that cases reporting the insertion of an intracranial neurostimulator implant, regardless of principal diagnosis, share similar resource utilization such that it is no longer necessary to subdivide these cases based on the diagnosis codes reported. Accordingly, we believe it is appropriate to remove the special logic defined as ''Epilepsy Principal Diagnosis'' from the definition for assignment to the proposed modified MS–DRGs, as the cases can be appropriately grouped along with cases reporting any MDC 01 diagnosis when reported with qualifying procedures, as part of the proposed restructured MS–DRGs.

Therefore, we are proposing to add 114 procedure code combinations to a new ''Intracranial Neurostimulator

Implant'' logic list in MS–DRGs 020, 021, and 022 that describe (1) the insertion of multiple or single array neurostimulator generators with the insertion of a neurostimulator lead into the brain or the cerebral ventricle and (2) the insertion of neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain. We are also proposing to delete the ''Major Device Implant,'' ''Epilepsy Principal Diagnosis,'' ''Neurostimulator'' logic lists from MS–DRGs 023 and 024. We refer the reader to Table 6P.2e associated with this FY 2026 IPPS/LTCH PPS proposed rule (and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) for the list of the 114 ICD–10–PCS procedure code combinations we propose to add to a new ''Intracranial Neurostimulator Implant'' logic list in MS–DRGs 020, 021, and 022.

To compare and analyze the impact of these potential modifications, we ran a simulation using the claims data from the September 2024 update of the FY 2024 MedPAR file. The following table reflects the simulation of our proposed changes in MS–DRGs 020, 021, and 022.

MS–DRG		Number of cases	Average length of stay	Average costs
020	All Cases	2,322	12.5	$71,9167
	—add cases reporting procedure codes describing the insertion of an intracranial neurostimulator implant.	100	4.1	70,495
	—add cases reporting one of the 57 procedure codes describing an intracranial vascular procedure with one of the 66 diagnosis codes describing hemorrhage as principal diagnosis.	140	13.6	73,810
	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with MCC.	2,562	12.2	71,964
021	All Cases	642	7.8	48,421
	—add cases reporting procedure codes describing the insertion of an intracranial neurostimulator implant.	134	2.2	47,421
	—add cases reporting one of the 57 procedure codes describing an intracranial vascular procedure with one of the 66 diagnosis codes describing hemorrhage as principal diagnosis.	45	9.3	54,617
	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with CC.	821	7	48,597
022	All Cases	385	2.4	28,243
	—add cases reporting procedure codes describing the insertion of an intracranial neurostimulator implant.	420	1.5	41,525
	—add cases reporting one of the 57 procedure codes describing an intracranial vascular procedure with one of the 66 diagnosis codes describing hemorrhage as principal diagnosis.	1	1	24,744
	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant without CC/MCC.	806	1.9	35,160

We believe that this simulation supports that the resulting MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use. As the table shows, for MS–DRG 020, there were a total of 2,322 cases with an average length of stay of 12.5 days and average costs of $71,916. For MS–DRG 021, there were a total of 642 cases with an average length of stay of 7.8 days and average costs of $48,421. For MS–DRG 022, there were a total of 385 cases with an average length of stay of 2.4 days and average costs of $28,243. A review of this simulation shows that adding a new ''Intracranial Neurostimulator Implant'' logic list, while also adding 57 procedure codes to the ''Intracranial Vascular Procedures'' logic list, and 66 diagnosis codes to the ''Hemorrhage Principal Diagnosis'' logic list in MS–DRGs 020, 021 and 022 has a limited effect on the average costs of these MS–DRGs, while leading to a grouping that is more coherent and better reflects the clinical severity and resource use involved in these cases.

In summary, for FY 2026, to more appropriately reflect utilization of resources for these procedures, we are proposing to add 114 procedure code combinations to a new ''Intracranial Neurostimulator Implant'' logic list in MS–DRGs 020, 021, and 022 that describe (1) the insertion of multiple or single array neurostimulator generators with the insertion of a neurostimulator lead into the brain or the cerebral ventricle and (2) the insertion of neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain. We are also proposing to add 57 procedure codes to the ''Intracranial Vascular Procedures'' logic list, and 66 diagnosis codes to the ''Hemorrhage Principal Diagnosis'' logic list of MS–DRGs 020, 021, and 022.

Additionally, we are also proposing to delete the ''Major Device Implant,'' ''Epilepsy Principal Diagnosis,'' ''Neurostimulator'' logic lists from MS–DRGs 023 and 024. Lastly, for consistency, we are proposing to change the titles of MS–DRGs 020, 021, and 022 from ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with MCC, with CC, and without CC/MCC, respectively'' to ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with MCC, with CC, and without CC/MCC, respectively,'' proposing to change the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to ''Craniotomy with Acute Complex Central Nervous System Principal Diagnosis with MCC or Antineoplastic Implant,'' and proposing to change the title of MS–DRG 024 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis without MCC'' to ''Craniotomy with Acute Complex Central Nervous System Principal Diagnosis without MCC'' to better reflect the assigned procedures effective October 1, 2025, for FY 2026.

b. Hypertensive Encephalopathy

For this FY 2026 IPPS/LTCH PPS proposed rule, we received a request to delete MS–DRGs 077, 078, and 079 (Hypertensive Encephalopathy with MCC, with CC, and without CC/MCC, respectively). Hypertensive encephalopathy refers to brain dysfunction that occurs when the brain's blood vessels can no longer regulate blood flow due to severe or sudden rises in blood pressure, causing brain swelling and damage. It is characterized by the insidious onset of headache, nausea, and vomiting, followed by non-localizing neurologic symptoms such as restlessness, confusion, and, if the hypertension is not treated, seizures and coma. The diagnosis is based on clinical presentation, elevated blood pressure, and neurological examination, often supported by brain imaging like CT or MRI. The treatment involves immediate and rapid lowering of blood pressure with appropriate medications administered in a controlled setting. ICD–10–CM diagnosis code I67.4 (Hypertensive encephalopathy) is used to report this diagnosis.

The requestor noted that effective FY 2025, a ''use additional code'' instructional note was added under diagnosis code I16.1 (Hypertensive emergency) in the ICD–10–CM Tabular List of Diseases and Injuries. Specifically, the instructional note states, ''use additional code, if applicable, to identify specific organ dysfunction, such as:'' and lists I67.4 as well as eight other ICD–10–CM diagnosis codes. The requestor stated that the addition of this ''use additional code'' instructional note has sequencing implications and requires I67.4 to be sequenced as a secondary diagnosis when hypertensive emergency and hypertensive encephalopathy are documented. As the GROUPER logic for MS–DRGs 077, 078, and 079 is defined by only diagnosis code I67.4, the requestor stated there will no longer be cases grouping to medical MS–DRGs 077, 078, and 079 because I67.4 will only be sequenced as a secondary diagnosis and I16.1 will have to be sequenced as the principal diagnosis. Instead, these cases will group to MDC 05 (Diseases and Disorders of the Circulatory System) medical MS–DRGs 304 and 305 (Hypertension with MCC and without MCC, respectively) since I16.1 is assigned to those MS–DRGs.

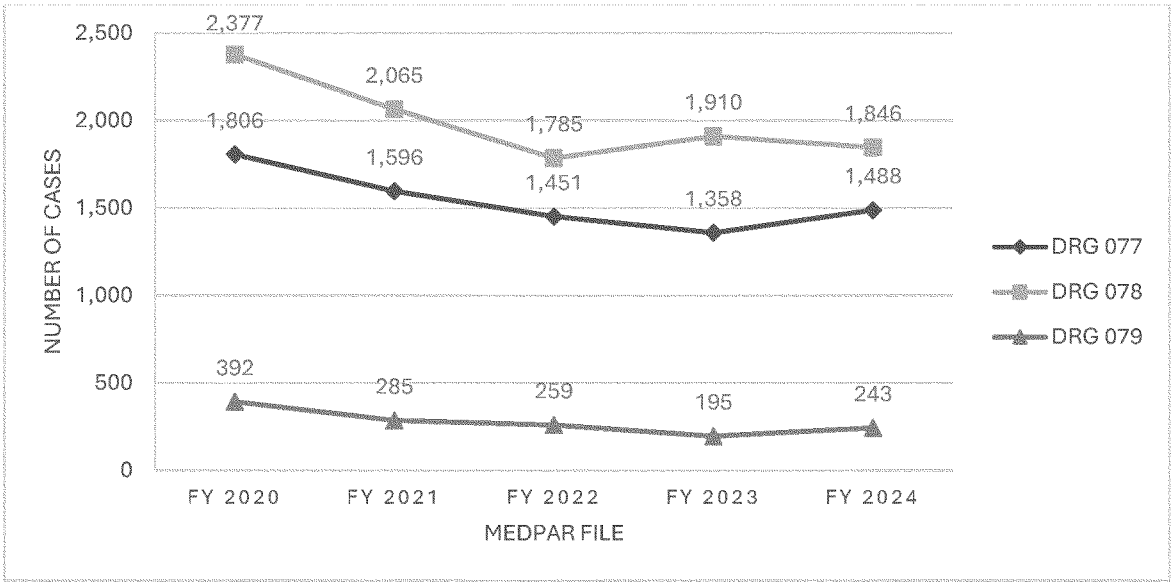
To begin our analysis, we reviewed the ICD–10–CM Tabular List of Diseases and Injuries. The requestor is correct a ''use additional code'' instructional note was added under diagnosis code I16.1 (Hypertensive emergency) in the ICD–10–CM Tabular List of Diseases and Injuries, effective FY 2025. According to the ICD–10–CM Official Guidelines for Coding and Reporting, ''certain conditions have both an underlying etiology and multiple body system manifestations due to the underlying etiology. For such conditions the ICD–10–CM has a coding convention that requires the underlying condition be sequenced first followed by the manifestation. Wherever such a combination exists there is a 'use additional code' note at the etiology code, and a 'code first' note at the manifestation code. These instructional notes indicate the proper sequencing order of the codes, etiology followed by manifestation.'' We note that no such ''code first'' note appears at ICD–10–CM diagnosis code I67.4 (Hypertensive encephalopathy) in the ICD–10–CM Tabular List of Diseases and Injuries meaning the sequencing depends on the circumstances of the encounter when hypertensive emergency and hypertensive encephalopathy are documented. If providers have cases involving hypertensive emergency and hypertensive encephalopathy for which they need ICD–10 coding assistance, we encourage them to submit their questions to the American Hospital Association's Central Office on ICD–10 at *https://www.codingclinicadvisor.com/*.

We then reviewed the GROUPER logic. The requestor is correct that diagnosis code I67.4 is the only diagnosis code listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual for MS–DRGs 077, 078, and 079. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*, for complete documentation of the GROUPER logic for MS–DRGs 077, 078, and 079. We note that a DRG for a principal diagnosis of hypertensive encephalopathy (48 FR 39876) has existed since 1983 when Congress amended the Social Security Act to include a national DRG-based hospital prospective payment system for all Medicare patients.

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for all cases in MS–DRGs 077, 078, and 079 to consider the resources involved in the cases reporting a principal diagnosis of hypertensive encephalopathy. Our findings are shown in this table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 077—All cases	1,488	5.0	$13,176
MS–DRG 078—All cases	1,846	3.3	8,591
MS–DRG 079—All cases	243	2.4	6,729

The data reflect a moderately low volume of cases in MS–DRGs 077, 078, and 079, relatively. We then evaluated the reporting of hypertensive encephalopathy in the inpatient setting over the past few years in medical MS–DRGs 077, 078, and 079. We analyzed claims data for MS–DRGs 077, 078, and 079 from the FY 2020 through the FY 2024 MedPAR files, which were used in our analysis of claims data for MS–DRG reclassification requests effective for FY 2022 through FY 2026 to trend the number of cases assigned to these MS–DRGs over time. Our findings are shown in the following graph:



The data show a general decline in the number of cases reporting hypertensive encephalopathy as a principal diagnosis in medical MS–DRGs 077, 078, and 079 for the past 5 years. We note that as discussed in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficient sets of claims data with demonstrated clinical similarity in developing diagnosis related groups rather than subsets based on single diagnoses. After review of the findings indicating a general decline in the number of cases reporting hypertensive encephalopathy as a principal diagnosis, and consideration of the intent of the MS–DRGs, we believe that there is no longer a clinical reason to maintain the MS–DRGs for hypertensive encephalopathy (MS–DRGs 077, 078, and 079) as they are defined by the reporting of one principal diagnosis code.

To explore mechanisms to ensure clinical coherence between cases reporting hypertensive encephalopathy as a principal diagnosis and the other cases with which they may potentially be grouped, we then conducted an examination of all the MS–DRGs where I67.4 was also reported as principal diagnosis to determine if the diagnosis was included in any other MS–DRGs outside of MDC 01, to assess the current MS–DRG assignment of this diagnosis code. Our findings are shown in the following table.

OTHER MS–DRGS REPORTING HYPERTENSIVE ENCEPHALOPATHY AS PRINCIPAL DIAGNOSIS

MDC	MS–DRG	Description	Number of cases	Average length of stay	Average costs
PRE	004	Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures.	1	52	$128,406
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC	1	16	114,582
01	026	Craniotomy and Endovascular Intracranial Procedures with CC	1	6	79,934
01	028	Spinal Procedures with MCC	1	26	58,049
01	037	Extracranial Procedures with MCC	4	5.5	27,923
01	038	Extracranial Procedures with CC	1	4	12,509
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC	5	8.2	29,325
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator	8	4.9	14,909
	981	Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC	10	10.3	31,543
	982	Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC	1	1	10,926
	987	Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC	2	8.5	28,020
		Total	35	9.3	32,956

As shown in the table, we found 35 cases reporting hypertensive encephalopathy as the principal diagnosis in MS–DRGs other than MS–DRGs 077, 078, and 079. We note that the majority of the listed MS–DRGs are assigned to MDC 01 with one exception: PreMDC MS–DRG 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures). Additionally, there were 11 cases that grouped to MS–DRGs 981, and 982 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, and with CC, respectively) and two cases that grouped to MS–DRG 987 (Non-Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC). After review of these data, we believe it would not be appropriate to reassign diagnosis code I67.4 to another MDC because it could inadvertently cause cases reporting a principal diagnosis of hypertensive encephalopathy with a nervous system procedure to be assigned to an unrelated MS–DRG. Further, we believe it is clinically appropriate to maintain the assignment of I67.4 in MDC 01 as the condition is consistent with other conditions reported by diagnosis codes assigned to MDC 01.

We then examined the MS–DRGs within MDC 01 to consider the possibility of reassigning the cases with a principal diagnosis of hypertensive encephalopathy to other MS–DRGs within MDC 01. In reviewing the claims data from the September 2024 update of the FY 2024 MedPAR file, and examining the clinical considerations, we believe that the cases reporting a principal diagnosis of hypertensive encephalopathy could suitably group to MS–DRGs 070, 071, and 072 (Nonspecific Cerebrovascular Disorders with MCC, with CC and, without CC/MCC, respectively), which contain other cerebrovascular diagnoses under the heading of ''Principal Diagnosis'' in the GROUPER logic list, noting that hypertensive encephalopathy is considered a cerebrovascular disorder, as it is a neurological condition directly caused by a sudden, severe elevation in blood pressure. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*, for complete documentation of the GROUPER logic for MS–DRGs 070, 071, and 072.

To determine how the resources for the cases in MS–DRGs 077, 078, and 079 compared to cases in MS–DRGs 070, 071, and 072, we examined the average costs and length of stay for cases in MS–DRGs 070, 071, and 072. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 070—All cases	16,979	6.4	$14,771
MS–DRG 071—All cases	16,596	4.5	9,381
MS–DRG 072—All cases	2,687	2.9	7,047

As reflected, the average costs of the 1,488 cases reporting a principal diagnosis of I67.4 with a secondary diagnosis designated as a MCC in MS–DRG 077 are slightly lower ($13,176 compared to $14,771) and the average length of stay is shorter (5 days compared to 6.4 days) than for all cases in MS–DRGs 070. The average costs of the 1,846 cases reporting a principal diagnosis of I67.4 with a secondary diagnosis designated as a CC in MS–DRG 078 are slightly lower ($8,591 compared to $9,381) and the average length of stay is shorter (3.3 days compared to 4.5 days) than for all cases in MS–DRGs 071. The average costs of the 243 cases reporting a principal diagnosis of I67.4 without reporting a secondary diagnosis designated as a CC or a MCC in MS–DRG 079 are slightly lower ($6,729 compared to $7,047) and the average length of stay is shorter (2.4 days compared to 2.9 days) than for all cases in MS–DRGs 072.

Our analysis demonstrates that the cases reporting a principal diagnosis of I67.4 currently grouping to medical MS–DRGs 077, 078, and 079 are generally aligned with the average costs for the cases currently grouping to MS–DRGs 070, 071, and 072. While the cases reporting a principal diagnosis code describing hypertensive encephalopathy have slightly lower costs and a shorter average length of stay than for cases in MS–DRGs 070, 071, and 072, we believe reassigning diagnosis code I67.4 to MS–DRGs 070, 071, and 072 will account for the subset of patients reporting this principal diagnosis, and will appropriately reflect the resources involved in evaluating and treating these patients.

During our review of this issue and the examination of the MS–DRGs within MDC 01, we noted that the title of MS–DRGs 067, 068, and 069 is ''Nonspecific CVA and Precerebral Occlusion without Infarction with MCC, with CC, and without CC/MCC, respectively'' and the title of MS–DRGs 070, 071, and 072 is ''Nonspecific Cerebrovascular Disorders, with MCC, with CC, and without CC/MCC, respectively.'' In examining the GROUPER logic for these MS–DRGs and reviewing the diagnoses listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual, we believe the titles for these MS–DRGs no longer accurately reflects the assigned diagnoses. Like MS–DRGs 077, 078, and 079, the titles of MS–DRGs 067, 068, 069, 070, 071, and 072 were established prior to the transition to ICD–10–CM. The terminology ''nonspecific'' in the titles for these MS–DRGs was appropriate to describe the ICD–9–CM diagnosis codes that were previously assigned to these DRGs, but as discussed in the HIPAA Administrative Simplification: Modification to Medical Data Code Set Standards To Adopt ICD–10–CM and ICD–10–PCS proposed rule (73 FR 49796 through 49803), in comparison to ICD–9–CM, ICD–10–CM diagnosis codes are very specific and that this specificity improves the richness of data for analysis and improves the accuracy of data used for medical research. Therefore, we believe it is appropriate to propose to revise the titles of these MS–DRGs for consistency.

In summary, for FY 2026, we are proposing to delete MS–DRGs 077, 078, and 079. Additionally, we are proposing to reassign ICD–10–CM diagnosis code I67.4 (Hypertensive encephalopathy) from MDC 01 MS–DRGs 077, 078, and 079 to MS–DRGs 070, 071, and 072. Lastly, for consistency, we are also proposing to change the titles of MS–DRGs 067, 068, and 069 from ''Nonspecific CVA and Precerebral Occlusion without Infarction with MCC, with CC, and without CC/MCC, respectively'' to ''Precerebral Occlusion without Infarction with MCC, with CC, and without CC/MCC, respectively'' and to change the titles of MS–DRGs 070, 071, and 072 from ''Nonspecific Cerebrovascular Disorders, with MCC, with CC, and without CC/MCC, respectively'' to ''Other Cerebrovascular Disorders with MCC, with CC, and without CC/MCC, respectively'' to better reflect the assigned diagnoses.

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

We identified a replication issue from the ICD–9 based MS–DRGs to the ICD–10 based MS–DRGs regarding the assignment of four ICD–10–CM diagnosis codes that describe encounters for adjustment and management of implanted devices of the special senses. Under the Version 32 ICD–9–CM based MS–DRGs, ICD–9–CM diagnosis code V53.09 (Fitting and adjustment of other devices related to nervous system and special senses), as shown in the following table, was assigned medical MS–DRGs 091, 092, and 093 (Other Disorders of Nervous System with MCC, with CC, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System). The four ICD–10–CM code translations also shown in the following table, that provide more detailed and specific information, also

currently group to MS–DRGs 091, 092, and 093 in the ICD–10 MS–DRGs Version 42.1. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 091, 092, and 093.

ICD–9–CM diagnosis code	Description	ICD–10–CM diagnosis code	Description
V53.09	Fitting and adjustment of other devices related to nervous system and special senses.	Z45.31	Encounter for adjustment and management of implanted visual substitution device.
		Z45.320	Encounter for adjustment and management of bone conduction device.
		Z45.321	Encounter for adjustment and management of cochlear device.
		Z45.328	Encounter for adjustment and management of other implanted hearing device.

During our review of this issue, we noted that under ICD–9–CM, diagnosis code V53.09 (Fitting and adjustment of other devices related to nervous system and special senses) did not further describe the type of device related to nervous system and special senses. This is in contrast to its four comparable ICD–10–CM code translations listed in the previous table that provide more detailed and specific information than the ICD–9–CM diagnosis code and do specify the type of device.

In reviewing the four ICD–10–CM diagnosis codes listed in the previous table and the devices they describe, we believe that that Z45.31 is more appropriately assigned to MDC 02 (Diseases and Disorders of the Eye) and codes Z45.320, Z45.321, and Z45.328 are more appropriately assigned to MDC 03 (Diseases and Disorders of the Ear, Nose, Mouth and Throat). We note that an ''implanted visual substitution device,'' also known as a ''visual prosthesis,'' is a medical implant designed to partially restore vision to a patient who is blind by directly stimulating the visual pathway in the retina or brain, essentially bypassing damaged photoreceptor cells in the eye and providing a basic visual perception through electrical stimulation. Bone conduction devices, also known as bone conduction hearing aids, amplify sound via bone conduction, or vibrations through the bones of the skull which directly stimulate a functioning cochlea. Cochlear devices and other implanted hearing devices are small electronic devices designed for patients with moderate to severe hearing loss caused by damage to the inner ear to help perceive sounds.

We analyzed claims data from the September 2024 update of the FY 2024 MedPAR file to determine if there were any cases reported with diagnosis codes Z45.31, Z45.320, Z45.321, or Z45.328. One case was found in MS–DRG 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis without CC/MCC) reporting principal diagnosis Z45.321 and procedure code 09PE0SZ (Removal of hearing device from left inner ear, open approach) with costs of $5,530 and a length of stay of one day.

We recognize that the volume of inpatient cases for patients with a principal diagnosis of Z45.31, Z45.320, Z45.321, or Z45.328 is low, however we believe that for clinical consistency, it is more appropriate for these cases to be assigned to MDCs that better describe the indication of the implanted devices of the special senses the codes describe. Accordingly, because the cases reporting principal diagnoses describing encounters for adjustment and management of implanted devices of the special senses are more clinically consistent in MDC 02 or MDC 03 depending on the type of device, and the diagnosis codes were initially assigned to MDC 01 MS–DRGs 091, 092, and 093 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, we are proposing to reassign ICD–10–CM diagnosis code Z45.31 from MS–DRGs 091, 092, and 093 to MDC 02 MS–DRG 123 (Neurological Eye Disorders). We are also proposing to reassign ICD–10–CM diagnosis codes Z45.320, Z45.321, and Z45.328 from MS–DRGs 091, 092, and 093 to MDC 03 MS–DRGs 154, 155, and 156 (Other Ear, Nose, Mouth and Throat Diagnoses with MCC, with CC, and without CC/MCC, respectively).

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

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

We received a request to create a new MS–DRG for cases reporting endovascular repair of abdominal aortic aneurysms that extend into at least one iliac artery to preserve blood flow to the external or internal iliac arteries. According to the requestor, aortic aneurysms extend into at least one of the iliac arteries in approximately 25% of patients with abdominal aortic aneurysms. The requestor (the manufacturer), stated that the GORE® EXCLUDER® Iliac Branch Endoprosthesis was approved by the Food and Drug Administration (FDA) in March of 2016 to be used exclusively with the GORE® EXCLUDER® Abdominal Aortic Aneurysm Endoprosthesis to isolate the common iliac artery from systemic blood flow and preserve blood flow in the external iliac and internal iliac arteries in patients with a common iliac or aortoiliac aneurysm, who have appropriate anatomy.[1] According to the requestor, maintaining flow to the internal iliac artery and pelvic circulation using iliac branch devices or alternative techniques aims to decrease complications associated with artery occlusion.[2] [3] [4] The requestor also stated that occluding the internal iliac artery can result in significant hip and/or

[1] van der Veen D, Holewijn S, Bellosta R, van Sterkenburg SMM, Heyligers JMM, Ficarelli I, Gómez Palonés FJ, Mangialardi N, Mosquera NJ, Holden A, Reijnen MMPJ; IceBERG Study Collaboration. One Year Outcomes of an International Multicentre Prospective Cohort Study on the Gore Excluder Iliac Branch Endoprosthesis for Aorto-Iliac Aneurysms. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):177–185. doi: 10.1016/j.ejvs.2021.04.006. Epub 2021 Jun 16. PMID: 34144884.

[2] Sousa LHDG, Baptista-Silva JCC, Vasconcelos V, Flumignan RLG, Nakano LCU. Internal iliac artery revascularisation versus internal iliac artery occlusion for endovascular treatment of aorto-iliac aneurysms. Cochrane Database of Systematic Reviews 2020, Issue 7. Art. No.: CD013168. DOI: 10.1002/14651858.CD013168.pub2.

[3] Parlani G, Verzini F, De Rango P, Brambilla D, Coscarella C, Ferrer C, Cao P. Long-term results of iliac aneurysm repair with iliac branched endograft: a 5-year experience on 100 consecutive cases. Eur J Vasc Endovasc Surg. 2012 Mar;43(3):287–92. doi: 10.1016/j.ejvs.2011.12.011. Epub 2012 Jan 10. PMID: 22240335.

[4] Taudorf M, Grønvall J, Schroeder TV, Lönn L. Endovascular Aneurysm Repair Treatment of Aortoiliac Aneurysms: Can Iliac Branched Devices Prevent Gluteal Claudication? J Vasc Interv Radiol. 2016 Feb;27(2):174–80. doi: 10.1016/j.jvir.2015.11.031. Epub 2015 Dec 22. PMID: 26706185.

buttock claudication, erectile dysfunction, and colonic and spinal cord ischemia.

According to the requestor, endovascular aneurysm repair (EVAR) procedures that preserve blood flow to the iliac arteries are technically more challenging than conventional EVAR of the abdominal aorta, and they require increased procedure time, fluoroscopy time, and anesthesia time. The requestor stated that tortuosity and/or stenosis in the iliac territory may increase the complexity or even prevent the deployment of devices, leading to treatment failure or causing early occlusion of the branches. In such cases, some patients may develop symptoms of pelvic ischaemia.[5] [6] The requestor stated that current guidelines advocate the preservation of at least one internal iliac artery in patients with common iliac artery aneurysms, and iliac branched devices were developed to preserve the perfusion in the internal iliac artery.[7]

The requestor also expressed concern that hospitals who treat Medicare patients with aortoiliac and common iliac aneurysms using endovascular procedures with endoprostheses are not classified appropriately based on the current MS–DRG assignment and the resources required. The requestor performed its own data analysis and indicated it found differences in resource utilization when comparing cases reporting standard EVAR of the abdominal aorta to cases reporting EVAR of the abdominal aorta combined with procedures to preserve flow to an iliac branch. According to the requestor, the disparity in resource coherency under the current MS–DRG assignment may reduce access to Medicare beneficiaries who could benefit from these procedures. The requestor stated a new MS–DRG would enable more precise payments and better resource coherency under the MS–DRGs.

The procedure codes that describe EVAR using an abdominal aortic aneurysm (AAA) endoprosthesis and the procedure codes that describe EVAR using an iliac branch endoprosthesis (IBE) that are used to treat aortoiliac and iliac artery aneurysms, respectively, are listed in the following tables.

PROCEDURE CODES DESCRIBING EVAR USING AN ABDOMINAL AORTIC ANEURYSM (AAA) ENDOPROSTHESIS

ICD–10–PCS code	Description
04V03DZ	Restriction of abdominal aorta with intraluminal device, percutaneous approach.
04V03EZ	Restriction of abdominal aorta with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach.
04V03FZ	Restriction of abdominal aorta with branched or fenestrated intraluminal device, three or more arteries, percutaneous approach.

PROCEDURE CODES DESCRIBING EVAR USING AN ILIAC BRANCH ENDOPROSTHESIS (IBE)

ICD–10–PCS code	Description
04VC3DZ	Restriction of right common iliac artery with intraluminal device, percutaneous approach.
04VC3EZ	Restriction of right common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach.
04VD3DZ	Restriction of left common iliac artery with intraluminal device, percutaneous approach.
04VD3EZ	Restriction of left common iliac artery with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach.
04VE3DZ	Restriction of right internal iliac artery with intraluminal device, percutaneous approach.
04VF3DZ	Restriction of left internal iliac artery with intraluminal device, percutaneous approach.
04VH3DZ	Restriction of right external iliac artery with intraluminal device, percutaneous approach.
04VJ3DZ	Restriction of left external iliac artery with intraluminal device, percutaneous approach.

Cases reporting a combination of these procedure codes (that is, any one procedure code from each list) for the endovascular treatment of aortoiliac and iliac artery aneurysms are currently assigned to MS–DRGs 268 and 269 (Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC and without MCC, respectively). Based on its analysis of Medicare claims data using the previously listed codes in MS–DRGs 268 and 269, and to facilitate more precise payments for these procedures, the requestor recommended that CMS assign cases reporting a procedure code describing EVAR using an AAA endoprosthesis with a procedure code describing EVAR using an IBE to a proposed new MS–DRG titled, ''Concomitant Endovascular Abdominal Aorta and Iliac Branch Procedures''.

In review of this request, we analyzed claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 268 and 269 and for cases reporting standard EVAR using an AAA endoprosthesis compared to cases reporting EVAR using an AAA endoprosthesis with an IBE that are used to treat aortoiliac and iliac artery aneurysms with the previously listed procedure codes. The findings from our analysis are shown in the following table.

[5] Donas KP, Criado FJ, Torsello G, Veith FJ, Minion DJ; PERICLES Registry Collaborators. Classification of Chimney EVAR-Related Endoleaks: Insights From the PERICLES Registry. J Endovasc Ther. 2017 Feb 1;24(1):72–74. doi: 10.1177/1526602816678994. Epub 2016 Nov 21. PMID: 27872319.

[6] Ghosh J, Murray D, Paravastu S, Farquharson F, Walker MG, Serracino-Inglott F. Contemporary management of aorto-iliac aneurysms in the endovascular era. Eur J Vasc Endovasc Surg. 2009 Feb;37(2):182–8. doi: 10.1016/j.ejvs.2008.11.001. Epub 2008 Nov 29. PMID: 19046903.

[7] van der Veen D, Holewijn S, Bellosta R, van Sterkenburg SMM, Heyligers JMM, Ficarelli I, Gómez Palonés FJ, Mangialardi N, Mosquera NJ, Holden A, Reijnen MMPJ; IceBERG Study Collaboration. One Year Outcomes of an International Multicentre Prospective Cohort Study on the Gore Excluder Iliac Branch Endoprosthesis for Aorto-Iliac Aneurysms. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):177–185. doi: 10.1016/j.ejvs.2021.04.006. Epub 2021 Jun 16. PMID: 34144884.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 268—All cases	2,519	9.1	$62,984
MS–DRG 268—Cases reporting standard EVAR using an AAA endoprosthesis	1,500	7.4	63,877
MS–DRG 268—Cases reporting EVAR using an AAA endoprosthesis with an IBE	193	8.2	68,145
MS–DRG 269—All cases	10,108	2.0	39,165
MS–DRG 269—Cases reporting standard EVAR using an AAA endoprosthesis	8,655	1.8	38,562
MS–DRG 269—Cases reporting EVAR using an AAA endoprosthesis with an IBE	871	1.8	48,159

As shown in the table, we identified a total of 2,519 cases within MS–DRG 268 with an average length of stay of 9.1 days and average costs of $62,984. Of the 2,519 cases, we found 1,500 cases reporting standard EVAR using an AAA endoprosthesis with an average length of stay of 7.4 days and average costs of $63,877 and 193 cases reporting EVAR using an AAA endoprosthesis with an IBE with an average length of stay of 8.2 days and average costs of $68,145. The data show that the cases reporting standard EVAR using an AAA endoprosthesis have a shorter average length of stay (7.4 days versus 8.2 days) and lower average costs ($63,877 versus $68,145) compared to the average costs of the cases reporting EVAR using an AAA endoprosthesis with an IBE. The data further show that the 193 cases reporting EVAR using an AAA endoprosthesis with an IBE have a shorter average length of stay (8.2 days versus 9.1 days) and higher average costs ($68,145 versus $62,984) compared to the average length of stay and average costs of all the cases in MS–DRG 268.

For MS–DRG 269, we identified a total of 10,108 cases with an average length of stay of 2.0 days and average costs of $39,165. Of the 10,108 cases, we found 8,655 cases reporting standard EVAR using an AAA endoprosthesis with an average length of stay of 1.8 days and average costs of $38,562 and 871 cases reporting EVAR using an AAA endoprosthesis with an IBE with an average length of stay of 1.8 days and average costs of $48,159. The data show that the cases reporting standard EVAR using an AAA endoprosthesis have a comparable average length of stay (1.8 days versus 1.8 days) and lower average costs ($38,562 versus $48,159) compared to the cases reporting EVAR using an AAA endoprosthesis with an IBE. The data further show that the 871 cases reporting EVAR using an AAA endoprosthesis with an IBE have a shorter average length of stay (1.8 days versus 2.0 days) and higher average costs ($48,159 versus $39,165) compared to the average length of stay and average costs of all the cases in MS–DRG 269.

The findings suggest that the cases reporting EVAR using an AAA endoprosthesis with an IBE utilize greater resources compared to the cases reporting standard EVAR using an AAA endoprosthesis. We agree that patients who have aortoiliac and iliac aneurysms are a more complex population to treat, contributing to increased resource utilization.

Based on our review and analysis of the cases reporting standard EVAR using an AAA endoprosthesis compared to the cases reporting EVAR using an AAA endoprosthesis with an IBE to treat aortoiliac and iliac artery aneurysms in MS–DRGs 268 and 269, we believe new MS–DRGs are warranted to differentiate the utilization of resources between standard EVAR to treat AAA and EVAR to treat AAA extending into the iliac artery.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that at least 500 or more cases are in each subgroup. It also failed to meet the criterion that there be at least a 20 percent difference in average costs between the CC and NonCC (without CC/MCC) subgroup and at least a $2,000 difference in average costs between the CC and NonCC (without CC/MCC) subgroup. The following table illustrates our findings.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	193	8.2	$68,145
With CC	419	2.3	48,415
Without CC/MCC	452	1.3	47,921

As discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We note that, as shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in the with MCC subgroup.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	193	8.2	$68,145
Without MCC	871	1.8	48,159

We then applied the criteria for a two-way split for the ''with CC/MCC'' and ''without CC/MCC'' subgroups. As shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 500 or more cases in the without CC/MCC subgroup and at least a 20 percent difference in average costs between the with CC/MCC and without CC/MCC subgroup.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With CC/MCC	612	4.2	$54,637
Without CC/MCC	452	1.3	47,921

We note that because the criteria for both of the two-way splits failed, a split (or CC subgroup) is not warranted for the proposed new base MS–DRG. As a result, for FY 2026, we are proposing to create new base MS–DRG 213 (Endovascular Abdominal Aorta and Iliac Branch Procedures). The following table reflects a simulation of the proposed new base MS–DRG.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
Proposed MS–DRG 213	1,064	3.0	$51,784

b. Concomitant Single Valve Procedure With Open Surgical Ablation

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44836 through 44848), we discussed a two-part request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. The first part of the request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. The second part of the request was to reassign cases describing standalone percutaneous endoscopic surgical ablation. In the part of the request relating to the costs of open concomitant surgical ablations, the requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open coronary artery bypass graft (CABG) + open surgical ablation
- Open mitral valve repair or mitral valve replacement (MVR) + open surgical ablation
- Open aortic valve repair or mitral valve replacement (AVR) + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

As discussed in the FY 2022 IPPS/LTCH PPS final rule, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations and stated our analysis showed while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found variation in the volume, length of stay, and average costs of the cases.

In the FY 2022 IPPS/LTCH PPS final rule, for the reasons discussed, we finalized our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) to sequence MS–DRGs 231–236 (Coronary Bypass, with or without PTCA, with or without Cardiac Catheterization or Open Ablation, with and without MCC, respectively) above MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2021. In addition, we also finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 and changed the titles of these MS–DRGs to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively'' to reflect this reassignment for FY 2022.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48845 through 48849), we discussed a request we received to again review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor stated they continue to believe that the average hospital costs for surgical ablation for atrial fibrillation demonstrates a cost disparity compared to all procedures within their respective MS–DRGs. The requestor suggested that when open surgical ablation is performed with MVR, or AVR or MVR/AVR + CABG that these procedures are either (1) assigned to a different family of MS–DRGs or (2) assigned to MS–DRGs 216 and 217 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC and with CC, respectively) similar to what CMS did with CABG and open ablation procedures in the FY 2022 rulemaking to better accommodate the added cost of open concomitant surgical ablation.

We stated our analysis using the September 2021 update of the FY 2021 MedPAR file reflected that the cases reporting an open concomitant surgical ablation code combination are predominately found in the higher (CC or MCC) severity level MS–DRGs of their current base MS–DRG assignment, suggesting that the patient's co-morbid conditions may also be contributing to the higher costs of these cases. Secondly, for the numerous procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure, the increase in average costs appeared to directly correlate with the number of procedures performed. For example, cases that describe ''Open MVR + Open surgical ablation'' generally demonstrated costs that were lower than cases that describe ''Open MVR + Open AVR + Open CABG + Open surgical ablation.''

Therefore, we stated we believe that additional time was needed to allow for further analysis of the claims data to

determine to what extent the patient's co-morbid conditions are also contributing to higher costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of these cases in these MS–DRGs. For the reasons summarized, and after consideration of the public comments we received, we did not make any MS–DRG changes for cases involving the open concomitant surgical ablation procedures for FY 2023.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58681 through 58690), we again received a request to review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor recommended that CMS reassign open concomitant surgical ablation procedures for atrial fibrillation (AF) from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217, and 218. The requestor further recommended that if CMS does not reassign cases involving open concomitant surgical ablation procedures to MS–DRGs 216, 217, and 218, in the alternative, CMS should create new MS–DRGs for all open mitral or aortic valve repair or replacement procedures with concomitant surgical ablation for AF to improve clinical coherence when three to four open heart procedures are performed in one setting.

The requestor stated that cases reporting open surgical ablation procedures for AF performed during open valve repair/replacement procedures are typically assigned to MS–DRGs 216, 217, 218, 219, 220, and 221, with the majority of the cases being assigned to MS–DRGs 219, 220, and 221 because of the surgical hierarchy in MDC 05 and because there is less of a need for cardiac catheterization in these cases. We stated in the final rule that the requestor performed its own data analysis, and stated their analysis showed that the data continues to demonstrate that claims with open surgical ablation procedures for AF are not clinically similar to the remaining cases in MS–DRGs 219, 220, and 221, and there are significant differences in resource utilization that reflect those clinical differences.

We noted in FY 2024 IPPS/LTCH PPS final rule that our analysis of the claims data suggested that it is the performance of an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure that is associated with increased hospital resource utilization, not solely the performance of open surgical ablation as suggested by the requestor, when compared to other cases in their respective MS–DRGs. Therefore, for the reasons discussed, we finalized our proposal to create MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) in MDC 05 for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure.

For this FY 2026 IPPS/LTCH PPS proposed rule, we again received a request to review the MS–DRG assignment of cases involving a single open surgical valve procedure with an open surgical ablation. The requestor recommended that CMS reassign cases involving a single open surgical valve procedure with an open surgical ablation from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). The requestor also suggested that if finalized, the title for MS–DRGs 216, 217, and 218 should be revised to ''Cardiac valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization or Open Ablation, with MCC, with CC or without CC/MCC, respectively.''

The requestor stated MS–DRGs primarily focus on the most resource intensive procedure, without fully accounting for the overall resource intensity and complexity of all procedures performed and stated treating AF as a secondary condition is one such example. The requestor stated that AF, if not treated early after diagnosis, continues to worsen and is associated with stroke and mortality risk, and significantly higher healthcare spending. According to the requestor, a majority of AF patients undergoing surgical ablation procedures are older and frailer than non-surgical ablation valvular patients, and these patients frequently require two or even three procedures during one hospital visit to treat multiple conditions (AF, valve disease, heart failure, blocked coronaries). The requestor further stated patients undergoing multiple cardiac procedures, including surgical ablation, typically require between two and four hours of additional time in the operating room, a longer length of stay, and are at an increased risk for adverse event in recovery and noted that much like cardiac catheterization procedures, in many instances adding surgical ablation to open valvular procedures also requires an atriotomy to better visualize the mitral valve and complete the surgical ablation, making these concomitant procedures significantly more complex than single valve procedures performed on their own. The requestor stated that the current MS–DRG assignments do not adequately pay hospitals for the resources associated with furnishing surgical ablation procedures and that therefore, it is increasingly becoming financially unviable for hospitals to perform these procedures to Medicare beneficiaries in a single admission.

The requestor asserted that reassigning cases involving a single open surgical valve procedure with an open surgical ablation, which are currently assigned in MS–DRGs 219, 220, and 221, to MS–DRGs 216, 217, and 218 would accommodate the clinical complexity of performing two or more open heart procedures, would enhance clinical coherence for patients undergoing multiple procedures within MDC 05, would more accurately reflect associated costs and resource utilization, and would help minimize the need for multiple patient admissions. The requestor performed its own data analysis of the Standard Analytical File (SAF) FY 2022 Q1—Q3 report and stated they identified 1,938 cases involving a single open surgical valve procedure with an open surgical ablation that were assigned to MS–DRGs 219, 220, and 221. The requestor stated their analysis showed that the impact of reassigning the 1,938 cases would result in better resource alignment with minimal relative weight changes. Specifically, the requestor stated that their analysis showed that if the cases involving a single open surgical valve procedure with an open surgical ablation that are currently assigned to MS–DRGs 219, 220, and 221 were reassigned to MS–DRGs 216, 217, and 218, the relative weights of MS–DRGs 216, 217, 218, 219, 220, and 221 would change by −5.35%, −4.48%, −2.59%, +0.47%, −0.93% and −0.12% respectively.

As previously noted, the requestor recommended that we consider cases involving a single open surgical valve procedure with an open surgical ablation, however the requestor did not provide a specific list of procedure codes for our consideration. Therefore, we reviewed the ICD–10–PCS classification and identified 81 procedure codes describing open surgical valve procedures and eight procedure codes describing open

surgical ablation procedures. We refer readers to Table 6P.3a associated with this FY 2026 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*), which sets forth the list of ICD–10–PCS procedure codes describing open surgical valve procedures and open surgical ablation procedures that we examined.

To address this request and to understand the resource use for the subset of cases reporting procedure codes describing a single open surgical valve procedure with an open surgical ablation, without reporting a procedure code describing the performance of a cardiac catheterization, that are currently grouping to MS–DRGs 219, 220, and 221, we examined claims data from the September 2024 update of the FY 2024 MedPAR file for the average length of stay and average costs for these cases. Our findings are shown in the following table:

MS–DRGs 219–221—Cases Reporting an Open Valve Procedure and an Open Surgical Ablation Procedure Without Reporting Cardiac Catheterization

MS–DRG		Number of cases	Average length of stay	Average costs
219	All cases	13,222	10	$69,728
	Cases reporting an open valve procedure and an open surgical ablation procedure without reporting cardiac catheterization.	1,657	10.1	67,532
220	All cases	9,636	6.2	49,514
	Cases reporting an open valve procedure and an open surgical ablation procedure without reporting cardiac catheterization.	999	6.9	53,603
221	All cases	1,146	3.6	46,900
	Cases reporting an open valve procedure and an open surgical ablation procedure without reporting cardiac catheterization.	41	5.6	48,353

As shown in the table, the data analysis performed indicates that the 1,657 cases in MS–DRG 219 reporting an open valve procedure and an open surgical ablation procedure, without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 219 (10.1 days versus 10 days) and lower average costs when compared to all the cases in MS–DRG 219 ($67,532 versus $69,728). The difference in average costs is $2,196 ($69,728 − $67,532 = $2,196) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a MCC in MS–DRG 219 when compared to all the cases in MS–DRG 219.

In MS–DRG 220, the 999 cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 220 (6.9 days versus 6.2 days) and higher average costs when compared to all the cases in MS–DRG 220 ($53,603 versus $49,514). The difference in average costs is $4,089 ($53,603 − $49,514 = $4,089) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC in MS–DRG 220 when compared to all the cases in MS–DRG 220.

In MS–DRG 221, the 41 cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 221 (5.6 days versus 3.6 days) and higher average costs when compared to all the cases in MS–DRG 221 ($48,353 versus $46,900). The difference in average costs is $1,453 ($48,353 − $46,900 = $1,453) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC in MS–DRG 221 when compared to all the cases in MS–DRG 221.

We then examined the data for cases in MS–DRGs 216, 217, and 218, and our findings are shown in the following table:

MS–DRG	Description	Number of cases	Average length of stay	Average costs
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC.	5,137	13.6	$88,193
217	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC.	1,571	6.8	59,943
218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC.	251	2.9	61,733

The data analysis performed indicates that the cases in MS–DRGs 219, 220, and 221 reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization have a generally longer average length of stay and lower average costs when compared to all cases in

MS–DRGs 216, 217, and 218. As shown in the table, the data analysis performed indicates that the 1,657 cases in MS–DRG 219 reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as an MCC have a shorter average length of stay (10.1 days versus 13.6 days) and lower average costs ($67,532 versus $88,193) when compared to all the cases in MS–DRG 216. The difference in average costs is $20,661 ($88,193 − $67,532 = $20,661) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a MCC in MS–DRG 219 when compared to all the cases in MS–DRG 216.

The 999 cases in MS–DRG 220 reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC have a longer average length of stay (6.9 days versus 6.8 days) and lower average costs ($53,603 versus $59,943) when compared to all the cases in MS–DRG 217. The difference in average costs is $6,340 ($59,943 − $53,603 = $6,340) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and with a secondary diagnosis code designated as a CC in MS–DRG 220 when compared to all the cases in MS–DRG 217.

The 41 cases in MS–DRG 221 reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC have a longer average length of stay (5.6 days versus 2.9 days) and lower average costs ($48,353 versus $61,733) when compared to all the cases in MS–DRG 218. The difference in average costs is $13,380 ($61,733 − $48,353 = $13,380) for the cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization, and without a secondary diagnosis code designated as a CC or MCC in MS–DRG 221 when compared to all the cases in MS–DRG 218.

While the data analysis reflects that cases that report an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization generally demonstrate slightly higher average costs in their respective MS–DRGs, we believe these cases are more suitably grouped to MS–DRGs 219, 220, and 221 where they are currently assigned, based on the closer similarities in resource utilization compared to all the cases in their respective MS–DRG. As discussed in prior rulemaking (86 FR 44878), the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We also provide outlier payments to mitigate extreme loss on individual cases. Moreover, the data do not indicate cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization utilize similar resources when compared to the cases assigned to MS–DRGs 216, 217, and 218. The cases are not clinically coherent with regard to resource utilization as reflected in the greater differences in average costs.

Further, in examining this request, we note that the requestor suggested that CMS reassign cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217, and 218 for FY 2026, however, as discussed in prior rulemaking (86 FR 44830, 87 FR 48847, and 88 FR 58683), MS–DRGs 216, 217, and 218 are defined by the performance of cardiac catheterization. We continue to be concerned about the effect on clinical coherence of assigning cases reporting an open valve procedure and an open surgical ablation procedure that do not also have a cardiac catheterization procedure reported to MS–DRGs that are defined by the performance of that procedure. Our claims analysis for this FY 2026 IPPS/LTCH PPS proposed rule continues to reflect the difference in average costs demonstrated by the two cohorts, as cases reporting the performance of a cardiac catheterization in MS–DRGs 216, 217, and 218 continue to demonstrate higher average costs.

As stated previously, our analysis of the claims data continues to reflect that cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization are clinically coherent in their currently assigned MS–DRGs. Therefore, we are proposing to maintain the structure of MS–DRGs 216, 217, and 218 for FY 2026. We are also proposing to maintain the title of MS–DRGs 216, 217, and 218 as ''Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively'' for FY 2026.

c. Transcatheter Aortic Valve Replacement Procedures for Aortic Regurgitation

Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure that involves a catheter being inserted into an artery, without an incision for most cases, and then guided to the heart. The catheter delivers the new valve without the need for the chest or heart to be surgically opened. For this FY 2026 IPPS/LTCH PPS proposed rule, we received a request to reassign cases reporting TAVR procedures for aortic regurgitation (AR) from MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement with or without MCC, respectively) to what the requester described as a more clinically and cost cohesive MS–DRG such as MS–DRG 215 (Other Heart Assist System Implant) and to revise the title of MS–DRG 215 to ''Other Heart Assist System Implant or Endovascular Cardiac Regurgitant Valve Replacement Procedures.''

According to the requestor, Medicare patients with severe, symptomatic AR often present with chronic, congestive heart failure, which equates to significantly greater diastolic heart failure, atrial fibrillation, and concomitant kidney, liver, and biventricular failure. As a result, managing this systemic damage requires a multidisciplinary care team, comprising of implanting physicians, cardiac surgeons, imaging cardiologists, and heart failure specialists, similar to the management required for cases currently assigned to MS–DRG 215. Further, the requestor stated TAVR procedures for AR prevent patients from devolving into heart failure and are clinically more comparable to short term heart assist device support. The requestor stated regurgitant valve disease, such as AR, is a whole-heart cardiac disease that has systemic manifestations that leads to biventricular heart failure and non-cardiac morbidity, while stenotic valve disease, such as aortic stenosis (AS), is less often associated with non-cardiac dysfunction. According to the requestor,

managing a diagnosis of AR leads to inpatient lengths of stay that are double the duration of the length of stay of patients with AS, as management of AS only requires the involvement of the implanting physician and the cardiac surgeon.

The requestor identified TAVR for AR with ICD–10–CM diagnosis code I35.1 (Nonrheumatic aortic (valve) insufficiency) and ICD–10–PCS procedure code 02RF38Z (Replacement of aortic valve with zooplastic tissue, percutaneous approach) and performed their own analysis of the FY2023 Final MedPAR data. The requestor stated they found the cases reporting a diagnosis of aortic regurgitation in MS–DRG 266 and 267 have 20% higher average costs (AR = $54,425 versus AS = $45,323), two times the length of stay (AR = 5 days versus AS = 2.5 days) and trigger outlier payments two times more often (AR = 11.43% versus AS = 5.82%) compared to the cases reporting a diagnosis of aortic stenosis in MS–DRGs 266 and 267. The requestor noted in order to perform their analysis, they excluded cases reporting procedure codes describing the insertion of a percutaneous short-term external heart assist device by removing cases that reported ICD–10–PCS procedure codes 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach) and 5A0221D (Assistance with cardiac output using impeller pump, continuous) from their analyses, as the requestor asserted those procedure codes were reassigned to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with MCC and without MCC, respectively) in FY 2024.

As stated previously, the requestor identified TAVR procedures for AR with ICD–10–CM diagnosis code I35.1 (Nonrheumatic aortic (valve) insufficiency) and ICD–10–PCS procedure code 02RF38Z (Replacement of aortic valve with zooplastic tissue, percutaneous approach). In reviewing this request, we identified five additional ICD–10–CM diagnosis codes that also describe aortic regurgitation and included these codes in our analysis. The five ICD–10–CM diagnosis codes we identified are listed in the following table.

ICD–10–CM code	Description
I06.1	Rheumatic aortic insufficiency.
I08.0	Rheumatic disorders of both mitral and aortic valves.
I08.2	Rheumatic disorders of both aortic and tricuspid valves.
I08.3	Combined rheumatic disorders of mitral, aortic and tricuspid valves.
I35.2	Nonrheumatic aortic (valve) stenosis with insufficiency.

Also, we identified eight additional ICD–10–PCS procedure codes that describe TAVR procedures as well, and similarly included these codes in our analysis. The eight ICD–10–PCS procedure codes we identified are listed in the following table.

ICD–10–PCS code	Description
02RF37H	Replacement of aortic valve with autologous tissue substitute, transapical, percutaneous approach.
02RF37Z	Replacement of aortic valve with autologous tissue substitute, percutaneous approach.
02RF38H	Replacement of aortic valve with zooplastic tissue, transapical, percutaneous approach.
02RF38N	Replacement of aortic valve with zooplastic tissue, using rapid deployment technique, percutaneous approach.
02RF3JH	Replacement of aortic valve with synthetic substitute, transapical, percutaneous approach.
02RF3JZ	Replacement of aortic valve with synthetic substitute, percutaneous approach.
02RF3KH	Replacement of aortic valve with nonautologous tissue substitute, transapical, percutaneous approach.
02RF3KZ	Replacement of aortic valve with nonautologous tissue substitute, percutaneous approach.

To begin our analysis, we reviewed the GROUPER logic. The requestor is correct that nine ICD–10–PCS codes that describe TAVR procedures mentioned previously are currently assigned to MS–DRGs 266 and 267. The requestor is also correct that in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58690 through 58696), we discussed a request we received to reassign certain cases reporting procedure codes describing the insertion of a short-term external heart assist device from MS–DRG 215 to MS–DRGs 001 and 002. We stated temporary heart assist devices are intended to support blood pressure and provide increased blood flow to critical organs in patients with cardiogenic shock, by drawing blood out of the heart and pumping it into the aorta, partially or fully bypassing the left ventricle to provide adequate circulation of blood (replace or supplement left ventricle pumping) while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support.

In the FY 2024 IPPS/LTCH PPS final rule, we stated that we examined the claims data and the data suggested that overall, cases reporting a procedure code describing the open insertion of a short-term external heart assist device may be more appropriately aligned with the average costs of the cases in MS–DRGs 001 and 002 in comparison to MS–DRG 215, even though the average length of stay is shorter. We also stated that we reviewed the clinical considerations along with this data analysis and agreed that cases reporting a procedure code that describes the open insertion of a short-term external heart assist device are generally more resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of short-term external heart devices by other approaches currently assigned to MS–DRG 215. Therefore, for the reasons discussed and after consideration of the public comments we received, we finalized our proposal to reassign ICD–10–PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MS–DRG 215 in MDC 05 to Pre-MDC MS–DRGs 001 and 002 when reported as a standalone procedure for FY 2024. Under this finalization, procedure code 02HA0RZ no longer needs to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 001 and 002. We refer the reader to the ICD–

10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 001, 002, 215, 266 and 267.

While the requestor stated that procedure code 02HA3RZ (Insertion of short-term external heart assist system into heart, percutaneous approach) and procedure code 5A0221D (Assistance with cardiac output using impeller pump, continuous) were reassigned to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with MCC and without MCC, respectively) in FY 2024, we note that our finalization in the FY 2024 IPPS/LTCH PPS final rule did not involve modifying the MS–DRG assignment of procedure code 02HA3RZ or procedure code 5A0221D. In Version 42.1, cases reporting procedure codes 02HA3RZ and 5A0221D, continue to be assigned to MS–DRG 215. We refer the reader to Appendix E of the ICD–10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the MS–DRG assignments of procedure codes 02HA0RZ, 02HA3RZ, and 5A0221D.

Next, we examined claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRG 266 and 267 to identify cases reporting one of the six ICD–10–CM codes listed previously that describe aortic regurgitation as a principal or a secondary diagnosis with one of the nine procedure codes that describe a TAVR procedure. Our findings are shown in the following table:

MS–DRGs 266–267—All Cases and Cases Reporting a Procedure Code Describing TAVR With a Principal or Secondary Diagnosis of Aortic Regurgitation

MS–DRG		Number of cases	Average length of stay	Average costs
266	All cases	22,083	4.5	$55,402
	Cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation.	3,616	5.7	56,010
267	All Cases	36,405	1.5	43,282
	Cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation.	4,521	1.6	41,189

As shown in the table, in MS–DRG 266, we identified a total of 22,083 cases with an average length of stay of 4.5 days and average costs of $55,402. Of those 22,083 cases, there were 3,616 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation, with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 266 ($56,010 compared to $55,402) and a longer average length of stay (5.7 days compared to 4.5 days). In MS–DRG 267, we identified a total of 36,405 cases with an average length of stay of 1.5 days and average costs of $43,282. Of those 36,405 cases, there were 3,616 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation, with average costs lower than the average costs in the FY 2024 MedPAR file for MS–DRG 267 ($41,189 compared to $43,282) and a longer average length of stay (1.6 days compared to 1.5 days).

We then examined claims data from the September 2024 update of the FY 2024 MedPAR for MS–DRG 215. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
215	3,257	8.2	$87,701

Our analysis indicates that the cases assigned to MS–DRG 215 have much higher average costs ($87,701 versus $56,010 or $41,189) and a much longer length of stay (8.2 days versus 5.7 days or 1.6 days) than the cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation currently assigned to MS–DRGs 266 or 267, respectively. Instead, the average costs and average length of stay for cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation appear to be generally more aligned with the average costs and average length of stay for all cases in MS–DRGs 266 and 267, where they are currently assigned.

In addition, based on our review of the clinical considerations, we do not believe the procedure codes describing a TAVR are clinically coherent with the procedure codes currently assigned to MS–DRG 215. Heart assist devices, such as ventricular assist devices and artificial heart systems, provide circulatory support by taking over most of the workload of the left ventricle. Blood enters the pump through an inflow conduit connected to the left ventricle and is ejected through an outflow conduit into the body's arterial system. Heart assist devices can provide temporary left, right, or biventricular support for patients whose hearts have failed and can also be used as a bridge for patients who are awaiting a heart transplant. While we agree that TAVR can be a treatment option for patients with severe AR who are at high risk for mortality or complications due to advanced age and multiple comorbidities, we do not believe the procedure codes describing TAVR should be assigned to MS–DRG 215. AR is a condition where the aortic valve doesn't close properly causing blood to leak back into the heart. While we acknowledge that if not treated AR can gradually worsen and lead to left ventricular enlargement and eventually heart failure, we believe that patients

with indications for heart assist devices tend to be more severely ill and these inpatient admissions are associated with greater resource utilization as evidenced by the higher average costs and longer lengths of stay. Therefore, for the reasons stated previously, we are proposing to maintain the GROUPER logic for MS–DRGs 266 and 267 for FY 2026. We are also proposing to maintain the title of MS–DRGs 215 as ''Other Heart Assist System Implant'' for FY 2026.

d. Percutaneous Coronary Atherectomy

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58704 through 58712), we discussed a request we received to review the MS–DRG assignment of cases describing percutaneous coronary intravascular lithotripsy (IVL). Coronary IVL is utilized in a subset of percutaneous coronary intervention (PCI) procedures when the artery is severely calcified. According to the requestor, PCIs involving coronary IVL are clinically more complex because coronary IVL is a therapy deployed exclusively in severely calcified coronary lesions, and these lesion types are associated with longer procedure times and increased utilization of hospital resources. In analyzing this request, we stated in the FY 2024 IPPS/LTCH PPS final rule that the data analysis showed that the average costs of cases reporting percutaneous coronary IVL, with or without involving the insertion of an intraluminal device, were higher than for all cases in their respective MS–DRG. Therefore for FY 2024, taking into consideration that it clinically requires greater resources to perform coronary intravascular lithotripsy, and after consideration of the public comments we received, we finalized our proposal to create MS–DRG 323 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC), MS–DRG 324 (Coronary Intravascular Lithotripsy with Intraluminal Device without MCC) and MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) in MDC 05.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69000 through 69002), we discussed requests to modify the GROUPER logic in a number of cardiac MS–DRGs under MDC 05 (Diseases and Disorders of the Circulatory System) for which we stated further research and analysis were required, and which we would continue to consider in connection with future rulemaking. Specifically, we discussed requests we received to modify the GROUPER logic of MS–DRGs 323, 324, and 325. In two separate but related requests, the requestors suggested that we add procedure codes that describe additional PCI procedures, such as percutaneous coronary rotational, laser, and orbital atherectomy, to the GROUPER logic of new MS–DRGs 323, 324, and 325.

In the FY 2025 IPPS/LTCH PPS final rule, we noted that as stated in prior rule making (88 FR 58708), atherectomy is distinct from coronary lithotripsy in that each of these procedures are defined by clinically distinct definitions and objectives. We stated additional analysis to assess for unintended consequences across the classification was needed as we have made a distinction between the root operations used to describe atherectomy (Extirpation) and the root operation used to describe lithotripsy (Fragmentation) in evaluating other requests in rulemaking. We stated we would need to consider the application of these two root operations in other scenarios where we have also specifically stated that Extirpation is not the same as Fragmentation and do not warrant similar MS–DRG assignment (85 FR 58572 through 58573). Furthermore, as MS–DRGs 323, 324, and 325 had recently become effective on October 1, 2023 (FY 2024), we stated additional time was needed to review and evaluate extensive modifications to the structure of these MS–DRGs.

For this FY 2026 IPPS/LTCH PPS proposed rule, we received a request to reassign percutaneous coronary atherectomy procedures from MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC and without MCC, respectively) and MS–DRGs 321 and 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices and without MCC, respectively) to MS–DRGs 323, 324, and 325 where cases reporting percutaneous coronary IVL are assigned. Atherectomy is a procedure used to remove plaque buildup from the inside of arteries. The requestor stated that coronary atherectomy and coronary IVL target the same step of the PCI treatment process (that is, reducing the burden of calcium by preparing the vessel prior to stent delivery). The requestor further stated that coronary atherectomy is more clinically similar to coronary IVL than other routine vessel preparation techniques (such as angioplasty) in that both coronary atherectomy and coronary IVL are used to modify severe coronary calcium, treat the same patient population, and have the same intended clinical use for complex vessel preparation. Complex vessel preparation is required to increase the diameter of an artery's lumen in severely calcified lesions and improves revascularization by debulking calcification which enables better intraluminal device deployment and improved drug uptake into the vessel wall. Similar to lithotripsy, after percutaneous atherectomy is performed, the provider can implant an intraluminal device, also called a stent, to keep the vessel open.

According to the requestor, removing percutaneous coronary atherectomy procedures from their current MS–DRG assignments and assigning them to MS–DRGs 323, 324, and 325 would reduce cost variance and improve clinical coherence across all PCI MS–DRGs. The requestor also stated that as atherectomy procedures involve more complex calcified lesions and require greater resources, it is not clinically or cost coherent to maintain their current MS–DRG assignments, therefore creating a new MS–DRG for all cases involving percutaneous coronary atherectomy procedures was a reasonable alternative option if CMS did not agree with the reassignment of these cases to MS–DRGs 323, 324, and 325.

The requestor identified eight ICD–10–PCS codes that they state describe percutaneous coronary atherectomy. The eight codes the requestor identified are listed in the following table.

ICD–10–PCS code	Description
02C03Z7	Extirpation of matter from coronary artery, one artery, orbital atherectomy technique, percutaneous approach.
02C03ZZ	Extirpation of matter from coronary artery, one artery, percutaneous approach.
02C13Z7	Extirpation of matter from coronary artery, two arteries, orbital atherectomy technique, percutaneous approach.
02C13ZZ	Extirpation of matter from coronary artery, two arteries, percutaneous approach.
02C23Z7	Extirpation of matter from coronary artery, three arteries, orbital atherectomy technique, percutaneous approach.
02C23ZZ	Extirpation of matter from coronary artery, three arteries, percutaneous approach.
02C33Z7	Extirpation of matter from coronary artery, four or more arteries, orbital atherectomy technique, percutaneous approach.

ICD–10–PCS code	Description
02C33ZZ	Extirpation of matter from coronary artery, four or more arteries, percutaneous approach.

While we agree with the requestor that the eight procedure codes listed in the previous table describe percutaneous coronary atherectomy, we note there are additional ICD–10–PCS codes that describe percutaneous coronary atherectomy in the GROUPER logic for MS–DRGs 250, 251, 321, and 322. Therefore, in reviewing this request, we identified 12 additional ICD–10–PCS procedure codes that also describe percutaneous or percutaneous endoscopic coronary atherectomy procedures and included these codes in our analysis. The 12 codes we identified are listed in the following table.

ICD–10–PCS code	Description
02C03Z6	Extirpation of matter from coronary artery, one artery, bifurcation, percutaneous approach.
02C04Z6	Extirpation of matter from coronary artery, one artery, bifurcation, percutaneous endoscopic approach.
02C04ZZ	Extirpation of matter from coronary artery, one artery, percutaneous endoscopic approach.
02C13Z6	Extirpation of matter from coronary artery, two arteries, bifurcation, percutaneous approach.
02C14Z6	Extirpation of matter from coronary artery, two arteries, bifurcation, percutaneous endoscopic approach.
02C14ZZ	Extirpation of matter from coronary artery, two arteries, percutaneous endoscopic approach.
02C23Z6	Extirpation of matter from coronary artery, three arteries, bifurcation, percutaneous approach.
02C24Z6	Extirpation of matter from coronary artery, three arteries, bifurcation, percutaneous endoscopic approach.
02C24ZZ	Extirpation of matter from coronary artery, three arteries, percutaneous endoscopic approach.
02C33Z6	Extirpation of matter from coronary artery, four or more arteries, bifurcation, percutaneous approach.
02C34Z6	Extirpation of matter from coronary artery, four or more arteries, bifurcation, percutaneous endoscopic approach.
02C34ZZ	Extirpation of matter from coronary artery, four or more arteries, percutaneous endoscopic approach.

We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for complete documentation of the GROUPER logic for MS–DRGs 250, 251, 321, and 322.

To begin our analysis, we examined claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 250, 251, 321, and 322 to identify cases reporting a procedure code describing percutaneous or percutaneous endoscopic coronary atherectomy and compared the results to all cases in their respective MS–DRG. Our findings are shown in the following table.

MS–DRG		Number of cases	Average length of stay	Average costs
250	All cases	3,047	4.4	$21,383
	Cases reporting percutaneous or percutaneous endoscopic coronary atherectomy.	493	4.6	25,139
251	All cases	2,515	2.4	14,521
	Cases reporting percutaneous or percutaneous endoscopic coronary atherectomy.	340	2.5	18,121
321	All cases	32,517	5.0	26,309
	Cases reporting percutaneous or percutaneous endoscopic coronary atherectomy.	3,307	5.1	31,886
322	All cases	46,600	2.4	16,792
	Cases reporting percutaneous or percutaneous endoscopic coronary atherectomy.	3,134	2.5	20,889

As shown by the table, in MS–DRG 250, we identified a total of 3,047 cases, with an average length of stay of 4.4 days and average costs of $21,383. Of those 3,047 cases, there were 493 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy without reporting the insertion of an intraluminal device, with higher average costs as compared to all cases in MS–DRG 250 ($25,139 compared to $21,383), and a longer average length of stay (4.6 days compared to 4.4 days). In MS–DRG 251, we identified a total of 2,515 cases with an average length of stay of 2.4 days and average costs of $14,521. Of those 2,515 cases, there were 340 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy without reporting the insertion of an intraluminal device, with higher average costs as compared to all cases in MS–DRG 251 ($18,121 compared to $14,521), and a longer average length of stay (2.5 days compared to 2.4 days).

In MS–DRG 321, we identified a total of 32,517 cases with an average length of stay of 5.0 days and average costs of $26,309. Of those 32,517 cases, there were 3,307 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy with the insertion of an intraluminal device, with higher average costs as compared to all cases in MS–DRG 321 ($31,886 compared to $26,309), and a longer average length of stay (5.1 days compared to 5.0 days). In MS–DRG 322, we identified a total of 46,600 cases with an average length of stay of 2.4 days and average costs of $16,792. Of those 46,600 cases, there were 3,134 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy with the insertion of an

intraluminal device, with higher average costs as compared to all cases in MS–DRG 322 ($20,889 compared to $16,792), and a longer average length of stay (2.5 days compared to 2.4 days). The data analysis shows that the average costs of cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, with or without involving the insertion of an intraluminal device, are higher than for all cases in their respective MS–DRG.

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 323, 324, and 325. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
323	4,429	6.0	$39,047
324	4,877	2.9	28,809
325	646	3.9	29,362

In MS–DRG 323, we found a total of 4,429 cases with an average length of stay of 6.0 days and average costs of $39,047. In MS–DRG 324, we found a total of 4,877 cases with an average length of stay of 2.9 days and average costs of $28,809. In MS–DRG 325, we found a total of 646 cases with an average length of stay of 3.9 days and average costs of $29,362.

The average costs of the 3,307 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy with the insertion of an intraluminal device in MS–DRG 321 are $7,161 less than the average costs of all cases in MS–DRG 323 ($39,047 − $31,886 = $7,161) and have an average length of stay that is less than the average length of stay of all cases in MS–DRG 323 (5.1 days versus 6.0 days). The average costs of the 3,134 cases reporting percutaneous or percutaneous endoscopic coronary atherectomy with the insertion of an intraluminal device in MS–DRG 322 are $7,920 less than the average costs of all cases in MS–DRG 324 ($28,809 − $20,899 = $7,920) and have an average length of stay that is less than the average length of stay of all cases in MS–DRG 324 (2.5 days versus 2.9 days). The average costs of the 493 cases in MS–DRG 250 and the 340 cases in MS–DRG 251 reporting percutaneous or percutaneous endoscopic coronary atherectomy without reporting a procedure code describing the insertion of an intraluminal device are $4,223 and $11,241 less than the average costs of all cases in MS–DRG 325 ($29,362 − $25,139 = $7,920; $29,362 − $18,121 = $11,241), respectively. These 493 cases in MS–DRG 250 have an average length of stay that is more than the average length of stay of all cases in MS–DRG 325 (4.6 days versus 3.9 days) while the 340 cases in MS–DRG 251 have an average length of stay that is less than the average length of stay of all cases in MS–DRG 325 (2.5 days versus 3.9 days).

Upon analysis of the claims data and our review of the request, we do not agree with reassigning cases reporting percutaneous or percutaneous endoscopic coronary atherectomy from MS–DRGs 250, 251, 321, and 322 to MS–DRGs 323, 324, and 325. While we agree that the performance of percutaneous or percutaneous endoscopic coronary atherectomy contributes to increased resource consumption for these PCI procedures, as previously noted, the data do not support that cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, with or without involving the insertion of an intraluminal device, utilize similar resources when compared to coronary IVL procedures currently assigned to MS–DRGs 323, 324, and 325. Additionally, as stated previously and in prior rule making (88 FR 58708), coronary atherectomy is distinct from coronary lithotripsy in that each of these procedures are defined by clinically distinct definitions and objectives. We continue to believe that the root operation Extirpation is not the same as the root operation Fragmentation and do not warrant similar MS–DRG assignment (85 FR 58572 through 58573).

We then explored alternative options, as was requested. As discussed in prior rulemaking (88 FR 58706), we continue to agree that clinically, the presence of severe calcification can increase the treatment difficulty and complexity of service. The data analysis clearly shows that cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, with or without involving the insertion of an intraluminal device, have higher average costs and longer lengths of stay compared to all the cases in their assigned MS–DRG. For these reasons, we are proposing to create new MS–DRGs for cases reporting procedure codes describing percutaneous or percutaneous endoscopic coronary atherectomy involving the insertion of an intraluminal device, as well as a new MS–DRG for cases reporting procedure codes describing percutaneous or percutaneous endoscopic coronary atherectomy without the insertion of an intraluminal device to address the differential in resource consumption.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the September 2024 update of the FY 2024 MedPAR file. The following table illustrates our findings for all 6,441 cases reporting procedure codes describing percutaneous or percutaneous endoscopic atherectomy involving the insertion of an intraluminal device.

Proposed new MS–DRG	Number of cases	Average length of stay	Average costs
Proposed new MS–DRG XXX Percutaneous Coronary Atherectomy with Intraluminal Device	6,441	3.8	$26,535

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule. As shown, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup.

Proposed new MS–DRG	Number of cases	Average length of stay	Average costs
With MCC	3,307	5.1	$31,886
With CC	1,861	2.8	21,961
Without CC/MCC	1,273	2	19,322

As discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that all five criteria were met. The following table illustrates our findings.

Proposed new MS–DRG	Number of cases	Average length of stay	Average costs
With MCC	3,307	5.1	$31,886
Without MCC	3,134	2.5	20,889

For the proposed new MS–DRGs for cases reporting procedure codes describing percutaneous or percutaneous endoscopic atherectomy involving the insertion of an intraluminal device, there is at least (1) 500 cases in the MCC subgroup and 500 cases in the without MCC subgroup; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

We then ran a simulation using the most recent claims data from the September 2024 update of the FY 2024 MedPAR file for all 833 cases reporting procedure codes describing percutaneous or percutaneous endoscopic atherectomy without the insertion of an intraluminal device. The following table illustrates our findings.

Proposed new MS–DRG	Number of cases	Average length of stay	Average costs
Proposed new MS–DRG XXX Percutaneous Coronary Atherectomy without Intraluminal Device	833	3.7	$22,275

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule. As shown, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least 500 cases in the MCC subgroup, CC subgroup, and NonCC subgroup.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	493	4.6	$25,139
With CC	257	2.7	19,080
Without CC/MCC	83	2	15,151

As discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups. We note that, as shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in the with MCC and the without MCC subgroups.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	493	4.6	$25,139
Without MCC	340	2.5	18,121

We then applied the criteria for a two-way split for the ''with CC/MCC'' and ''without CC/MCC'' subgroups. As shown in the table that follows, a two-way split of this base MS–DRG also failed to meet the criterion that there be

at least 500 cases in the without CC/MCC subgroup.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With CC/MCC	750	3.9	$23,063
Without CC/MCC	83	2	15,151

We note that because the criteria for both of the two-way splits failed, a split (or CC subgroup) is not warranted for the proposed new base MS–DRG. As a result, for FY 2026, we are proposing to create a base MS–DRG for cases reporting procedure codes describing percutaneous or percutaneous endoscopic atherectomy without the insertion of an intraluminal device.

In summary, for FY 2026, taking into consideration that it clinically requires greater resources to perform percutaneous or percutaneous endoscopic coronary atherectomy, we are proposing to create two new MS–DRGs with a two-way severity level split for cases describing percutaneous or percutaneous endoscopic coronary atherectomy involving the insertion of an intraluminal device in MDC 05. We are also proposing to create a new base MS–DRG for cases describing percutaneous or percutaneous endoscopic coronary atherectomy without an intraluminal device. These proposed new MS–DRGs are proposed new MS–DRG 359 (Percutaneous Coronary Atherectomy with Intraluminal Device with MCC), proposed new MS–DRG 360 (Percutaneous Coronary Atherectomy with Intraluminal Device without MCC) and proposed new MS–DRG 318 (Percutaneous Coronary Atherectomy without Intraluminal Device). We refer the reader to Table 6P.4a and Table 6P.4b associated with this FY 2026 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the list of procedure codes we are proposing to define in the logic for each of the proposed new MS–DRGs. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.10. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule.

e. Complex Aortic Arch Procedures

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

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

According to the requestor, the manufacturer of the GORE® TAG® Thoracic Branch Endoprosthesis (TBE), reassignment of the procedure code describing endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device to MS–DRG 216 would result in higher payment and better account for the differences in resource use of the cases reporting this procedure than other cases in their respective MS–DRGs where they are currently assigned. The GORE® TAG® TBE provides endovascular repair of pathologies of the descending thoracic aorta requiring a proximal landing zone including the left subclavian artery. It is a modular device that consists of three implantable fabric tubes supported by a nitinol framework. The GORE® TAG® TBE is indicated for endovascular repair of lesions such as aortic aneurysms, traumatic transections, and dissections of the descending thoracic aorta with treatment extending to the aortic arch, while maintaining flow into the left subclavian artery (Zone 2 of the aortic arch), in patients who are at high risk for debranching subclavian procedures and who have appropriate anatomy. According to the requestor, patients with lesions in the aortic arch are often more clinically complex and more difficult to treat than patients with lesions in lower parts of the aorta due to vascular tortuosity, proximity to the heart, involvement of arch vessels that feed into the head and brain, and risk of stroke and paraplegia or paraparesis from emboli released into arteries that provide blood flow to the left arm and head. The requestor stated that for lesions involving the left subclavian artery, the only other treatment options available today include open surgical repair with a synthetic graft or a hybrid procedure which includes a non-branched endovascular device and an open surgical bypass procedure of the head vessels. Per the requestor, for arch lesions involving the brachiocephalic and left common carotid arteries, a TBE device enables hybrid treatment with one fewer bypass procedure.

The requestor identified cases reporting endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device by the presence of ICD–10–PCS codes 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach) and 02VW3DZ (Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach) on the same claim and performed its own analysis of the claims data. The requestor stated they found 90 cases reporting endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device, and these cases are 49% (+$32,326), 60% (+$27,727), and 38% (+$15,432) more costly compared to all cases in MS–DRGs 219, 220, and 221, respectively. While acknowledging that cases reporting endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device typically do not require a cardiac catheterization procedure, the requestor asserted that this claims analysis

demonstrates cases reporting endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device require resources similar to cases in MS–DRG 216.

As mentioned previously, the requestor stated we could also consider reassigning cases reporting procedure codes describing other complex aortic arch branch procedures to MS–DRG 216. The requestor stated to be considered a similar ''complex aortic arch procedure'' the case should report an ICD–10–PCS code describing the endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device with an ICD–10–PCS code describing a Zone 0 or a Zone 1 Bypass procedure. Zone 0 is in the ascending aorta, proximal to the brachiocephalic artery and Zone 1 covers the portion of the aortic arch between the brachiocephalic artery and the left common carotid artery. The requestor identified cases reporting these ''other complex aortic arch procedures'' as cases reporting ICD–10–PCS codes as reflected in the following table.

ICD–10–PCS code	Description
02VX3EZ	Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach.
with one of the following:	
031409J	Bypass left subclavian artery to right extracranial artery with autologous venous tissue, open approach.
031409K	Bypass left subclavian artery to left extracranial artery with autologous venous tissue, open approach.
03140AJ	Bypass left subclavian artery to right extracranial artery with autologous arterial tissue, open approach.
03140AK	Bypass left subclavian artery to left extracranial artery with autologous arterial tissue, open approach.
03140JJ	Bypass left subclavian artery to right extracranial artery with synthetic substitute, open approach.
03140JK	Bypass left subclavian artery to left extracranial artery with synthetic substitute, open approach.
03140KJ	Bypass left subclavian artery to right extracranial artery with nonautologous tissue substitute, open approach.
03140KK	Bypass left subclavian artery to left extracranial artery with nonautologous tissue substitute, open approach.
03140ZJ	Bypass left subclavian artery to right extracranial artery, open approach.
03140ZK	Bypass left subclavian artery to left extracranial artery, open approach.
03LJ0CZ	Occlusion of left common carotid artery with extraluminal device, open approach.
03LJ0ZZ	Occlusion of left common carotid artery, open approach.
03LJ3BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous approach.
03LJ3DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous approach.
03LJ4CZ	Occlusion of left common carotid artery with extraluminal device, percutaneous endoscopic approach.
03LJ4ZZ	Occlusion of left common carotid artery, percutaneous endoscopic approach.
031J09J	Bypass left common carotid artery to right extracranial artery with autologous venous tissue, open approach.
031J09K	Bypass left common carotid artery to left extracranial artery with autologous venous tissue, open approach.
031J09Y	Bypass left common carotid artery to upper artery with autologous venous tissue, open approach.
031J0AJ	Bypass left common carotid artery to right extracranial artery with autologous arterial tissue, open approach.
031J0AK	Bypass left common carotid artery to left extracranial artery with autologous arterial tissue, open approach.
031J0AY	Bypass left common carotid artery to upper artery with autologous arterial tissue, open approach.
031J0JJ	Bypass left common carotid artery to right extracranial artery with synthetic substitute, open approach.
031J0JK	Bypass left common carotid artery to left extracranial artery with synthetic substitute, open approach.
031J0JY	Bypass left common carotid artery to upper artery with synthetic substitute, open approach.
031J0KJ	Bypass left common carotid artery to right extracranial artery with nonautologous tissue substitute, open approach.
031J0KK	Bypass left common carotid artery to left extracranial artery with nonautologous tissue substitute, open approach.
031J0KY	Bypass left common carotid artery to upper artery with nonautologous tissue substitute, open approach.
031J0ZJ	Bypass left common carotid artery to right extracranial artery, open approach.
031J0ZK	Bypass left common carotid artery to left extracranial artery, open approach.
031J0ZY	Bypass left common carotid artery to upper artery, open approach.

In analyzing this request, we note the requestor is correct that the following ICD–10–PCS codes specifically describe procedures involving the GORE® TAG® TBE: 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach), in combination with 02VW3DZ (Restriction of thoracic aorta, descending with intraluminal device, percutaneous approach). The requestor is also correct that procedure codes 02VX3EZ and 02VW3DZ are assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. Additionally, we agree that the ICD–10–PCS codes as reflected in the previous table can describe other complex aortic arch procedures, and when reported MS–DRGs 216, 217, 218, 219, 220, and 221 would be assigned. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*, for complete documentation of the GROUPER logic for MS–DRGs 216, 217, 218, 219, 220, and 221. We note that the GORE® TAG® TBE was approved for new technology add-on payments for FY 2023 (87 FR 48966 through 48969) FY 2024 (88 FR 58800), and FY 2025 (89 FR 69124). We refer readers to section II.E.5 of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule for a discussion regarding the proposed FY 2026 status of technologies approved for FY 2025 new technology add-on payments, including the GORE® TAG® TBE.

To explore mechanisms to address this request and to understand the resource use for the subset of cases reporting procedure codes 02VX3EZ and 02VW3DZ, and cases reporting

''other complex aortic arch procedures'', we began our analysis by examining claims data from the September 2024 update of the FY 2024 MedPAR file for cases assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. Our findings are shown in the following table:

MS–DRGS 216–221—CASES REPORTING ENDOVASCULAR RESTRICTION OF THE THORACIC AORTA WITH A BRANCHED OR FENESTRATED INTRALUMINAL DEVICE AND CASES REPORTING OTHER COMPLEX AORTIC ARCH PROCEDURES

MS–DRG		Number of cases	Average length of stay	Average costs
216	All cases	5,137	13.6	$88,193
	Cases reporting 02VX3EZ and 02VW3DZ	4	25.3	156,361
	Cases reporting other complex aortic arch procedures	0	0	0
217	All cases	1,571	6.8	59,943
	Cases with 02VX3EZ and 02VW3DZ	1	2	46,235
	Cases reporting other complex aortic arch procedures	0	0	0
218	All cases	251	2.9	61,733
	Cases with 02VX3EZ and 02VW3DZ	0	0	0
	Cases reporting other complex aortic arch procedures	0	0	0
219	All cases	13,222	10	69,728
	Cases with 02VX3EZ and 02VW3DZ	81	11.4	97,336
	Cases reporting other complex aortic arch procedures	10	20.7	112,213
220	All cases	9,636	6.2	49,514
	Cases with 02VX3EZ and 02VW3DZ	64	5.2	76,700
	Cases reporting other complex aortic arch procedures	10	6.9	87,003
221	All cases	1,146	3.6	46,900
	Cases with 02VX3EZ and 02VW3DZ	32	1.9	56,765
	Cases reporting other complex aortic arch procedures	0	0	0

As shown in the table, the data analysis performed indicates that the 4 cases in MS–DRG 216 reporting procedure codes 02VX3EZ and 02VW3DZ have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 216 (25.3 days versus 13.6 days) and higher average costs when compared to all the cases in MS–DRG 216 ($156,361 versus $88,193). The difference in average costs is $68,168 ($156,361 − $88,193 = $68,168) for the cases reporting procedure codes 02VX3EZ and 02VW3DZ in MS–DRG 216 when compared to all the cases in MS–DRG 216. There were zero cases reporting other complex aortic arch procedures in MS–DRG 216. In MS–DRG 217, the one case reporting procedure codes 02VX3EZ and 02VW3DZ has a length of stay that is shorter than the average length of stay for all the cases in MS–DRG 217 (2 days versus 6.8 days) and lower costs when compared to all the cases in MS–DRG 217 ($46,235 versus $59,943). The difference in average costs is $13,708 ($59,943 − $46,235 = $13,708) for the cases reporting procedure codes 02VX3EZ and 02VW3DZ in MS–DRG 217 when compared to all the cases in MS–DRG 217. There were zero cases reporting other complex aortic arch procedures in MS–DRG 217. In MS–DRG 218, there were zero cases reporting procedure codes 02VX3EZ and 02VW3DZ or other complex aortic arch procedures.

The 81 cases in MS–DRG 219 reporting procedure codes 02VX3EZ and 02VW3DZ have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 219 (11.4 days versus 10 days) and higher average costs when compared to all the cases in MS–DRG 219 ($97,336 versus $69,728). The difference in average costs is $27,608 ($97,336 − $69,728 = $27,608) for the cases reporting procedure codes 02VX3EZ and 02VW3DZ in MS–DRG 219 when compared to all the cases in MS–DRG 219. The 10 cases in MS–DRG 219 reporting procedure codes describing other complex arch procedures have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 219 (20.7 days versus 10 days) and higher average costs when compared to all the cases in MS–DRG 219 ($112,213 versus $69,728). The difference in average costs is $42,485 ($112,213 − $69,728 = $42,485) for the cases reporting procedure codes describing other complex arch procedures in MS–DRG 219 when compared to all the cases in MS–DRG 219.

In MS–DRG 220, the 64 cases reporting procedure codes 02VX3EZ and 02VW3DZ have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 220 (5.2 days versus 6.2 days) and higher average costs when compared to all the cases in MS–DRG 220 ($76,700 versus $49,514). The difference in average costs is $27,186 ($76,700 − $49,514 = $27,186) for the cases reporting procedure codes 02VX3EZ and 02VW3DZ in MS–DRG 220 when compared to all the cases in MS–DRG 220. The 10 cases reporting procedure codes describing other complex arch procedures have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 220 (6.9 days versus 6.2 days) and higher average costs when compared to all the cases in MS–DRG 220 ($87,003 versus $49,514). The difference in average costs is $37,489 ($87,003 − $49,514 = $37,489) for the cases reporting procedure codes describing other complex arch procedures in MS–DRG 220 when compared to all the cases in MS–DRG 220.

In MS–DRG 221, the 32 cases reporting procedure codes 02VX3EZ and 02VW3DZ have an average length of stay that is shorter than the average length of stay for all the cases in MS–DRG 221 (1.9 days versus 3.6 days) and higher average costs when compared to all the cases in MS–DRG 221 ($56,765 versus $46,900). The difference in average costs is $9,865 ($56,765 − $46,900 = $9,865) for the cases reporting procedure codes 02VX3EZ and 02VW3DZ in MS–DRG 221 when compared to all the cases in MS–DRG 221. There were zero cases reporting other complex aortic arch procedures in MS–DRG 221.

Our analysis of the claims data for cases reporting procedure codes 02VX3EZ and 02VW3DZ and cases reporting procedure codes describing other complex arch procedures demonstrated a relatively low volume of cases in comparison to all the cases in their respective MS–DRGs (that is, in 216, 217, 218, 219, 220, and 221). Analysis of the claims data also demonstrates that the cases had an average length of stay generally longer than all the cases in their respective MS–DRGs. The data analysis indicates that the average costs of the 182 cases reporting procedure codes 02VX3EZ and 02VW3DZ and the 20 cases reporting procedure codes describing other complex arch procedures are generally higher when compared to the average costs of all cases in MS–DRGs 216, 217, 218, 219, 220, and 221. Specifically, most of these cases have average costs that are considerably higher than the average costs of all cases in MS–DRG 216. We reviewed these data and do not believe that proposing to reassign the cases reporting procedure codes 02VX3EZ and 02VW3DZ and the cases reporting procedure codes describing other complex arch procedures to MS–DRG 216, even if there is no cardiac catheterization procedure reported and no secondary diagnosis designated as an MCC reported, would fully address the difference in resource utilization in these cases. Accordingly, we do not believe the data adequately support a potential reassignment of these cases to MS–DRG 216. Therefore we decided to further explore alternative options to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped in conjunction with the separate but related request we received to review and reconsider the MS–DRG assignments for another subset of codes describing aortic arch procedures, as discussed later in this section.

The second request we received was to reassign cases reporting thoracic aortic arch replacement combined with restriction of the descending thoracic aorta from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively).

The requestor, the manufacturer of the Thoraflex™ Hybrid device (also known as the Terumo Aortic Hybrid device), stated that hospital resource utilization for cases involving the Thoraflex™ Hybrid device is significantly higher compared to all cases in MS–DRGs 216, 217, 218, 219, 220, and 221, creating substantial financial loss for the hospitals that offer this technology. The Thoraflex™ Hybrid device is a dual-purpose medical device that replaces the ascending aorta and aortic arch while also stabilizing and repairing the descending thoracic aorta in a single procedure. It is indicated for the open surgical repair or replacement of damaged or diseased vessels of the aortic arch and descending aorta with or without involvement of the ascending aorta in cases of aneurysm and/or dissection. According to the requestor, when the Thoraflex™ Hybrid device is implanted within the aorta, it creates a channel for the blood to bypass the damaged or diseased part of the vessel and keep flowing as the graft and stented sections of the implant replace the parts of the aorta that are not working properly.

The requestor stated that aortic pathologies such as aneurysms and dissections that involve the aortic arch and descending thoracic aorta continue to present surgical challenges and carry risks such as stroke, cerebral malperfusion, paralysis, and renal malperfusion. These risks must be mitigated by intense and patient specific goal-oriented care. According to the requestor, hospitals treating aortic arch pathologies must be able to deploy rapid neurology, neurosurgery, and nephrology all within hours to ensure a good patient outcome. According to the requestor, all these attributes attest to the difficulty and complexity of thoracic aortic arch replacement combined with restriction of the descending thoracic aorta and care of the patient.

The requestor identified cases reporting thoracic aortic arch replacement combined with restriction of the descending thoracic aorta by the presence of ICD–10–PCS code X2RX0N7 (Replacement of thoracic aorta, arch using branched synthetic substitute with intraluminal device, open approach, new technology group 7) in combination with X2VW0N7 (Restriction of thoracic aorta, descending using branched synthetic substitute with intraluminal device, open approach, new technology group 7) on the same claim and performed its own analysis of the claims data. The requestor stated they found that while the volume of cases reporting thoracic aortic arch replacement combined with restriction of the descending thoracic aorta is <1% of total volume in MS–DRGs 216, 217, 218, 219, 220, and 221, the average costs and average lengths of stay of these cases are significantly greater than all other cases in MS–DRG 216.

In analyzing this request, we note the requestor is correct that the following ICD–10–PCS codes specifically describe procedures involving the Thoraflex™ Hybrid device: X2RX0N7 (Replacement of thoracic aorta arch with branched synthetic substitute with intraluminal device, new technology group 7) in combination with X2VW0N7 (Restriction of thoracic descending aorta with branched synthetic substitute with intraluminal device, new technology group 7). The requestor is also correct that procedure codes X2RX0N7 and X2VW0N7 are assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*, for complete documentation of the GROUPER logic for MS–DRGs 216, 217, 218, 219, 220, and 221. The Thoraflex™ Hybrid device was approved for new technology add-on payments for FY 2023 (87 FR 48974 through 48976), FY 2024 (88 FR 58800), and FY 2025 (89 FR 69124). We refer readers to section II.E.5 of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule for a discussion regarding the proposed FY 2026 status of technologies approved for FY 2025 new technology add-on payments, including the Thoraflex™ Hybrid device.

To explore mechanisms to address this request and to understand the resource use for the subset of cases reporting procedure codes X2RX0N7 and X2VW0N7, we began our analysis by examining claims data from the September 2024 update of the FY 2024 MedPAR file for cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. Our findings are shown in the following table:

MS–DRGs 216–221—Cases Reporting Thoracic Aortic Arch Replacement Combined With Restriction of the Descending Thoracic Aorta

MS–DRG		Number of cases	Average length of stay	Average costs
216	All cases	5,137	13.6	$88,193
	Cases reporting X2RX0N7 and X2VW0N7	20	23	158,920
217	All cases	1,571	6.8	59,943
	Cases reporting X2RX0N7 and X2VW0N7	2	21.5	160,014
218	All cases	251	2.9	61,733
	Cases reporting X2RX0N7 and X2VW0N7	0	0	0
219	All cases	13,222	10	69,728
	Cases reporting X2RX0N7 and X2VW0N7	61	16.9	154,134
220	All cases	9,636	6.2	49,514
	Cases reporting X2RX0N7 and X2VW0N7	14	8.9	84,004
221	All cases	1,146	3.6	46,900
	Cases reporting X2RX0N7 and X2VW0N7	1	3	97,825

As shown in the table, the data analysis performed indicates that the 20 cases in MS–DRG 216 reporting procedure codes X2RX0N7 and X2VW0N7 have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 216 (23 days versus 13.6 days) and higher average costs when compared to all the cases in MS–DRG 216 ($158,920 versus $88,193). The difference in average costs is $70,727 ($158,920 − $88,193 = $70,727) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 in MS–DRG 216 when compared to all the cases in MS–DRG 216. In MS–DRG 217, the 2 cases reporting procedure codes X2RX0N7 and X2VW0N7 have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 217 (21.5 days versus 6.8 days) and higher average costs when compared to all the cases in MS–DRG 217 ($160,014 versus $59,943). The difference in average costs is $100,071 ($160,014 − $59,943 = $100,071) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 in MS–DRG 217 when compared to all the cases in MS–DRG 217. In MS–DRG 218, there were zero cases reporting procedure codes X2RX0N7 and X2VW0N7.

The 61 cases in MS–DRG 219 reporting procedure codes X2RX0N7 and X2VW0N7 have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 219 (16.9 days versus 10 days) and higher average costs when compared to all the cases in MS–DRG 219 ($154,134 versus $69,728). The difference in average costs is $84,406 ($154,134 − $69,728 = $84,406) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 in MS–DRG 219 when compared to all the cases in MS–DRG 219. In MS–DRG 220, the 14 cases reporting procedure codes X2RX0N7 and X2VW0N7 have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 220 (8.9 days versus 6.2 days) and higher average costs when compared to all the cases in MS–DRG 220 ($84,004 versus $49,514). The difference in average costs is $34,490 ($84,004 − $49,514 = $34,490) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 in MS–DRG 220 when compared to all the cases in MS–DRG 220. In MS–DRG 221, the one case reporting procedure codes X2RX0N7 and X2VW0N7 has a length of stay that is shorter than the average length of stay for all the cases in MS–DRG 221 (3 days versus 3.6 days) and higher average costs when compared to all the cases in MS–DRG 221 ($97,825 versus $46,900). The difference in average costs is $50,925 ($97,825 − $46,900 = $50,925) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 in MS–DRG 221 when compared to all the cases in MS–DRG 221.

We reviewed these data and note the average costs of the 98 cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta are higher when compared to the average costs of all cases in MS–DRGs 216, 217, 218, 219, 220, and 221. The difference in average costs of the 98 cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta is $56,445 ($144,638 − $88,193 = $56,445) for the cases reporting procedure codes X2RX0N7 and X2VW0N7 when compared to all the cases in MS–DRG 216, which is the highest severity level ''with MCC'' MS–DRG. We reviewed these data and do not believe that proposing to reassign all cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta to MS–DRGs 216, 217, and 218, even if there is no cardiac catheterization procedure reported and no secondary diagnosis designated as an MCC reported, would fully address the difference in resource utilization in these cases as the average costs of the cases reporting procedure codes X2RX0N7 and X2VW0N7 are much higher when compared to all the cases in MS–DRG 216. Accordingly, we do not believe the data adequately support a potential reassignment of these cases to MS–DRGs 216, 217, and 218, respectively.

We also do not believe that the small subset cases that report the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta warrants the creation of a new MS–DRG at this time. As stated in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnosis related groups rather than smaller subsets. Moreover, as stated in prior rulemaking (85 FR 58472), we have concerns regarding making proposed MS–DRG changes based on a specific, single technology (the Thoraflex™ Hybrid device) identified by only one unique procedure code combination versus considering proposed changes based on a group of related procedure codes that can be reported to describe the same type or class of technology, which is more consistent with the intent of the MS–DRGs.

To explore other mechanisms to address this request, we then reexamined the separate but related request discussed previously to reassign cases reporting procedure codes describing endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device and cases reporting other complex aortic arch procedures. In examining these requests, we note that the first requestor suggested that CMS reassign cases reporting procedure codes describing endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device from MS–DRGs 219, 220, and 221 to MS–DRG 216 and the second requestor suggested that CMS reassign cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta without a procedure code describing the performance of a cardiac catheterization from MS–DRGs 219, 220, and 221 to MS–DRGs 216, 217, and 218 for FY 2026. As discussed in prior rulemaking (86 FR 44830, 87 FR 48847, and 88 FR 58683), MS–DRGs 216, 217, and 218 are defined by the performance of cardiac catheterization. We are concerned about the effect on clinical coherence of assigning cases that do not also have a cardiac catheterization procedure reported to MS–DRGs that are defined by the performance of that procedure.

However, we do note that in our examination of both requests, the data analysis indicates that the average costs of these complex aortic arch procedures, such as the cases reporting procedure codes describing endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device, the cases reporting the procedure code combination describing thoracic aortic arch replacement combined with restriction of the descending thoracic aorta, and the cases reporting other complex aortic arch procedures, are higher when compared to the average costs of all cases in MS–DRGs 216, 217, 218, 219, 220, and 221. Analysis of the claims data also suggests that these cases reporting complex aortic arch procedures are associated with increased hospital resource utilization.

We reviewed these data and note, clinically, aortic arch pathologies are serious clinical conditions associated with an increased likelihood of death but also the potential for significant functional limitations. The aortic arch is the segment of the aorta that helps distribute blood to the head and upper extremities via the brachiocephalic trunk, the left common carotid, and the left subclavian artery. The aortic arch also plays a role in blood pressure homeostasis via baroreceptors found within the walls of the aortic arch that help prevent quick, drastic changes in blood pressure. Aortic aneurysms and aortic dissection that involve the aortic arch are associated with extremely high mortality and morbidity and the data analysis clearly shows that cases reporting complex aortic arch procedures have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS–DRG.

Therefore, based on our review of the clinical issues and the claims data, we are proposing to create a new MS–DRG to better differentiate these complex aortic arch procedures from other cases in their respective MS–DRGs, based on treatment difficulty, clinical similarity, and resource use. To compare and analyze the impact of our suggested modifications, we ran a simulation using the claims data from the September 2024 update of the FY 2024 MedPAR file.

Proposed new MS–DRG	Number of cases	Average length of stay	Average costs
Proposed new MS–DRG XXX Complex Aortic Arch Procedures	300	11.2	$104,826

For the cases reporting complex aortic arch procedures, we identified a total of 300 cases using the claims data from the September 2024 update of the FY 2024 MedPAR file, so the criterion that there are at least 500 or more cases in each subgroup could not be met. Therefore, we are not proposing to subdivide the proposed new MS–DRG for complex aortic arch procedures into severity levels.

In summary, for FY 2026, taking into consideration that it clinically requires greater resources to perform complex aortic arch procedures, we are proposing to create a new base MS–DRG for cases reporting complex aortic arch procedures in MDC 05. The proposed new MS–DRG is proposed new MS–DRG 209 (Complex Aortic Arch Procedures). We refer the reader to Table 6P.5a associated with this FY 2026 IPPS/LTCH PPS proposed rule (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for the list of procedure codes we are proposing to define in the logic for the proposed new MS–DRG. We note that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.10. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule.

f. Deep Vein Thrombophlebitis

Consistent with our annual review of the MS–DRGs, we consider changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In our review of the claims data from the September 2024 update of the FY 2024 MedPAR file, we identified a low volume of cases for MS–DRGs 294 and 295 (Deep Vein Thrombophlebitis with CC/MCC and without CC/MCC, respectively). Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
294	146	4.1	$10,808
295	0	0	0

A deep vein thrombophlebitis (DVT) is a blood clot that forms in one of the deep veins of the body, most commonly occurring in the veins of the pelvis, calf, or thigh. The 35 ICD–10–CM diagnosis codes describing deep vein thrombophlebitis currently assigned to MS–DRGs 294 and 295 are shown in the following table.

DIAGNOSIS CODES DESCRIBING DEEP VENOUS THROMBOPHLEBITIS (DVT) IN MS–DRGS 294–295

ICD–10–CM code	Description
I80.10	Phlebitis and thrombophlebitis of unspecified femoral vein.
I80.11	Phlebitis and thrombophlebitis of right femoral vein.
I80.12	Phlebitis and thrombophlebitis of left femoral vein.
I80.13	Phlebitis and thrombophlebitis of femoral vein, bilateral.
I80.201	Phlebitis and thrombophlebitis of unspecified deep vessels of right lower extremity.
I80.202	Phlebitis and thrombophlebitis of unspecified deep vessels of left lower extremity.
I80.203	Phlebitis and thrombophlebitis of unspecified deep vessels of lower extremities, bilateral.
I80.209	Phlebitis and thrombophlebitis of unspecified deep vessels of unspecified lower extremity.
I80.211	Phlebitis and thrombophlebitis of right iliac vein.
I80.212	Phlebitis and thrombophlebitis of left iliac vein.
I80.213	Phlebitis and thrombophlebitis of iliac vein, bilateral.
I80.219	Phlebitis and thrombophlebitis of unspecified iliac vein.
I80.221	Phlebitis and thrombophlebitis of right popliteal vein.
I80.222	Phlebitis and thrombophlebitis of left popliteal vein.
I80.223	Phlebitis and thrombophlebitis of popliteal vein, bilateral.
I80.229	Phlebitis and thrombophlebitis of unspecified popliteal vein.
I80.231	Phlebitis and thrombophlebitis of right tibial vein.
I80.232	Phlebitis and thrombophlebitis of left tibial vein.
I80.233	Phlebitis and thrombophlebitis of tibial vein, bilateral.
I80.239	Phlebitis and thrombophlebitis of unspecified tibial vein.
I80.241	Phlebitis and thrombophlebitis of right peroneal vein.
I80.242	Phlebitis and thrombophlebitis of left peroneal vein.
I80.243	Phlebitis and thrombophlebitis of peroneal vein, bilateral.
I80.249	Phlebitis and thrombophlebitis of unspecified peroneal vein.
I80.251	Phlebitis and thrombophlebitis of right calf muscular vein.
I80.252	Phlebitis and thrombophlebitis of left calf muscular vein.
I80.253	Phlebitis and thrombophlebitis of calf muscular vein, bilateral.
I80.259	Phlebitis and thrombophlebitis of unspecified calf muscular vein.
I80.291	Phlebitis and thrombophlebitis of other deep vessels of right lower extremity.
I80.292	Phlebitis and thrombophlebitis of other deep vessels of left lower extremity.
I80.293	Phlebitis and thrombophlebitis of other deep vessels of lower extremity, bilateral.
I80.299	Phlebitis and thrombophlebitis of other deep vessels of unspecified lower extremity.
I80.3	Phlebitis and thrombophlebitis of lower extremities, unspecified.
I82.220	Acute embolism and thrombosis of inferior vena cava.
I82.221	Chronic embolism and thrombosis of inferior vena cava.

In light of the initial findings of only 146 cases for MS–DRG 294 and zero cases in MS–DRG 295, we further reviewed the MedPAR claims data for cases assigned to MS–DRGs 294 and 295 for the past 5 fiscal years. As reflected in the following tables, the data indicate that the number of cases grouping to MS–DRGs 294 and 295 has declined.

FY and MedPAR data reviewed for MS–DRG 294	Number of cases	Average length of stay	Average costs
FY 2022 (FY 2020 MedPAR)	222	4.3	$8,962
FY 2023 (FY 2021 MedPAR)	227	4.2	9,325
FY 2024 (FY 2022 MedPAR)	177	4.8	9,665
FY 2025 (FY 2023 MedPAR)	178	4.6	10,404
FY 2026 (FY 2024 MedPAR)	146	4.1	10,808

FY and MedPAR data reviewed for MS–DRG 295	Number of cases	Average length of stay	Average costs
FY 2022 (FY 2020 MedPAR)	20	3.4	$7,323
FY 2023 (FY 2021 MedPAR)	11	2.5	4,988
FY 2024 (FY 2022 MedPAR)	0	0	0
FY 2025 (FY 2023 MedPAR)	0	0	0
FY 2026 (FY 2024 MedPAR)	0	0	0

We note that, if, during our annual MS–DRG analysis we identify that there are only a few patients in a respective MS–DRG, consistent with our established process in deciding whether to propose to make further modifications, we consider if there have been potential changes in the clinical characteristics of the patients, treatment patterns, or resource utilization. A principle of the MS–DRGs and the characteristics of a meaningful DRG classification scheme is the ability to detect such changes and accordingly, propose clinically appropriate modifications that are also consistent with resource utilization. We have noted in prior rulemaking that we prefer to have a substantial number of cases in an MS–DRG because having larger clinical cohesive groups within an MS–DRG provides greater stability for annual updates to the relative payment weights. In light of these considerations, and the low volume of cases in MS–DRGs 294 and 295, we believed it was appropriate to further analyze how to potentially reclassify these cases.

Accordingly, using the September 2024 update of the FY 2024 MedPAR file, we examined whether there were other MS–DRGs to which these cases could appropriately be reassigned. As part of this analysis, we also reviewed the base DRG by severity claims data for MS–DRG 294 because the MS–DRG includes cases reporting an MCC as well as cases reporting a CC. As previously noted, there were zero cases identified in MS–DRG 295, which would only consist of NonCC cases. Therefore, we analyzed the claims data to determine the number of cases, the average length of stay, and average costs for the 146 cases in MS–DRG 294 by severity level (1=MCC and 2=CC). Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
294–1	45	5.4	$14,085
294–2	101	3.5	9,348
294 base DRG total	146	4.1	10,808

We note that medical MS–DRGs 299, 300, and 301 (Peripheral Vascular Disorders with MCC, with CC, and without CC/MCC, respectively) also include diagnoses describing other types of phlebitis and thrombophlebitis in the logic for case assignment, consistent with the diagnosis codes in the logic for case assignment to MS–DRGs 294 and 295. As such, we reviewed the claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 299, 300, and 301 to examine the resource utilization associated with cases assigned to these MS–DRGs. Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
299	14,129	5.5	$14,742
300	18,038	3.9	9,757
301	3,807	2.5	6,723

As shown in the data, the 45 cases reporting an MCC in MS–DRG 294 have an average length of stay of 5.4 days with average costs of $14,085, which is comparable to the cases in MS–DRG 299 reporting an MCC that have an average length of stay of 5.5 days with average costs of $14,742. The 101 cases reporting a CC in MS–DRG 294 have an average length of stay of 3.5 days with average costs of $9,348, which is comparable to the cases in MS–DRG 300 reporting an CC that have an average length of stay of 3.9 days with average costs of $9,757.

Based on our analysis and review of the cases grouping to MS–DRGs 294 and 295, we believe it is appropriate to delete these MS–DRGs and reassign the cases currently assigned to MS–DRGs 294 and 295 to MS–DRGs 299, 300, and 301, which are clinically consistent and also align with the resource utilization for these cases. Accordingly, for FY 2026, we are proposing to delete MS–DRGs 294 and 295 and reassign the previously listed 35 diagnosis codes describing deep vein thrombophlebitis to MS–DRGs 299, 300, and 301. We refer the reader to the ICD–10 MS–DRG Version 42.1 Definitions Manual (which is available via the internet on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) for complete documentation of the GROUPER logic for MS–DRGs 299, 300, and 301.

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

a. Hip or Knee Procedures With Periprosthetic Joint Infection

We received a request to reassign cases reporting a hip or knee procedure with a principal diagnosis of periprosthetic joint infection (PJI) from the lower severity level ''without CC/MCC'' MS–DRG to the higher severity level ''with CC'' MS–DRG when there is no major complication or comorbidity (MCC) or complication or comorbidity (CC) reported. According to the requestor, PJI is a devastating healthcare condition that occurs in one percent to two percent (1% to 2%) of primary joint replacements.[8] PJI is also the primary cause for revision arthroplasty in most developed markets. The requestor stated that patients undergoing revision for PJI experience higher mortality rates ranging from 0.8 to 4 percent at 1 year and 12.9 to 25.9 percent at 5 years following revision surgery.

According to the requestor, management of PJI requires complex treatment strategies including multiple surgical revisions and long-term antimicrobial treatment, leading to substantially higher costs versus aseptic revision arthroplasty. The requestor asserted that when missed or undertreated, PJI leads to persistence of

[8] Corvec S, Portillo ME, Pasticci BM, Borens O, Trampuz A. Epidemiology and new developments in the diagnosis of prosthetic joint infection. Int J Artif Organs 2012;35:923–934.

infection and multiple surgical revisions causing poor function or disability, considerably impairing quality of life.

The requestor stated that current treatment options for PJI include chronic suppressive antibiotics; debridement, antibiotics, and implant retention (DAIR); one-stage revision; two-stage revision; and amputation. According to the requestor, regardless of the treatment option selected for the knee or hip, the presence of PJI as the principal diagnosis appears to significantly increase the length of stay and the resource utilization of these cases in comparison to all other cases assigned to the respective MS–DRGs.

Using the FY 2023 MedPAR file that informed FY 2025 rulemaking, the requestor stated it performed its own analysis of cases reporting PJI as the principal diagnosis. The requestor provided the following list of ICD–10–CM diagnosis codes it used to identify the presence of a PJI in the hip or knee joint.

ICD–10–CM code	Description
T84.51XA	Infection and inflammatory reaction due to internal right hip prosthesis, initial encounter.
T84.51XD	Infection and inflammatory reaction due to internal right hip prosthesis, subsequent encounter.
T84.51XS	Infection and inflammatory reaction due to internal right hip prosthesis, sequela.
T84.52XA	Infection and inflammatory reaction due to internal left hip prosthesis, initial encounter.
T84.52XD	Infection and inflammatory reaction due to internal left hip prosthesis, subsequent encounter.
T84.52XS	Infection and inflammatory reaction due to internal left hip prosthesis, sequela.
T84.53XA	Infection and inflammatory reaction due to internal right knee prosthesis, initial encounter.
T84.53XD	Infection and inflammatory reaction due to internal right knee prosthesis, subsequent encounter.
T84.53XS	Infection and inflammatory reaction due to internal right knee prosthesis, sequela.
T84.54XA	Infection and inflammatory reaction due to internal left knee prosthesis, initial encounter.
T84.54XD	Infection and inflammatory reaction due to internal left knee prosthesis, subsequent encounter.
T84.54XS	Infection and inflammatory reaction due to internal left knee prosthesis, sequela.

The requestor stated that cases involving the DAIR procedure are commonly assigned to MS–DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 480, 481, and 482 (Hip and Femur Procedures Except Major Joint with MCC, with CC, and without CC/MCC, respectively) or MS–DRG 485, 486, and 487 (Knee Procedures with Principal Diagnosis of Infection with MCC, with CC, and without CC/MCC, respectively). According to the requestor, in each of the scenarios reviewed, the average cost and average length of stay for cases with a principal diagnosis of PJI that grouped to the ''with CC'' or ''without CC/MCC'' MS–DRG are similar or higher and longer than the other cases assigned to the same MS–DRGs.

The requestor also stated that one-stage hip or knee revision procedures are typically assigned to MS–DRGs 466, 467, and 468 and the findings from their analysis showed the presence of a PJI as the principal diagnosis with a hip or knee revision procedure show a longer length of stay and a similar or higher average cost than for the other aseptic revision arthroplasties.

In addition, the requestor stated that its analysis of cases reporting PJI with the last treatment option, amputation, assigned to MS–DRGs 474, 475, and 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders with MCC, with CC, and without CC/MCC, respectively) also showed a longer average length of stay and higher average costs compared to all other non-PJI cases in MS–DRGs 474, 475, and 476, further supporting the request to reassign cases to the ''with CC'' severity level MS–DRG.

In summary, the requestor specifically recommended the following modifications to the listed MS–DRGs for cases reporting a hip or knee procedure with a principal diagnosis of PJI:

Current MS–DRG assignment	Requested MS–DRG assignment
465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC).	MS–DRG 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC).
MS–DRG 468 (Revision of Hip or Knee Replacement without CC/MCC)	MS–DRG 467 (Revision of Hip or Knee Replacement with CC).
MS–DRG 476 (Amputation for Musculoskeletal System and Connective Tissue Disorders without CC/MCC).	MS–DRG 475 (Amputation for Musculoskeletal System and Connective Tissue Disorders with CC).
MS–DRG 482 (Hip and Femur Procedures Except Major Joint without CC/MCC).	MS–DRG 481 (Hip and Femur Procedures Except Major Joint with CC).
MS–DRG 487 (Knee Procedures with Principal Diagnosis of Infection without CC/MCC).	MS–DRG 486 (Knee Procedures with Principal Diagnosis of Infection with CC).

We reviewed claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 463, 464, 465, 466, 467, 468, 474, 475, 476, 480, 481, 482, 485, 486, and 487 and for cases reporting a principal diagnosis of PJI with a hip or knee procedure. We refer the reader to Table 6P. 6a for the list of diagnosis codes we analyzed to identify a PJI and for the list of procedure codes we analyzed from the previously listed MS–DRGs to identify a hip or knee procedure. Findings from our analysis are shown in the following table.

MS–DRG	Description	Number of cases	Average length of stay	Average costs
463	All cases	3,909	14.2	$45,233
	Cases with principal diagnosis of PJI with hip or knee procedure	804	13.9	50,127
464	All cases	5,775	7.3	26,757

MS–DRG	Description	Number of cases	Average length of stay	Average costs
	Cases with principal diagnosis of PJI with hip or knee procedure	1,358	7.7	32,474
465	All cases	1,496	3.0	16,794
	Cases with principal diagnosis of PJI with hip or knee procedure	237	4.3	22,689
466	All cases	4,282	9.0	43,314
	Cases with principal diagnosis of PJI with hip or knee procedure	460	11.2	40,433
467	All cases	17,682	4.1	30,612
	Cases with principal diagnosis of PJI with hip or knee procedure	947	6.5	28,505
468	All cases	12,986	1.8	24,921
	Cases with principal diagnosis of PJI with hip or knee procedure	160	4	23,978
474	All cases	2,417	12.2	35,707
	Cases with principal diagnosis of PJI with hip or knee procedure	112	13.6	47,240
475	All cases	2,634	7.3	19,577
	Cases with principal diagnosis of PJI with hip or knee procedure	166	7	20,739
476	All cases	322	3.5	10,454
	Cases with principal diagnosis of PJI with hip or knee procedure	27	4.1	14,101
480	All cases	26,238	7.3	26,430
	Cases with principal diagnosis of PJI with hip or knee procedure	136	11.7	38,407
481	All cases	62,141	4.9	19,153
	Cases with principal diagnosis of PJI with hip or knee procedure	234	7.4	24,138
482	All cases	13,842	3.5	14,886
	Cases with principal diagnosis of PJI with hip or knee procedure	30	4.6	19,122
485	All cases	1,297	9.5	29,761
	Cases with principal diagnosis of PJI with hip or knee procedure	521	9.6	31,779
486	All cases	2,574	6.0	19,679
	Cases with principal diagnosis of PJI with hip or knee procedure	985	5.8	21,376
487	All cases	632	4.1	14,615
	Cases with principal diagnosis of PJI with hip or knee procedure	194	4	16,616

The findings show that the cases reporting a PJI with a hip or knee procedure in MS–DRGs 466, 467, and 468 have a slightly longer average length of stay and lower average costs compared to the average length of stay and average costs of all the cases in their respective MS–DRGs. Therefore, because the resource utilization of these cases is generally comparable to all the cases in their respective MS–DRGs, we believe the cases reporting a PJI in MS–DRGs 466, 467, and 468 appear to be grouping appropriately in their current MS–DRG assignment.

The findings show that for the cases reporting a PJI with a hip or knee procedure in MS–DRGs 463, 464, 465, 474, 475, 476, 485, 486, and 487, the average length of stay is comparable to the average length of stay of all the cases in their respective MS–DRGs, however, the average length of stay for the cases reporting a PJI with a hip or knee procedure in MS–DRGs 480, 481, and 482 are notably longer compared to the average length of stay of all the cases in their respective MS–DRGs. Findings from our analysis also show that the average costs of the cases reporting a PJI with a hip or knee procedure in MS–DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 are higher compared to the average costs of all the cases in their respective MS–DRGs with a difference in average costs of approximately $5,459 for cases reporting a PJI with a hip or knee procedure across MS–DRGs 463, 464, and 465, a difference in average costs of approximately $5,190 for cases reporting a PJI with a hip or knee procedure across MS–DRGs 474, 475, and 476, and a difference in average costs of approximately $7,306 for cases reporting a PJI with a hip or knee procedure across MS–DRGs 480, 481 and 482. However, because MS–DRGs 485, 486, and 487 currently include a principal diagnosis of infection in the logic for case assignment to these MS–DRGs, the difference in average costs for the cases reporting a PJI with a hip or knee procedure compared to the average costs of all the cases in their respective MS–DRG is minimal ($2,018, $1,697, and $2,001, respectively).

Based on our review and analysis of the data, we disagree with the request to reassign PJI cases from the lower severity ''without CC/MCC'' level MS–DRG to the higher severity ''with CC'' level MS–DRG suggested by the requestor as the average costs of the PJI cases in the ''without CC/MCC'' level are not comparable and do not align with the average costs of all the cases at the ''with CC'' level. In addition, our findings show that other than for MS–DRGs 466, 467, and 468, the cases reporting a PJI with a hip or knee procedure at the higher ''with CC'' level and the highest ''with MCC'' level have higher average costs compared to all the cases in their respective MS–DRG. For example, as reflected in the findings of our analysis for MS–DRGs 463, 464, and 465, if we were to reassign the 237 cases reporting a PJI with a hip or knee procedure with an average length of stay of 4.3 days and average costs of $22,689 from MS–DRG 465 to MS–DRG 464 where we found a total of 5,775 cases with an average length of stay of 7.3 days and average costs of $26,757, the 1,358 cases reporting a PJI with a hip or knee procedure with an average length of stay of 7.7 days and average costs of $32,474 in MS–DRG 464 and the 804 cases reporting a PJI with a hip or knee procedure with an average length of stay of 13.9 days and average costs of $50,127 in MS–DRG 463 would continue to not be comparable from a resource perspective as compared to all the cases in their assigned MS–DRGs. We believe the data support proposing a new base MS–DRG for the cases reporting a PJI with a hip or knee procedure in MS–DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 to better reflect the complexity of services, resource utilization, and severity of illness of these patients.

Consistent with our established process as discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to

create subgroups in a base MS–DRG. We note that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG failed to meet the criterion that at least 500 or more cases are in the without CC/MCC subgroup. The following table illustrates our findings.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	1,052	13.6	$48,305
With CC	1,758	7.6	30,256
Without CC/MCC	293	4.3	21,505

As discussed in section II.C.1.b. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups and found that all five criteria were met. The following table illustrates our findings.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
With MCC	1,052	13.6	$48,305
Without MCC	2,051	7.1	29,006

For the proposed new MS–DRGs for cases reporting a PJI with a hip or knee procedure, there is at least (1) 500 cases in the MCC subgroup and 500 cases in the without MCC subgroup; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

As a result, for FY 2026, we are proposing to create new MS–DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively). The following table reflects a simulation of the proposed new MS–DRGs.

Proposed new MS–DRGs	Number of cases	Average length of stay	Average costs
Proposed MS–DRG 403	1,052	13.6	$48,305
Proposed MS–DRG 404	2,051	7.1	29,006

b. Arthroscopy

Consistent with our annual review of the MS–DRGs, we consider changes in resource consumption, treatment patterns, technology, and any other factors that may change the relative use of hospital resources. In our review of the claims data from the September 2024 update of the FY 2024 MedPAR file, we identified an extremely low volume of cases for MS–DRG 509 (Arthroscopy). Specifically, we found 16 cases with an average length of stay of 5.2 days and average costs of $18,239.

An arthroscopy is a surgical procedure that allows orthopaedic surgeons to see the inside of a joint through a small incision and with specialized instruments (for example, arthroscope). The ICD–10–PCS codes describing arthroscopy and currently assigned to MS–DRG 509 are shown in the following table.

PROCEDURE CODES DESCRIBING ARTHROSCOPY IN MS–DRG 509

ICD–10–PCS code	Description
0RJ04ZZ	Inspection of occipital-cervical joint, percutaneous endoscopic approach.
0RJ14ZZ	Inspection of cervical vertebral joint, percutaneous endoscopic approach.
0RJ34ZZ	Inspection of cervical vertebral disc, percutaneous endoscopic approach.
0RJ44ZZ	Inspection of cervicothoracic vertebral joint, percutaneous endoscopic approach.
0RJ54ZZ	Inspection of cervicothoracic vertebral disc, percutaneous endoscopic approach.
0RJ64ZZ	Inspection of thoracic vertebral joint, percutaneous endoscopic approach.
0RJ94ZZ	Inspection of thoracic vertebral disc, percutaneous endoscopic approach.
0RJA4ZZ	Inspection of thoracolumbar vertebral joint, percutaneous endoscopic approach.
0RJB4ZZ	Inspection of thoracolumbar vertebral disc, percutaneous endoscopic approach.
0RJE4ZZ	Inspection of right sternoclavicular joint, percutaneous endoscopic approach.
0RJF4ZZ	Inspection of left sternoclavicular joint, percutaneous endoscopic approach.
0RJG4ZZ	Inspection of right acromioclavicular joint, percutaneous endoscopic approach.
0RJH4ZZ	Inspection of left acromioclavicular joint, percutaneous endoscopic approach.

PROCEDURE CODES DESCRIBING ARTHROSCOPY IN MS–DRG 509—Continued

ICD–10–PCS code	Description
0RJJ4ZZ	Inspection of right shoulder joint, percutaneous endoscopic approach.
0RJK4ZZ	Inspection of left shoulder joint, percutaneous endoscopic approach.
0RJL4ZZ	Inspection of right elbow joint, percutaneous endoscopic approach.
0RJM4ZZ	Inspection of left elbow joint, percutaneous endoscopic approach.
0RJN4ZZ	Inspection of right wrist joint, percutaneous endoscopic approach.
0RJP4ZZ	Inspection of left wrist joint, percutaneous endoscopic approach.
0RJQ4ZZ	Inspection of right carpal joint, percutaneous endoscopic approach.
0RJR4ZZ	Inspection of left carpal joint, percutaneous endoscopic approach.
0RJS4ZZ	Inspection of right carpometacarpal joint, percutaneous endoscopic approach.
0RJT4ZZ	Inspection of left carpometacarpal joint, percutaneous endoscopic approach.
0RJU4ZZ	Inspection of right metacarpophalangeal joint, percutaneous endoscopic approach.
0RJV4ZZ	Inspection of left metacarpophalangeal joint, percutaneous endoscopic approach.
0RJW4ZZ	Inspection of right finger phalangeal joint, percutaneous endoscopic approach.
0RJX4ZZ	Inspection of left finger phalangeal joint, percutaneous endoscopic approach.
0SJ04ZZ	Inspection of lumbar vertebral joint, percutaneous endoscopic approach.
0SJ34ZZ	Inspection of lumbosacral joint, percutaneous endoscopic approach.
0SJ54ZZ	Inspection of sacrococcygeal joint, percutaneous endoscopic approach.
0SJ64ZZ	Inspection of coccygeal joint, percutaneous endoscopic approach.
0SJ74ZZ	Inspection of right sacroiliac joint, percutaneous endoscopic approach.
0SJ84ZZ	Inspection of left sacroiliac joint, percutaneous endoscopic approach.
0SJ94ZZ	Inspection of right hip joint, percutaneous endoscopic approach.
0SJB4ZZ	Inspection of left hip joint, percutaneous endoscopic approach.
0SJC4ZZ	Inspection of right knee joint, percutaneous endoscopic approach.
0SJD4ZZ	Inspection of left knee joint, percutaneous endoscopic approach.
0SJF4ZZ	Inspection of right ankle joint, percutaneous endoscopic approach.
0SJG4ZZ	Inspection of left ankle joint, percutaneous endoscopic approach.
0SJH4ZZ	Inspection of right tarsal joint, percutaneous endoscopic approach.
0SJJ4ZZ	Inspection of left tarsal joint, percutaneous endoscopic approach.
0SJK4ZZ	Inspection of right tarsometatarsal joint, percutaneous endoscopic approach.
0SJL4ZZ	Inspection of left tarsometatarsal joint, percutaneous endoscopic approach.
0SJM4ZZ	Inspection of right metatarsal-phalangeal joint, percutaneous endoscopic approach.
0SJN4ZZ	Inspection of left metatarsal-phalangeal joint, percutaneous endoscopic approach.
0SJP4ZZ	Inspection of right toe phalangeal joint, percutaneous endoscopic approach.
0SJQ4ZZ	Inspection of left toe phalangeal joint, percutaneous endoscopic approach.

In light of our initial findings of 16 cases for MS–DRG 509, we further reviewed the MedPAR claims data for cases assigned to MS–DRG 509 for the past 5 fiscal years. As reflected in the following table, the data indicate that the number of cases grouping to MS–DRG 509 has steadily declined.

FY and MedPAR data reviewed	Number of cases	Average lenth of stay	Average costs
FY 2022 (FY 2020 MedPAR)	25	3.9	$10,372
FY 2023 (FY 2021 MedPAR)	31	4.2	10,882
FY 2024 (FY 2022 MedPAR)	34	4.3	11,380
FY 2025 (FY 2023 MedPAR)	21	5.4	13,683
FY 2026 (FY 2024 MedPAR)	16	5.2	18,239

We note that, if, during our annual MS–DRG analysis we identify that there are only a few patients in a respective MS–DRG, consistent with our established process, we consider if there have been potential changes in the clinical characteristics of the patients, treatment patterns, or resource utilization. A principle of the MS–DRGs and the characteristics of a meaningful DRG classification scheme is the ability to detect such changes and accordingly, propose clinically appropriate modifications that are also consistent with resource utilization.

We believe that the volume of cases reporting the arthroscopy procedures in the inpatient setting has shifted to the outpatient setting over the years; it is usually performed as an outpatient procedure. Of the 16 cases found to report an arthroscopy procedure in the FY 2024 MedPAR data, 13 cases also reported another procedure. For example, one case that reported procedure code 0RJK4ZZ (Inspection of left shoulder joint, percutaneous endoscopic approach) also reported procedure code 0RBK4ZZ (Excision of left shoulder joint, percutaneous endoscopic approach). Procedure code 0RBK4ZZ is assigned to MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively). However, because of the surgical hierarchy, the resulting assignment is MS–DRG 509.

Using the September 2024 update of the FY 2024 MedPAR file, we also reviewed the base DRG by severity claims data for MS–DRG 509 to determine the number of cases, average length of stay and average costs for the 16 cases by severity level (1=MCC, 2=CC and 3=NonCC). Our findings are shown in the following table.

MS–DRG	Number of cases	Average length of stay	Average costs
509–1	4	5.5	$15,196
509–2	7	6.1	27,880
509–3	5	3.6	7,177
509 base DRG total	16	5.2	18,239

Next, we reviewed the claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively); MS–DRGs 513 and 514 (Hand or Wrist Procedures, Except Major Thumb or Joint Procedures with CC/MCC and without CC/MCC, respectively); and MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) because these MS–DRGs are considered to be clinically appropriate and consistent with the arthroscopy procedure code descriptions in MS–DRG 509 previously listed that specify the anatomic site. Our findings are shown in the following tables.

MS–DRG	Number of cases	Average length of stay	Average costs
510	916	6.4	$25,000
511	2,538	4.3	18,701
512	1,303	2.6	14,582
513	1,335	5.0	14,219
514	317	2.6	9,556
515	4,095	8.4	28,466
516	10,522	5.0	18,832
517	5,951	2.9	14,067

Based on our analysis and review of the cases grouping to MS–DRG 509, we believe it is appropriate to delete MS–DRG 509 and reassign the 47 procedure codes describing arthroscopy of various anatomic sites to clinically appropriate MS–DRGs that also align with the resource utilization for these cases. For example, of the 16 cases found to group to MS–DRG 509, in addition to identifying 13 cases reporting additional procedures as previously discussed, we also identified 11 cases reporting diagnosis codes designated as a CC or MCC where the average length of stay and average costs of those cases are comparable with the average length of stay and average costs of the cases in the MS–DRGs considered clinically appropriate for their reassignment. Therefore, for FY 2026, of the 47 procedure codes previously listed describing arthroscopy of various anatomic sites, we are proposing to:

1. Reassign the 8 procedure codes describing arthroscopy of the shoulder or elbow joint to MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively).

2. Reassign the 10 procedure codes describing arthroscopy of the hand or wrist joint to MS–DRGs 513 and 514 (Hand or Wrist Procedures, Except Major Thumb or Joint Procedures with CC/MCC and without CC/MCC, respectively).

3. Reassign the 29 procedure codes describing arthroscopy of various vertebral joints and other musculoskeletal joints to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

We refer the reader to Table 6P.7a for the detailed list of procedure codes with the proposed MS–DRG reassignments.

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

We identified an inconsistency in the GROUPER logic for MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively) related to the ICD–10–CM diagnosis codes describing a principal diagnosis of infection. The logic for case assignment to MS–DRGs 456, 457, and 458 as displayed in the ICD–10 MS–DRG Definitions Manual Version 42.1 (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) is comprised of four logic lists. The first logic list is entitled ''Spinal Fusion Except Cervical'' and is defined by a list of procedure codes designated as O.R. procedures that describe spinal fusion procedures of the thoracic, thoracolumbar, lumbar, lumbosacral, sacrococcygeal, and sacroiliac joint. (We note that 12 procedure codes describing Fusion of coccygeal joint were deleted effective with discharges beginning April 1, 2025, in version 42.1). The second logic list is entitled ''Spinal Curvature/Malignancy/Infection'' and is defined by a list of diagnosis codes describing spinal curvature, spinal malignancy, and spinal infection that are used to define the logic for case assignment when any one of the listed diagnosis codes is reported as the principal diagnosis. The third logic list is entitled ''OR Secondary Diagnosis'' and is defined by a list of diagnosis codes describing curvature of the spine that are used to define the logic for case assignment when any one of the listed codes is reported as a secondary diagnosis. The fourth logic list is entitled ''Extensive Fusions'' and is defined by a list of procedure codes designated as O.R. procedures that describe extensive spinal fusion procedures. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 42.1 (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) for

complete documentation of the GROUPER logic for MS–DRGs 456, 457, and 458.

In the second logic list entitled ''Spinal Curvature/Malignancy/Infection'' there are a subset of diagnosis codes describing spinal infections. In our review and analysis of MS–DRGs 456, 457, and 458, we identified additional diagnosis codes within the ICD–10–CM classification describing spinal infections that are not currently listed in the logic for case assignment to MS–DRGs 456, 457, and 458. Specifically, we identified the following 47 diagnoses that we believe are clinically appropriate to add to the existing diagnosis codes describing spinal infections in MS–DRGs 456, 457, and 458.

ICD–10–CM code	Description
A02.24	Salmonella osteomyelitis.
A54.40	Gonococcal infection of musculoskeletal system, unspecified.
A54.41	Gonococcal spondylopathy.
A54.43	Gonococcal osteomyelitis.
A54.49	Gonococcal infection of other musculoskeletal tissue.
M46.21	Osteomyelitis of vertebra, occipito-atlanto-axial region.
M46.22	Osteomyelitis of vertebra, cervical region.
M46.23	Osteomyelitis of vertebra, cervicothoracic region.
M46.30	Infection of intervertebral disc (pyogenic), site unspecified.
M46.31	Infection of intervertebral disc (pyogenic), occipito-atlanto-axial region.
M46.32	Infection of intervertebral disc (pyogenic), cervical region.
M46.33	Infection of intervertebral disc (pyogenic), cervicothoracic region.
M46.34	Infection of intervertebral disc (pyogenic), thoracic region.
M46.35	Infection of intervertebral disc (pyogenic), thoracolumbar region.
M46.36	Infection of intervertebral disc (pyogenic), lumbar region.
M46.37	Infection of intervertebral disc (pyogenic), lumbosacral region.
M46.38	Infection of intervertebral disc (pyogenic), sacral and sacrococcygeal region.
M46.39	Infection of intervertebral disc (pyogenic), multiple sites in spine.
M46.50	Other infective spondylopathies, site unspecified.
M46.51	Other infective spondylopathies, occipito-atlanto-axial region.
M46.52	Other infective spondylopathies, cervical region.
M46.53	Other infective spondylopathies, cervicothoracic region.
M46.54	Other infective spondylopathies, thoracic region.
M46.55	Other infective spondylopathies, thoracolumbar region.
M46.56	Other infective spondylopathies, lumbar region.
M46.57	Other infective spondylopathies, lumbosacral region.
M46.58	Other infective spondylopathies, sacral and sacrococcygeal region.
M46.59	Other infective spondylopathies, multiple sites in spine.
M86.00	Acute hematogenous osteomyelitis, unspecified site.
M86.09	Acute hematogenous osteomyelitis, multiple sites.
M86.10	Other acute osteomyelitis, unspecified site.
M86.19	Other acute osteomyelitis, multiple sites.
M86.20	Subacute osteomyelitis, unspecified site.
M86.29	Subacute osteomyelitis, multiple sites.
M86.30	Chronic multifocal osteomyelitis, unspecified site.
M86.39	Chronic multifocal osteomyelitis, multiple sites.
M86.40	Chronic osteomyelitis with draining sinus, unspecified site.
M86.49	Chronic osteomyelitis with draining sinus, multiple sites.
M86.50	Other chronic hematogenous osteomyelitis, unspecified site.
M86.59	Other chronic hematogenous osteomyelitis, multiple sites.
M86.60	Other chronic osteomyelitis, unspecified site.
M86.69	Other chronic osteomyelitis, multiple sites.
M86.8X0	Other osteomyelitis, multiple sites.
M86.8X9	Other osteomyelitis, unspecified sites.
M86.9	Osteomyelitis, unspecified.
T84.63XA	Infection and inflammatory reaction due to internal fixation device of spine, initial encounter.
T84.69XA	Infection and inflammatory reaction due to internal fixation device of other site, initial encounter.

Therefore, for clinical consistency and because these codes describe spinal infections that could reasonably require a spinal fusion procedure, we are proposing to add the previously listed diagnosis codes to the logic list entitled ''Spinal Curvature/Malignancy/Infection'' in MS–DRGs 456, 457, and 458, effective October 1, 2025, for FY 2026.

We also identified eight diagnosis codes currently listed in the second logic list entitled ''Spinal Curvature/Malignancy/Infection'' for case assignment to MS–DRGs 456, 457, and 458 that we believe are not clinically appropriate to maintain in the list. Specifically, we identified the following diagnoses.

ICD–10–CM code	Description
M4850XA	Collapsed vertebra, not elsewhere classified, site unspecified, initial encounter for fracture.
M4854XA	Collapsed vertebra, not elsewhere classified, thoracic region, initial encounter for fracture.
M4855XA	Collapsed vertebra, not elsewhere classified, thoracolumbar region, initial encounter for fracture.
M4856XA	Collapsed vertebra, not elsewhere classified, lumbar region, initial encounter for fracture.

ICD–10–CM code	Description
M4857XA	Collapsed vertebra, not elsewhere classified, lumbosacral region, initial encounter for fracture.
M4858XA	Collapsed vertebra, not elsewhere classified, sacral and sacrococcygeal region, initial encounter for fracture.
M8008XA	Age-related osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture.
M8088XA	Other osteoporosis with current pathological fracture, vertebra(e), initial encounter for fracture.

The previously listed diagnosis codes do not describe a spinal curvature, malignancy or infection, rather they describe compression fractures of various anatomic sites (for example, collapsed vertebra) and osteoporosis is a condition where the bones become weakened leading to an increased risk of bone fracture. Therefore, for clinical consistency and to ensure accuracy in the logic for case assignment, we are proposing to remove the eight previously listed diagnosis codes from the logic list entitled ''Spinal Curvature/Malignancy/Infection'' in MS–DRGs 456, 457, and 458, effective October 1, 2025, for FY 2026.

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

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of our review of the claims data from the September 2024 update of the FY 2024 MedPAR file of cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we are proposing to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this proposed rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

1. Control of Bleeding in the Genitourinary Tract

During the review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure codes describing the control of bleeding in the genitourinary tract are reported in conjunction with ICD–10–CM diagnosis codes in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs, and Immunologic Disorders), the cases group to MS–DRGs 981 through 983. The five ICD–10–CM procedure codes reviewed, as well as their current MDC assignments, are found in the table:

ICD–10–PCS code	Description	MDC
0W3R0ZZ	Control bleeding in genitourinary tract, open approach	05; 11; 12; 13; 17; 21; 24
0W3R3ZZ	Control bleeding in genitourinary tract, percutaneous approach	05; 11; 12; 13; 17; 21; 24
0W3R4ZZ	Control bleeding in genitourinary tract, percutaneous endoscopic approach	05; 11; 12; 13; 17; 21; 24
0W3R7ZZ	Control bleeding in genitourinary tract, via natural or artificial opening	05; 11; 12; 13; 17; 21; 24
0W3R8ZZ	Control bleeding in genitourinary tract, via natural or artificial opening endoscopic	05; 11; 12; 13; 17; 21; 24

We refer the reader to Appendix E of the ICD–10 MS–DRG Version 42.1 Definitions Manual, which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html*, for the MS–DRG assignment for each procedure code listed and further discussion of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS.

The principal diagnosis most frequently reported with the five ICD–10–PCS procedure codes describing the control of bleeding in the genitourinary tract in MDC 16 is ICD–10–CM code D68.32 (Hemorrhagic disorder due to extrinsic circulating anticoagulants). Hemorrhagic disorder due to extrinsic circulating anticoagulants is a condition that occurs when bleeding is caused by anticoagulants or antithrombotics, which are medicines commonly used to treat or prevent blood clots by decreasing the amount of clotting proteins in the blood.

We examined claims data from the September 2024 update of the FY 2024 MedPAR file to identify the average length of stay and average costs for cases reporting a procedure code describing the control of bleeding in the genitourinary tract with a principal diagnosis in MDC 16, which are currently grouping to MS–DRGs 981 through 983, as well as all cases in MS–DRGs 981 through 983. Our findings are shown in the following table.

MS–DRGs 981–983—All Cases and Cases Reporting a Procedure Code Describing the Control of Bleeding in the Genitourinary Tract and a Principal Diagnosis in MDC 16

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—All cases	19,155	11.7	$40,259
MS–DRG 981—Cases reporting procedure code describing the control of bleeding in the genitourinary tract and a principal diagnosis in MDC 16	23	9	27,900
MS–DRG 982—All cases	9,392	5.7	21,951
MS–DRG 982—Cases reporting procedure code describing the control of bleeding in the genitourinary tract and a principal diagnosis in MDC 16	64	4.3	13,462
MS–DRG 983—All cases	1,831	2.6	15,837
MS–DRG 983—Cases reporting procedure code describing the control of bleeding in the genitourinary tract and a principal diagnosis in MDC 16	5	2.8	9,416

We then examined the MS–DRGs within MDC 16 and determined that the cases reporting procedure codes describing the control of bleeding in the genitourinary tract with a principal diagnosis in MDC 16 would most suitably group to MS–DRGs 802, 803, and 804 (Other O.R. Procedures of the Blood and Blood Forming Organs with MCC, with CC, and without CC/MCC, respectively), which contains a group of procedures that are only infrequently related to the diagnoses in the MDC, but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 802, 803, and 804 as a whole, we examined the average costs and length of stay for cases in MS–DRGs 802, 803, and 804. Our findings are shown in this table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 802—All cases	417	11.6	$37,595
MS–DRG 803—All cases	452	5.3	16,762
MS–DRG 804—All cases	209	2.2	12,605

We reviewed the data and noted for this subset of cases, the average costs are lower and the average length of stays are generally shorter than for cases in MS–DRGs 802, 803, and 804. However, we believe that when an ICD–10–PCS procedure code describing the control of bleeding in the genitourinary tract is reported with a principal diagnosis in MDC 16 (typically hemorrhagic disorder due to extrinsic circulating anticoagulants), the procedure is related to the principal diagnosis. Because a procedure code describing the control of bleeding in the genitourinary tract would be expected to be related to a principal diagnosis describing a hemorrhagic disorder due to extrinsic circulating anticoagulants, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add the five procedure codes listed previously to MDC 16. Under this proposal, cases reporting a procedure code describing the control of bleeding in the genitourinary tract with a principal diagnosis of a hemorrhagic disorder due to extrinsic circulating anticoagulants (diagnosis code D68.32) in MDC 16 would group to MS–DRGs 802, 803, and 804.

2. Removal of Infusion Device From Peritoneal Cavity

During the review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure codes describing the removal of an infusion device from the peritoneal cavity are reported in conjunction with ICD–10–CM diagnosis codes in MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs), the cases group to MS–DRGs 981 through 983. The three ICD–10–PCS procedure codes reviewed, as well as their current MDC assignments, are found in the table:

ICD–10–PCS code	Description	MDC
0WPG03Z	Removal of infusion device from peritoneal cavity, open approach	06; 21
0WPG33Z	Removal of infusion device from peritoneal cavity, percutaneous approach	06; 21
0WPG43Z	Removal of infusion device from peritoneal cavity, percutaneous endoscopic approach	06; 21

We refer the reader to Appendix E of the ICD–10 MS–DRG Version 42.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html*) for the MS–DRG assignment for each procedure code listed and further discussion of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS.

The principal diagnosis most frequently reported with the three ICD–10–PCS procedure codes describing the removal of an infusion device from the peritoneal cavity in MDC 21 is ICD–10–CM code T85.71XA (Infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter).

We examined claims data from the September 2024 update of the FY 2024 MedPAR file to identify the average length of stay and average costs for cases reporting a procedure code describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis in MDC 21, which are currently grouping to MS–DRGs 981 through 983, as well as all cases in MS–

DRGs 981 through 983. Our findings are shown in the following table.

MS–DRGs 981–983—All Cases and Cases Reporting a Procedure Code Describing the Removal of an Infusion Device From the Peritoneal Cavity and a Principal Diagnosis in MDC 21

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 981—All cases	19,155	11.7	$40,259
MS–DRG 981—Cases reporting procedure code describing the removal of an infusion device from the peritoneal cavity and a principal diagnosis in MDC 21	85	8.8	25,556
MS–DRG 982—All cases	9,392	5.7	21,951
MS–DRG 982—Cases reporting procedure code describing the removal of an infusion device from the peritoneal cavity and a principal diagnosis in MDC 21	1	4	11,845
MS–DRG 983—All cases	1,831	2.6	15,837
MS–DRG 983—Cases reporting procedure code describing the removal of an infusion device from the peritoneal cavity and a principal diagnosis in MDC 21	0	0	0

We then examined the MS–DRGs within MDC 21 and determined that the cases reporting procedure codes describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis in MDC 21 would most suitably group to MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively), which contains other operating room procedures performed for injuries as further detailed below.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 907, 908, and 909 as a whole, we examined the average costs and length of stay for cases in MS–DRGs 907, 908, and 909. Our findings are shown in this table.

MS–DRG	Number of cases	Average length of stay	Average costs
MS–DRG 907—All cases	7,754	9.4	$34,049
MS–DRG 908—All cases	6,625	4.8	17,938
MS–DRG 909—All cases	1,721	2.7	12,154

We reviewed the data and noted for the subset of cases reporting procedure codes describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis in MDC 21, the average costs are lower and the average length of stays are shorter than for cases in MS–DRGs 907, 908, and 909. However, we believe that when an ICD–10–PCS procedure code describing the removal of an infusion device from the peritoneal cavity is reported with a principal diagnosis in MDC 21 (typically infection and inflammatory reaction due to peritoneal dialysis catheter), the procedure is related to the principal diagnosis. Because a procedure code describing the removal of an infusion device from the peritoneal cavity would be expected to be related to a principal diagnosis describing an infected catheter used for peritoneal dialysis causing inflammation in the surrounding tissue, it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing to add the three procedure codes listed previously to MDC 21. Under this proposal, cases reporting a procedure code describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis of an infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter (diagnosis code T85.71XA) in MDC 21 would group to MS–DRGs 907, 908, and 909.

In addition to the internal review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned. We did not receive any requests suggesting reassignment.

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the average length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to propose MS–DRG assignments for the cases in a similar manner. Generally, we propose to move only those procedures for which we have an adequate number of discharges to analyze the data.

Additionally, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. We did not receive any requests suggesting reassignment. Further, based on the results of our review of the claims data from the September 2024 update of the FY 2024 MedPAR file we did not identify any cases for reassignment. Therefore, for FY 2026 we are not proposing to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

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

a. Background

Under the IPPS MS–DRGs (and former CMS MS–DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed.

Generally, if the procedure was not expected to require the use of the operating room, the patient would be considered medical (non-O.R.). Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS- DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, we recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.C.13 of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we are making Table 6B.—New Procedure Codes—FY 2026 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.html.* We also refer readers to the ICD–10 MS–DRG Version 42.1 Definitions Manual at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS- DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19230) that, as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of certain surgical approaches to evaluate whether to subdivide a subset of MS–DRGs based on a specific surgical approach. We stated we plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. We also stated that in consideration of the PHE, we believed it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review.

For this FY 2026 IPPS/LTCH PPS proposed rule, we continue to believe additional time is necessary as we continue to develop our process and methodology. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58749), we have signaled in prior rulemaking that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we will consider as we examine the designation of a procedure in the ICD–10–PCS classification system. We are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. We are considering the feedback received on what factors and/or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system as we continue to develop our process and

methodology and will provide more detail on this analysis and the methodology for conducting this comprehensive review in future rulemaking. We encourage the public to continue to submit feedback and comments on any other factors in consideration of our refinement efforts to recognize and differentiate consumption of resources under the ICD–10 MS–DRGs.

For this FY 2026 IPPS/LTCH PPS proposed rule, we received requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. In this section of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we detail and respond to those requests. In this section of the preamble of this proposed rule, we also discuss the proposal we are making based on our internal review and analysis and the process that was utilized for evaluating each procedure code. For each procedure, we considered—

- Whether the procedure would typically require the resources of an operating room;
- Whether it is an extensive or a non-extensive procedure; and
- To which MS–DRGs the procedure should be assigned.

We note that many MS–DRGs require the presence of any O.R. procedure. As a result, cases with a principal diagnosis associated with a particular MS–DRG would, by default, be grouped to that MS–DRG. Therefore, we do not list these MS–DRGs in our discussion in this section of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule. Instead, we only discuss MS–DRGs that require explicitly adding the relevant procedure codes to the GROUPER logic in order for those procedure codes to affect the MS–DRG assignment as intended.

For procedures that would not typically require the resources of an operating room, we determined if the procedure should affect the MS–DRG assignment. In cases where we are proposing to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also are proposing one or more MS–DRGs with which these procedures are clinically aligned and to which the procedure code would be assigned.

In addition, cases that contain O.R. procedures will map to MS–DRGs 981, 982, or 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987, 988, or 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) when they do not contain a principal diagnosis that corresponds to one of the MDCs to which that procedure is assigned. These procedures need not be assigned to MS–DRGs 981 through 989 in order for this to occur. Therefore, we did not specifically address that aspect in summarizing the request and our response to that request or the proposal we are making based on our internal review and analysis in this section of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule.

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

(1) Open Drainage of the Mandible

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44895 through 44896), we discussed a request we received to change the designation of procedure codes 0N9R0ZZ (Drainage of maxilla, open approach), 0N9T0ZZ (Drainage of right mandible, open approach), and 0N9V0ZZ (Drainage of left mandible, open approach), from non-O.R. to O.R. procedures. In the FY 2022 final rule, we stated that we disagreed that the procedures describing the open drainage of the maxilla or mandible typically require the resources of an operating room. We stated that if admission is required for the treatment of a jaw infection, the admission is quite likely due to the need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting. After consideration of the public comments we received, we finalized our proposal to maintain the non-O.R. designation of ICD–10–PCS procedure codes 0N9R0ZZ, 0N9T0ZZ, and 0N9V0ZZ, without modification, for FY 2022.

For this FY 2026 IPPS/LTCH PPS proposed rule, we again received a request to change the designation of ICD–10–PCS codes 0N9T0ZZ (Drainage of right mandible, open approach), and 0N9V0ZZ (Drainage of left mandible, open approach), from non-O.R. to O.R. The requestor identified procedure code 0W950ZZ (Drainage of lower jaw, open approach) that is currently designated as an O.R. procedure and stated that the body part value of mandible is more specific than body part value of lower jaw. The requestor also stated that in the ICD–10–PCS classification, other procedure codes that describe drainage procedures performed on body parts deeper than subcutaneous tissue, such as muscles, tendons, and bone, are designated as O.R. procedures. Therefore, the requestor stated that procedure codes 0N9T0ZZ and 0N9V0ZZ should also be recognized as O.R. procedures for purposes of MS–DRG assignment. The requestor did not provide a specific list of the procedure codes that describe drainage procedures performed on body parts deeper than subcutaneous tissue, such as muscles, tendons, and bone, that are currently designated as O.R. procedures for CMS to review.

In the ICD–10 MS–DRGs Definitions Manual Version 42.1, procedure codes 0N9T0ZZ and 0N9V0ZZ are currently designated as non-O.R. procedures for purposes of MS–DRG assignment. We reviewed this issue and continue to disagree that the procedures describing the open drainage of the mandible are typically performed in the operating room under general anesthesia. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44896), these procedures can be done in an oral surgeon's office, or an outpatient setting and are rarely performed in the inpatient setting. Therefore, we are proposing to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9T0ZZ and 0N9V0ZZ.

In our review of this issue, we agree with the requestor that in the ICD–10 MS–DRGs Definitions Manual Version 42.1, procedure code 0W950ZZ (Drainage of lower jaw, open approach) is currently designated as an O.R. procedure for purposes of MS–DRG assignment. While we have stated in prior rulemaking that a correlation cannot be made between procedures performed in general anatomic regions and procedures performed in specific body parts because these procedures coded with the general anatomic regions body part represent a broader range of procedures that cannot be coded to a specific body part, we continue to believe if admission is required for the treatment of a jaw infection, the admission is quite likely due to the need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting. Like procedures that describe the open drainage of mandible, procedures to drain the lower jaw can also be done in an oral surgeon's office or an outpatient setting and are rarely performed in the inpatient setting. We agree that procedures that describe the open drainage of mandible consume resources comparable to the related ICD–10–PCS procedure code that describes the open drainage of the jaw. These procedures do not typically require the resources of an operating room and are not surgical in nature. Therefore, for clinical consistency, we are proposing to remove procedure code 0W950ZZ (Drainage of lower jaw, open approach) from the FY 2026 ICD–10 MS–DRGs Version 43 Definitions Manual in Appendix E—Operating

Room Procedures and Procedure Code/MS–DRG Index as an O.R. procedure. Under this proposal, this procedure would no longer impact MS–DRG assignment.

(2) Introduction of Paclitaxel-Coated Balloon Catheter Technology

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69094 through 69096), we summarized and responded to comments we received regarding the O.R. designation and MS–DRG assignment of 16 procedure codes that describe introduction of the AGENT™ Paclitaxel-Coated Balloon Catheter technology that is indicated to treat coronary in-stent restenosis (ISR) in patients with coronary artery disease. The following procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology were finalized following the March 19, 2024, ICD–10 Coordination and Maintenance Committee meeting and made available via the CMS website on June 5, 2024, at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*. We refer the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials.

ICD–10–PCS code	Description
XW0J3HA	Introduction of paclitaxel-coated balloon technology, one balloon into coronary artery, one artery, percutaneous approach, new technology group 10.
XW0J3JA	Introduction of paclitaxel-coated balloon technology, two balloons into coronary artery, one artery, percutaneous approach, new technology group 10.
XW0J3KA	Introduction of paclitaxel-coated balloon technology, three balloons into coronary artery, one artery, percutaneous approach, new technology group 10.
XW0J3LA	Introduction of paclitaxel-coated balloon technology, four or more balloons into coronary artery, one artery, percutaneous approach, new technology group 10.
XW0K3HA	Introduction of paclitaxel-coated balloon technology, one balloon into coronary artery, two arteries, percutaneous approach, new technology group 10.
XW0K3JA	Introduction of paclitaxel-coated balloon technology, two balloons into coronary artery, two arteries, percutaneous approach, new technology group 10.
XW0K3KA	Introduction of paclitaxel-coated balloon technology, three balloons into coronary artery, two arteries, percutaneous approach, new technology group 10.
XW0K3LA	Introduction of paclitaxel-coated balloon technology, four or more balloons into coronary artery, two arteries, percutaneous approach, new technology group 10.
XW0L3HA	Introduction of paclitaxel-coated balloon technology, one balloon into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0L3JA	Introduction of paclitaxel-coated balloon technology, two balloons into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0L3KA	Introduction of paclitaxel-coated balloon technology, three balloons into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0K3LA	Introduction of paclitaxel-coated balloon technology, four or more balloons into coronary artery, two arteries, percutaneous approach, new technology group 10.
XW0L3HA	Introduction of paclitaxel-coated balloon technology, one balloon into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0L3JA	Introduction of paclitaxel-coated balloon technology, two balloons into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0L3KA	Introduction of paclitaxel-coated balloon technology, three balloons into coronary artery, three arteries, percutaneous approach, new technology group 10.
XW0M3LA	Introduction of paclitaxel-coated balloon technology, four or more balloons into coronary artery, four or more arteries, percutaneous approach, new technology group 10.

For FY 2026, we received a request to reconsider the designation and MS–DRG assignment of the previously listed 16 procedure codes. Specifically, the requestor (the manufacturer) requested that the procedure codes be designated as O.R. procedures and assigned to the following surgical MS–DRGs:

- MS–DRG 250 Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC
- MS–DRG 251 Percutaneous Cardiovascular Procedures without Intraluminal Device without MCC
- MS–DRG 321 Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices
- MS–DRG 322 Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC
- MS–DRG 323 Coronary Intravascular Lithotripsy with Intraluminal Device with MCC
- MS–DRG 324 Coronary Intravascular Lithotripsy with Intraluminal Device without MCC
- MS–DRG 325 Coronary Intravascular Lithotripsy without Intraluminal Device

According to the requestor, the root operation CMS identified as the most appropriate (that is, Introduction in the Administration section), and the predecessor code selected, (procedure code 3E073GC (Introduction of other therapeutic substance into coronary artery, percutaneous approach)), only involves a therapeutic substance being delivered via infusion or injection. The requestor stated that the procedure to administer the paclitaxel via the drug coated balloon (DCB) catheter is a surgical procedure as described in the instructions for use, with the drug delivery occurring using controlled prolonged balloon inflation during which the patient is monitored for signs of ischemia or arrythmia. The requestor stated that the procedure to deliver the paclitaxel is more appropriate as an O.R. procedure than a non-O.R. procedure. The requestor acknowledged that while the MS–DRG assignment for existing percutaneous coronary intervention (PCI) procedures is driven by vessel preparation or the use of an intraluminal device, it should not preclude the designation of the procedure codes identifying use of an AGENT™ Paclitaxel-Coated Balloon Catheter technology that describes the

delivery of the paclitaxel to the coronary vessel(s) as O.R. procedures.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69095 through 69096), we stated that under our established process, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new procedure codes. We noted that because the procedure codes describing the use of an AGENT™ Paclitaxel-Coated Balloon Catheter are describing delivery of the paclitaxel to the coronary vessel(s), the predecessor code is 3E073GC, which is designated as a non-O.R. procedure and does not affect MS–DRG assignment. We also stated that, as discussed at the March 19, 2024, ICD–10 Coordination and Maintenance Committee meeting and in the commenters' feedback, a preparatory step (that is, vessel preparation by either angioplasty, atherectomy, or lithotripsy) is required to be performed first, before the AGENT™ Paclitaxel-Coated Balloon Catheter is deployed. We noted that each type of vessel preparation procedure is designated as an O.R. procedure and maps to one of the previously listed surgical MS–DRGs. We also noted that based on the surgical hierarchy, the reporting of one of the vessel preparation steps (that is, angioplasty, atherectomy, or lithotripsy), or placement of a new stent in connection with the use of the AGENT™ Paclitaxel-Coated Balloon Catheter would result in assignment to one of the previously listed surgical MS–DRGs. We noted that use of the AGENT™ Paclitaxel-Coated Balloon Catheter to deliver the paclitaxel to the coronary vessel(s) cannot occur in the absence of a surgical vessel preparation and therefore, it is the vessel preparation procedure that will determine the surgical MS–DRG assignment to one of the previously listed surgical MS–DRGs.

We reviewed the instructions for use submitted by the requestor regarding the procedure to insert the drug-coated balloon catheter. The instructions for use state:

> Note: For optimal DCB results, adequate lesion preparation is essential. This should include predilatation with a non-coated coronary balloon. Intravascular imaging to guide lesion preparation and to assess the adequacy of the final result is strongly recommended.
>
> Caution: Lesion preparation is necessary to prevent delamination of the balloon's drug coating while traversing patient anatomy. The TransPax coating is designed to facilitate drug transfer into the vessel wall upon contact. Do not use the AGENT Drug-Coated Balloon Catheter for lesion preparation.

We also note that the FDA-approved indication states, ''The AGENT™ Paclitaxel-Coated Balloon Catheter is intended to be used after appropriate vessel preparation in adult patients undergoing percutaneous coronary intervention (PCI) in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating in-stent restenosis (ISR).'' We further note that, as reflected in the March 19, 2024, ICD–10 Coordination and Maintenance Committee meeting materials, ''The AGENT™ Drug-Coated Balloon (DCB) has been designated by the FDA as an implant for PMA purposes. Per FDA guidance, the drug component is considered a permanent implant because it remains in the body for greater than 30 days.''

As such, we continue to disagree with designating the procedure to delivery paclitaxel to a coronary vessel as identified by any one of the previously listed 16 procedure codes as O.R. procedures. As stated earlier in this section, the MS–DRG assignment is dependent on the surgical vessel preparation procedure that would be reported when the AGENT™ Paclitaxel-Coated Balloon Catheter technology is used to deliver the paclitaxel to the coronary vessel(s) and result in assignment to one of the previously listed surgical MS–DRGs. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 available in association with this FY 2026 IPPS/LTCH PPS proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* for complete documentation of the GROUPER logic for the previously listed surgical MS–DRGs under MDC 05. For the reasons discussed, we are maintaining the designation of the 16 procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology as non-O.R. for FY 2026.

(3) Endoscopic Drainage of the Ureter With Drainage Device

During our internal review, we noted that procedure codes that describe drainage of the ureter with a drainage device, via a natural or artificial opening endoscopic approach, are not recognized as O.R. procedures for purposes of MS–DRG assignment. We identified the following three related codes:

ICD–10–PCS code	Description
0T9680Z	Drainage of right ureter with drainage device, via natural or artificial opening endoscopic.
0T9780Z	Drainage of left ureter with drainage device, via natural or artificial opening endoscopic.
0T9880Z	Drainage of bilateral ureters with drainage device, via natural or artificial opening endoscopic.

Upon further review and consideration, we believe that procedure codes 0T9680Z, 0T9780Z, and 0T9880Z that describe the drainage of the ureter with a drainage device via a natural or artificial opening endoscopic approach warrant designation as O.R. procedures. These procedures involve the use of a cystoscope and include the insertion of a small tube (called a ureteral stent or drainage tube) into one or both of the ureters (the tubes that carry urine from the kidneys to the bladder) to drain urine from a blocked or partially blocked ureter and must be performed by a urologist who specializes in diagnosing and treating conditions of the urinary tract, genitals, and adrenal glands through surgery. These procedures are typically performed in an operating room under anesthesia, can take about 30 minutes or more, including preparation time, and require that a patient's vital signs be monitored by the health care team for the duration of the procedure.

Therefore, we are proposing to add procedure codes 0T9680Z, 0T9780Z, and 0T9880Z to the FY 2026 ICD–10 MS–DRG Version 43 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures assigned to MS–DRG 264 (Other Circulatory System O.R. Procedures) in MDC 05 (Diseases and Disorders of the Circulatory System); MS–DRGs 656, 657, and 658 (Kidney and Ureter Procedures for Neoplasm, with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 659, 660, and 661 (Kidney and Ureter Procedures for Non-Neoplasm, with MCC, with CC, and without CC/MCC, respectively) in

MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract); 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).

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

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as an MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 IPPS/LTCH PPS final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

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

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete summation of the comments we received for each of the nine guiding principles and our responses to those comments.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we

were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), we stated that as the new unspecified edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we also requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. We stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58755 through 58759), based on our analysis of the impact on resource use for the ICD–10–CM Z codes that describe homelessness and after consideration of public comments, we finalized changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC. We stated our expectation that finalizing the changes would encourage the increased documentation and reporting of the diagnosis codes describing social and economic circumstances and serve as an example for providers that, when they document and report SDOH codes, CMS can further examine the claims data and consider future changes to the designation of these codes when reported as a secondary diagnosis. We further stated CMS would continue to monitor and evaluate the reporting of the diagnosis codes describing social and economic circumstances.

In the FY 2025 proposed rule (89 FR 35995), we noted that since the FY 2021 IPPS/LTCH PPS final rule we have continued to solicit feedback regarding the nine guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We stated we had encouraged the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code when providing feedback or comments. We also noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26748 through 26750) we illustrated how the nine guiding principles might be applied in evaluating changes to the severity designations of diagnosis codes in our discussion of our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness. After consideration of the ongoing feedback and comments we had received, we proposed to finalize the nine guiding principles. After consideration of the public comments received, and for the reasons discussed, we finalized the nine guiding principles as listed previously in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69076 through 69078). Accordingly, we stated that our evaluations to determine the extent to which the presence of a diagnosis code as a secondary diagnosis results in increased hospital resource use will include a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of the nine guiding principles.

Additionally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69079 through 69084), based on our analysis of the impact on resource use for the ICD–10–CM diagnosis codes that describe inadequate housing and housing instability, and after consideration of public comments, we finalized changes to the severity levels for seven diagnosis codes for FY 2025.

For this FY 2026 IPPS/LTCH PPS proposed rule, we did not receive any requests to change the severity level designations of specific ICD–10–CM diagnosis codes. At this time, we believe it is appropriate to continue to formulate future next steps in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, rather than proposing to change the designation of individual ICD–10–CM diagnosis codes. Therefore, we are not proposing any severity designation changes for FY 2026.

As we continue our comprehensive CC/MCC analysis, we may consider proposing changes for other diagnosis codes in the future based on our analysis of the impact on resource use, per our methodology, as previously described, and consideration of the guiding principles consistent with our annual process and will provide more detail in future rulemaking. We have updated the Impact on Resource Use Files on the CMS website so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2024 MedPAR files. These files are posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*.

For new diagnosis codes approved for FY 2026, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We note that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.C.9 of the preamble of this FY 2026 IPPS/LTCH

PPS proposed rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2026.

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

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 2026 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*:

- Table 6I.1—Proposed Additions to the MCC List—FY 2026;
- Table 6I.2—Proposed Deletions to the MCC List—FY 2026;
- Table 6J.1—Proposed Additions to the CC List—FY 2026; and
- Table 6J.2—Proposed Deletions to the CC List—FY 2026.

d. Proposed CC Exclusions List for FY 2026

In the September 1, 1987, final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987, proposed notice (52 FR 18886) and the September 1, 1987, final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;
- Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and
- Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 42.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual (available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*) and includes three lists identified as Part 1, Part 2 and Part 3. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC. Part 3 is the list of diagnosis codes that are designated as a CC or MCC and included in the definition of the logic for the listed MS–DRGs. When reported as a secondary diagnosis and grouped to one of the listed MS–DRGs, the diagnosis is excluded from acting as a CC/MCC for severity in DRG assignment (that is, suppression logic).

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69093), we stated that, because commenters had raised concerns regarding the principal diagnoses listed under Part 1 of Appendix C—CC Exclusions List in Principal Diagnosis Collection Lists 1379 and 1380 that exclude diagnosis codes N18.5 (Chronic kidney disease, stage 5) and N18.6 (End stage renal disease) from acting as a CC or MCC under the CC exclusion logic in accordance with the list of five principles established in 1987, we intended to perform a broad review of the conditions in these lists to determine if any modifications are warranted and to ensure they continue to be clinically appropriate. We note that the Principal Diagnosis Collection List numbers may change because of updates that are made to the list annually through rulemaking. Therefore, while under Version 41.1 the principal diagnoses listed in Principal Diagnosis Collection List numbers 1379 and 1380 exclude diagnosis codes N18.5 and N18.6 from acting as a CC or MCC, under Version 42.1, the principal diagnoses listed in Principal Diagnosis Collection List numbers 1330 and 1331 exclude diagnosis codes N18.5 and N18.6 from acting as a CC or MCC. Accordingly, we reviewed the list of principal diagnosis codes listed in Principal Diagnosis Collection List numbers 1330 and 1331 that exclude diagnosis codes N18.5 and N18.6 from acting as a CC or MCC to assess clinical appropriateness.

The findings from our review indicate several of the listed conditions, when reported as a principal diagnosis, are not applicable to exclude the designated N18.5 or N18.6 secondary CC/MCC diagnosis code under application of our five established principles finalized in the September 1, 1987, final notice (52 FR 33154) previously discussed. For example, diagnosis codes describing diabetes with other specified complications such as arthropathy, periodontal disease, or a foot ulcer, and diagnosis codes describing endometriosis, are not chronic and acute manifestations of, or closely related conditions to, chronic kidney disease, stage 5 (code N18.5) or end stage renal disease (code N18.6), nor are they describing codes for the same condition that cannot coexist.

As previously described, the Principal Diagnosis Collection List numbers may change because of updates that are made to the list annually through rulemaking. We note that, under proposed Version 43, the proposed Principal Diagnosis Collection List number to exclude diagnosis codes N18.5 and N18.6 from acting as a CC or MCC is 1335. We are therefore proposing to remove the diagnosis codes listed in Table 6P.8a associated with this FY 2026 IPPS/LTCH PPS proposed rule and available via the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* from Principal Diagnosis Collection List number 1335 under proposed Version 43. Findings from our internal review also indicated that diagnosis code I12.9 (Hypertensive chronic kidney disease with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) is currently listed in Principal Diagnosis Collection List number 1331 and excludes diagnosis code N18.6 from acting as an MCC, however, diagnosis code I12.9 is not currently listed in the Principal Diagnosis Collection List number 1330 to exclude diagnosis code

N18.5. We believe it is clinically appropriate to add diagnosis code I12.9 to Principal Diagnosis Collection List number 1335 under Version 43 because it would not be expected that a secondary diagnosis of N18.5 would be reported with a principal diagnosis of I12.9. During our internal review we also identified diagnosis code I13.0 (Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) and diagnosis code I13.10 (Hypertensive heart and chronic kidney disease without heart failure, with stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) that we believe are appropriate to add to Principal Diagnosis Collection List number 1335 to exclude diagnosis codes N18.5 and N18.6 from acting as a CC/MCC when reported because the conditions describe chronic kidney disease, stage 5 and end stage renal disease (ESRD) and it would not be clinically appropriate to have a principal diagnosis describing stage 1 through stage 4 chronic kidney disease reported with chronic kidney disease, stage 5 or ESRD.

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

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

We also performed an internal review of the diagnoses listed in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive. The diagnoses listed in Part 2 of Appendix C are assigned as an MCC only for patients discharged alive, otherwise the codes are assigned as a NonCC. The diagnoses listed in Part 2 in Version 42.1 are shown in the following table.

ICD–10–CM code	Description
I46.2	Cardiac arrest due to underlying cardiac condition.
I46.8	Cardiac arrest due to other underlying condition.
I46.9	Cardiac arrest, cause unspecified.
I49.01	Ventricular fibrillation.
R09.2	Respiratory arrest.
R57.0	Cardiogenic shock.
R57.1	Hypovolemic shock.
R57.8	Other shock.

In developing Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive (72 FR 47161 through 47168), the claims data were evaluated to determine if there was a difference in resource use between cases in which the patient was discharged alive or died during the hospital stay. For most secondary diagnoses, the charges were similar for the two groups. There were, however, a few diagnoses where the difference in charges and clinical considerations supported a different CC designation for patients who died before discharge. For these diagnoses, the patients who were discharged alive required significantly more hospital resources than the patients who died. Therefore, when reported as a secondary diagnosis, each of the diagnoses is designated as an MCC in cases where the patient is discharged alive and as a NonCC in cases where the patient died.

We analyzed claims data from the September 2024 update of the FY 2024 MedPAR file for the diagnoses currently listed in Appendix C—Part 2. Our findings are reflected in the following table:

ICD–10–CM code	Description	Patient discharged alive (without discharge status 20)			Patient expired (with discharge status 20)		
		Number of cases	Avg LOS	Average cost	Number of cases	Avg LOS	Average cost
I46.2	Cardiac arrest due to underlying cardiac condition.	8,241	11.6	$61,108	5,766	5.3	$33,173
I46.8	Cardiac arrest due to other underlying condition.	3,884	15.6	62,505	6,133	5.8	25,979
I46.9	Cardiac arrest, cause unspecified	13,121	13.3	59,732	28,437	5.2	24,933
I49.01	Ventricular fibrillation	10,705	9.9	52,118	6,788	4.6	28,949
R09.2	Respiratory arrest	367	8.7	33,536	375	5.5	17,280
R57.0	Cardiogenic shock	46,537	12.5	58,432	23,335	6.8	39,457
R57.1	Hypovolemic shock	32,614	10.8	39,051	6,476	8.3	38,697
R57.8	Other shock	37,728	12.4	50,374	11,570	8.4	43,215

As shown in the table, the data reflect that most of the conditions currently listed in Appendix C—Part 2, utilize hospital resources as expected, with the patients who were discharged alive (without discharge status 20) requiring significantly more hospital resources than the patients who expired (with discharge status 20), as demonstrated by the longer lengths of stay and higher average costs of these cases. We note however, that the resource utilization for cases reporting R57.1 (Hypovolemic shock) as a secondary diagnosis appear to be comparable whether the patient

was discharged alive or the patient expired. As reflected in the table, the claims data from the September 2024 update of the FY 2024 MedPAR file reflect that code R57.1 was reported as a secondary diagnosis in 32,614 cases where the patient was discharged alive. These cases had average costs of $39,051 and an average length of stay of 10.8 days. In the 6,476 cases where R57.1 was reported as a secondary diagnosis and the patient expired, the average costs were slightly lower ($38,697 versus $39,051) and the average length of stay was slightly shorter (8.3 days versus 10.8 days). We reviewed this issue and note clinically, the recommended treatment for hypovolemic shock is immediate intervention with fluid resuscitation with intravenous (IV) fluids, blood transfusions, and vasoactive drugs. Hypovolemic shock generally has a lower mortality rate and responds to timely treatment. As the claims data no longer reflect that patients reporting hypovolemic shock as secondary diagnosis that are discharged alive require significantly more hospital resources than the patients who expire, we are proposing to remove code R57.1 from the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive. Under this proposal, when reported as a secondary diagnosis, R57.1 (Hypovolemic shock) will be assigned as an MCC when the patient is discharged alive or if the patient expires.

Based on our review, we considered if it was appropriate to add other diagnosis codes describing shock to Appendix C—Part 2. Specifically, we considered code T79.4XXA (Traumatic shock, initial encounter). ICD–10–CM diagnosis code T79.4XXA is currently designated as an MCC when reported as secondary diagnoses. Traumatic shock represents a unique pathological condition that begins with multiple, usually blunt, trauma and may conclude with acute respiratory distress syndrome, coagulopathy, sepsis, multiple organ dysfunction syndrome and death.

We analyzed claims data from the September 2024 update of the FY 2024 MedPAR file for cases reporting T79.4XXA as a secondary diagnosis and our findings are reflected in the following table:

ICD–10–CM code	Description	Patient discharged alive (without discharge status 20)			Patient expired (with discharge status 20)		
		Number of cases	Avg LOS	Average cost	Number of cases	Avg LOS	Average cost
T79.4XXA	Traumatic shock, initial encounter	1,187	16.1	$79,218	553	6.5	$48,880

As reflected in the table, the claims data from the September 2024 update of the FY 2024 MedPAR file indicate that T79.4XXA was reported as a secondary diagnosis in 1,187 cases where the patient was discharged alive. These cases had average costs of $79,218 and an average length of stay of 16.1 days. In the 553 cases where T79.4XXA was reported as a secondary diagnosis and the patient expired, the average costs were considerably lower ($48,880 versus $79,218) and the average length of stay was much shorter (6.5 days versus 16.1 days).

As the data reflect that cases reporting traumatic shock, initial encounter, as a secondary diagnosis for patients that are discharged alive require significantly more hospital resources than the patients who expire, we are proposing to add code T79.4XXA to the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive. Under this proposal, when reported as a secondary diagnosis, T79.4XXA (Traumatic shock, initial encounter) would be assigned as an MCC only when the patient is discharged alive.

We are proposing changes to the ICD–10 MS–DRGs Version 43 CC Exclusion List based on the diagnosis code updates as discussed in section II.C.13. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions proposed for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code proposed for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the proposed deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this FY 2026 IPPS/LTCH PPS proposed rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

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

To identify new, revised, and deleted diagnosis and procedure codes, for FY 2026, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code Titles for this FY 2026 IPPS/LTCH PPS proposed rule.

These tables are not published in the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule. As discussed in section II.C.11. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

We are proposing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. In

addition, the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations.

Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We note that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this FY 2026 IPPS/LTCH PPS proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2026;
- Table 6B.—New Procedure Codes—FY 2026;
- Table 6C.—Invalid Diagnosis Codes—FY 2026;
- Table 6D.—Invalid Procedure Codes—FY 2026;
- Table 6E.—Revised Diagnosis Code Titles—FY 2026;
- Table 6F.—Revised Procedure Code Titles—FY 2026;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026;
- Table 6I.1.—Proposed Additions to the MCC List—FY 2026;
- Table 6I.2.—Proposed Deletions to the MCC List—FY 2026;
- Table 6J.1.—Proposed Additions to the CC List—FY 2026; and
- Table 6J.2.—Proposed Deletions to the CC List—FY 2026.

10. Proposed Changes to the Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this FY 2026 IPPS/LTCH PPS proposed rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69100), we stated our intent to consider if the development of evaluation criteria would be useful for future proposed modifications to the surgical hierarchy for MS–DRGs that have meaningful changes to the clinical logic. We are continuing to examine what factors should be taken into account as we consider any future proposals. We welcome feedback and other suggestions to be submitted via the Medicare Electronic Application Request Information System™ (MEARIS™) at *https://mearis.cms.gov/public/home* by October 20, 2025.

Based on the changes that we are proposing to make for FY 2026, as discussed in section II.C. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the proposed ICD–10 MS–DRG Definitions Manual Version 43 to modify the existing surgical hierarchy in MDC 05 and MDC 08 for FY 2026 is illustrated in the following tables. We note that because the current methodology involves weighing the average costs of each MS–DRG in the surgical class by

frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class, that the surgical hierarchy of other MS–DRGs in the MDC may need to be adjusted based on the MS–DRG classification changes that are proposed to ensure that the average weighted cost for each base MS–DRG in each MDC are monotonically decreasing. We further note that the proposed Version 43 surgical hierarchy as illustrated in the following tables may be subject to further modifications based on the finalized changes to the MS–DRG classifications for FY 2026.

		Current version 42 surgical hierarchy	Proposed version 43 surgical hierarchy
MDC 05 (Diseases and Disorders of the Circulatory System)			
Proposed New MS–DRG 209	Complex Aortic Arch Procedures	N/A	1
MS–DRG 212	Concomitant Aortic and Mitral Valve Procedures	2	2
MS–DRG 215	Other Heart Assist System Implant	1	3
MS–DRGs 216–218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization.	3	4
MS–DRGs 231–232	Coronary Bypass with PTCA	4	5
MS–DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization	6	6
MS–DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	5	7
MS–DRGs 219–221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization.	3	8
MS–DRGs 233–234	Coronary Bypass with Cardiac Catheterization or Open Ablation	4	9
Proposed New MS–DRG 213	Endovascular Abdominal Aorta with Iliac Branch Procedures	N/A	10
MS–DRGs 266–267	Endovascular Cardiac Valve Replacement and Supplement Procedures	7	11
MS–DRGs 276–277	Cardiac Defibrillator Implant	6	12
MS–DRGs 268–269	Aortic and Heart Assist Procedures Except Pulsation Balloon	8	13
MS–DRGs 235–236	Coronary Bypass without Cardiac Catheterization	4	14
MS–DRG 245	AICD Generator Procedures	14	15
MS–DRGs 270–272	Other Major Cardiovascular Procedures	11	16
MS–DRGs 228–229	Other Cardiothoracic Procedures	9	17
MS–DRGs 319–320	Other Endovascular Cardiac Valve Procedures	10	18
MS–DRGs 278–279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures.	20	19
MS–DRGs 323–324	Coronary Intravascular Lithotripsy with Intraluminal Device	17	20
MS–DRGs 239–241	Amputation for Circulatory System Disorders Except Upper Limb and Toe.	12	21
MS–DRG 265	AICD Lead Procedures	15	22
MS–DRGs 273–274	Percutaneous and Other Intracardiac Procedures	16	23
MS–DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device	17	24
MS–DRG 263	Vein Ligation and Stripping	25	25
MS–DRGs 252–254	Other Vascular Procedures	21	26
Proposed New MS–DRGs 359–360	Percutaneous Coronary Atherectomy with Intraluminal Device	N/A	27
MS–DRGs 242–244	Permanent Cardiac Pacemaker Implant	13	28
MS–DRGs 260–262	Cardiac Pacemaker Revision Except Device Replacement	24	29
Proposed New MS–DRG 318	Percutaneous Coronary Atherectomy without Intraluminal Device	N/A	30
MS–DRGs 321–322	Percutaneous Cardiovascular Procedures with Intraluminal Device	18	31
MS–DRGs 258–259	Cardiac Pacemaker Device Replacement	23	32
MS–DRGs 255–257	Upper Limb and Toe Amputation for Circulatory System Disorders	22	33
MS–DRGs 250–251	Percutaneous Cardiovascular Procedures without Intraluminal Device	19	34
MS–DRG 264	Other Circulatory System O.R. Procedures	26	35
MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)			
MS–DRGs 426–428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical.	1	1
MS–DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical.	2	5
MS–DRGs 429–430	Combined Anterior and Posterior Cervical Spinal Fusion	3	2
MS–DRGs 456–458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions.	4	3
MS–DRGs 447–448	Multiple Level Spinal Fusion Except Cervical	5	4
Proposed New MS–DRGs 403–404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection.	N/A	6
MS–DRGs 450–451	Single Level Spinal Fusion Except Cervical	6	7
MS–DRGs 461–462	Bilateral or Multiple Major Joint Procedures of Lower Extremity	7	10
MS–DRGs 463–465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders.	8	8
MS–DRGs 466–468	Revision of Hip or Knee Replacement	9	9
MS–DRGs 521–522	Hip Replacement with Principal Diagnosis of Hip Fracture	10	18
MS–DRGs 469–470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity or Total Ankle Replacement.	11	21
MS–DRGs 471–473	Cervical Spinal Fusion	12	11

		Current version 42 surgical hierarchy	Proposed version 43 surgical hierarchy
MS–DRGs 474–476	Amputation for Musculoskeletal System and Connective Tissue Disorders.	13	12
MS–DRGs 477–479	Biopsies of Musculoskeletal System and Connective Tissue	14	14
MS–DRGs 480–482	Hip and Femur Procedures Except Major Joint	15	19
MS–DRG 483	Major Joint or Limb Reattachment Procedures of Upper Extremities	16	13
MS–DRGs 485–487	Knee Procedures with Principal Diagnosis of Infection	17	17
MS–DRGs 488–489	Knee Procedures without Principal Diagnosis of Infection	17	27
MS–DRGs 518–520	Back and Neck Procedures Except Spinal Fusion or Disc Device or Neurostimulator.	18	20
MS–DRGs 492–494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur	19	15
MS–DRGs 495–497	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur.	20	25
MS–DRGs 498–499	Local Excision and Removal of Internal Fixation Devices of Hip and Femur.	21	16
MS–DRGs 500–502	Soft Tissue Procedures	22	24
MS–DRGs 503–505	Foot Procedures	23	23
MS–DRG 506	Major Thumb or Joint Procedures	24	29
MS–DRGs 507–508	Major Shoulder or Elbow Joint Procedures	25	26
MS–DRGs 510–512	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures.	26	22
MS–DRGs 513–514	Hand or Wrist Procedures, Except Major Thumb or Joint Procedures	27	28
MS–DRGs 515–517	Other Musculoskeletal System and Connective Tissue O.R. Procedures	28	30

For issues pertaining to the surgical hierarchy, as with other MS–DRG related requests, we encourage interested parties to submit comments no later than October 20, 2025, via MEARIS™ at *https://mearis.cms.gov/public/home*, so that they can be considered for possible inclusion in the annual proposed rule.

11. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014, meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-9-cm-diagnosis-procedure-codes-abbreviated-and-full-code-titles*.

The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The Committee encourages participation in the previously mentioned process by health-related organizations. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. Members of the public may submit comments on the proposed procedure code topics to CMS at: *ICDProcedureCodeRequest@cms.hhs.gov* and may submit comments on the proposed diagnosis code topics to the CDC/NCHS at: *nchsicd10cm@cdc.gov*. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies.

The Committee presented proposals for coding changes for implementation in FY 2026 at a public meeting held on September 10–11, 2024, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 15, 2024.

In lieu of holding its Spring 2025 meeting, the Committee solicited comments on the Spring 2025 ICD–10–PCS procedure code topics. The deadline for submitting comments on these code proposals is April 18, 2025. Any new diagnosis and procedure codes for which there is consensus of public support, and for which complete tabular and indexing changes would be made by June 2025 would be included in the October 1, 2025, update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets. As discussed in earlier sections of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles, and Table 6F.—Revised Procedure Code

Titles for this FY 2026 IPPS/LTCH PPS proposed rule, which are available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*.

The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Therefore, although we make the code titles available for the IPPS proposed rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available on the CMS website as discussed in section VI. of the Addendum to the proposed rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 10–11, 2024, meeting and the materials for the Spring 2025 ICD–10–PCS procedure code topics can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the topics relating to diagnosis codes discussed at the September 10–11, 2024, meeting can be found at: *https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements, submitting comments, and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

CMS implemented 50 new procedure codes including cardiac stereotactic body radiotherapy (SBRT), transplantation of the larynx, repositioning of long bones using a ring external fixation device with automated strut adjustment, supplementing the right atrium with heterotopic bioprosthetic valve(s), the administration of emapalumab-Izsg anti-IFNy monoclonal antibody, and the administration of tarlatamab-dlle antineoplastic into the ICD–10–PCS classification effective with discharges on and after April 1, 2025. The procedure codes are as follows:

Procedure code	Description	O.R.	MDC	MS–DRG
D228DZZ**	Stereotactic other photon radiosurgery of conduction mechanism.	N	05	317
0B118D6*	Bypass trachea to esophagus with intraluminal device, via natural or artificial opening endoscopic.	N		
0CYS0Z0	Transplantation of larynx, allogeneic, open approach	Y	03	143–145
			04	166–168
			21	907–909
			24	957–959
0CYS0Z1	Transplantation of larynx, syngeneic, open approach	Y	03	143–145
			04	166–168
			21	907–909
			24	957–959
0DX80Z7	Transfer small intestine to vagina, open approach	Y	13	748
			21	907–909
			24	957–959
0DX84Z7	Transfer small intestine to vagina, percutaneous endoscopic approach.	Y	13	748
			21	907–909
			24	957–959
0TT00Z0	Resection of right kidney, open approach, allogeneic	Y	11	656–661
			21	907–909
			24	957–959
0TT00Z1	Resection of right kidney, open approach, syngeneic	Y	11	656–661
			21	907–909
			24	957–959
0TT00Z2	Resection of right kidney, open approach, zooplastic	Y	11	656–661
			21	907–909
			24	957–959
0TT10Z0	Resection of left kidney, open approach, allogeneic	Y	11	656–661
			21	907–909
			24	957–959
0TT10Z1	Resection of left kidney, open approach, syngeneic	Y	11	656–661
			21	907–909
			24	957–959
0TT10Z2	Resection of left kidney, open approach, zooplastic	Y	11	656–661
			21	907–909
			24	957–959
0U7C7DJ*	Dilation of cervix with intraluminal device, temporary, via natural or artificial opening.	N		
10D10ZZ	Extraction of products of conception, retained, open approach.	Y	14	770
				796–798
3E0U0GC*	Introduction of other therapeutic substance into joints, open approach.	N		
X2KA30A	Bypass left atrium using conduit through coronary sinus to right atrium, percutaneous approach, new technology group 10.	Y	05	270–272
			21	907–909
X2U93YA	Supplement right atrium with intraluminal device, heterotopic bioprosthetic valve(s), percutaneous approach, new technology group 10.	Y	05	266–267

Procedure code	Description	O.R.	MDC	MS–DRG
XNS40GA	Reposition right humeral shaft with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNS43GA	Reposition right humeral shaft with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNS50GA	Reposition left humeral shaft with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNS53GA	Reposition left humeral shaft with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNS60GA	Reposition right radius with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS63GA	Reposition right radius with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS70GA	Reposition left radius with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS73GA	Reposition left radius with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS80GA	Reposition right ulna with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS83GA	Reposition right ulna with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS90GA	Reposition left ulna with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNS93GA	Reposition left ulna with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	510–512 907–909 957–959
XNSA0GA	Reposition right upper femur with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSA3GA	Reposition right upper femur with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSB0GA	Reposition left upper femur with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSB3GA	Reposition left upper femur with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSC0GA	Reposition right lower femur with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSC3GA	Reposition right lower femur with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSD0GA	Reposition left lower femur with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSD3GA	Reposition left lower femur with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSE0GA	Reposition right femoral shaft with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSE3GA	Reposition right femoral shaft with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSF0GA	Reposition left femoral shaft with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	480–482 907–909 956
XNSF3GA	Reposition left femoral shaft with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	480–482 907–909 956

Procedure code	Description	O.R.	MDC	MS–DRG
XNSG0GA	Reposition right tibia with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNSG3GA	Reposition right tibia with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNSH0GA	Reposition left tibia with ring external fixation device with automated strut adjustment, open approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XNSH3GA	Reposition left tibia with ring external fixation device with automated strut adjustment, percutaneous approach, new technology group 10.	Y	08 21 24	492–494 907–909 957–959
XW033MA*	Introduction of emapalumab-lzsg anti-IFNy monoclonal antibody into peripheral vein, percutaneous approach, new technology group 10.	N		
XW033NA*	Introduction of tarlatamab-dlle antineoplastic into peripheral vein, percutaneous approach, new technology group 10.	N		
XW043MA*	Introduction of emapalumab-lzsg anti-IFNy monoclonal antibody into central vein, percutaneous approach, new technology group 10.	N		
XW043NA*	Introduction of tarlatamab-dlle antineoplastic into central vein, percutaneous approach, new technology group 10.	N		
XXE5X5A*	Measurement of immune response, whole blood cellular assessment via microfluidic deformability, new technology group 10.	N		

* As the procedure codes are designated as non-O.R. procedures, there is no assigned MDC or MS–DRG. The ICD–10 MS–DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a complication or comorbidity (CC) or major complication or comorbidity (MCC), procedures or services performed, age, sex, and discharge status.
** Non-O.R. procedure affecting the MS–DRG assignment.

The 50 procedure codes are also reflected in Table 6B.—New Procedure Codes, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. As with the other new procedure codes and MS–DRG assignments included in Table 6B in association with this FY 2026 IPPS/LTCH PPS proposed rule, we are soliciting public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2026, as well as any other options for the GROUPER logic.

We note that Change Request (CR) 13917, Transmittal 12995, titled ''April 2025 Update to the Medicare Severity-Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 42.1'' was issued on December 12, 2024 (available on the CMS website at: *https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12995cp*) regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 42.1, effective with discharges on and after April 1, 2025, reflecting the new procedure codes. The updated software, along with the updated ICD–10 MS–DRG Version 42.1 Definitions Manual and the Definitions of Medicare Code Edits Version 42.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the September 7, 2001, final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of the Medicare Modernization Act (Pub. L. 108–173) included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

However, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the

annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. With this new April 1 update, CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We are continuing to use several aspects of our existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes efforts to accommodate the requested implementation date for each request submitted. However, the Committee determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. As discussed earlier in this section of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, there were code proposals presented for an April 1, 2025, implementation at the September 10–11, 2024, Committee meetings. Following the receipt of public comments, the code proposals were approved and finalized, therefore, there were new codes implemented April 1, 2025.

Consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2024 and provided the updated code files in December 2024. The NCHS provided the ICD–10–CM Official Guidelines for Coding and Reporting in January 2025. By February 27, 2025, we made available the updated Version 42.1 ICD–10 MS–DRG GROUPER software and related materials on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

ICD–9–CM addendum and code title information are published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum*. ICD–10–CM and ICD–10–PCS addendum and code title information are published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10*. CMS also sends electronic files containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at *https://www.cdc.gov/nchs/icd/icd-10-cm/files.html*. Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

For FY 2025, there are currently 74,044 diagnosis codes and 78,986 procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this FY 2026 IPPS/LTCH PPS proposed rule (and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*), there are 487 new diagnosis codes and 14 new procedure codes that have been finalized for FY 2026 at the time of the development of this FY 2026 IPPS/LTCH PPS proposed rule and 50 new procedure codes that were effective with discharges on and after April 1, 2025. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

12. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we would reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Proposed Changes for FY 2026

As discussed in section II.C.3. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, for FY 2026, under MDC 01, we are proposing to add procedure code combinations that describe the insertion of multiple or single array generators and the insertion of neurostimulator lead into the brain or cerebral ventricle and the procedure code combinations that describe the insertion of a neurostimulator generator into the skull and the insertion of a neurostimulator lead into the brain to a new ''intracranial neurostimulator implant'' logic list in MS–DRGs 020, 021, and 022. A subset of the procedures currently assigned to MS–DRGs 023 and 024 are being proposed for reassignment to MS–DRGs 020, 021, and 022. We are also proposing to revise the title of MS–DRG 020 from ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with MCC'' to ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with MCC''; revise the title of MS–DRG 021 from ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC'' to ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with CC''; revise the title of MS–DRG 022 from ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage without CC/MCC'' to ''Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant without CC/MCC''; revise the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to ''Craniotomy with Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant''; and revise the title of MS–DRG 024 from ''Craniotomy with Major Device Implant or Acute Complex CNS Principal

Diagnosis without MCC'' to ''Craniotomy with Acute Complex CNS Principal Diagnosis without MCC''.

Additionally, as discussed in section II.C.4. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, for FY 2026, under MDC 05, we are proposing new MS–DRG 209 (Complex Aortic Arch Procedures) and new MS–DRG 213 (Endovascular Abdominal Aorta with Iliac Branch Procedures). A subset of the procedures currently assigned to MS–DRGs 216, 217, 218, 219, 220 and 221 are being proposed for assignment to proposed new MS–DRG 209 and a subset of the procedures currently assigned to MS–DRGs 268, 269, 270, 271, and 272 are being proposed for assignment to proposed new MS–DRG 213.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 023, 024, 216, 217, 218, 219, 220, 221, 268, 269, 270, 271, and 272 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the following table. Therefore, we are proposing that if the applicable proposed MS–DRG changes are finalized, we also would add MS–DRGs 020, 021, and 022 and proposed new MS–DRGs 209 and 213 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes to the titles of MS–DRGs 023 and 024 in the list of MS–DRGs subject to the policy as reflected in the following table. We are also proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

MDC	MS–DRG	MS–DRG title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC.
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC.
01	020	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with MCC.
01	021	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant with CC.
01	022	Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage or Intracranial Neurostimulator Implant without CC/MCC.
01	023	Craniotomy with Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant.
01	024	Craniotomy with Acute Complex CNS Principal Diagnosis without MCC.
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC.
01	026	Craniotomy and Endovascular Intracranial Procedures with CC.
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC.
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC.
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator.
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC.
03	140	Major Head and Neck Procedures with MCC.
03	141	Major Head and Neck Procedures with CC.
03	142	Major Head and Neck Procedures without CC/MCC.
05	209	Complex Aortic Arch Procedures.
05	213	Endovascular Abdominal Aorta with Iliac Branch Procedures.
05	215	Other Heart Assist System Implant.
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC.
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC.
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC.
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC.
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC.
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC.
05	242	Permanent Cardiac Pacemaker Implant with MCC.
05	243	Permanent Cardiac Pacemaker Implant with CC.
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC.
05	245	AICD Generator Procedures.
05	258	Cardiac Pacemaker Device Replacement with MCC.
05	259	Cardiac Pacemaker Device Replacement without MCC.
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC.
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC.
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC.
05	265	AICD Lead Procedures.
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC.
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC.
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC.
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC.
05	270	Other Major Cardiovascular Procedures with MCC.
05	271	Other Major Cardiovascular Procedures with CC.
05	272	Other Major Cardiovascular Procedures without CC/MCC.
05	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC.
05	276	Cardiac Defibrillator Implant with MCC or Carotid Sinus Neurostimulator.

MDC	MS–DRG	MS–DRG title
05	277	Cardiac Defibrillator Implant without MCC.
05	319	Other Endovascular Cardiac Valve Procedures with MCC.
05	320	Other Endovascular Cardiac Valve Procedures without MCC.
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC.
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC.
08	466	Revision of Hip or Knee Replacement with MCC.
08	467	Revision of Hip or Knee Replacement with CC.
08	468	Revision of Hip or Knee Replacement without CC/MCC.
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement.
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC.
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC.
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC.

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be included in the FY 2026 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

D. Recalibration of the FY 2026 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2026, we are proposing to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2024 MedPAR data used in this proposed rule include discharges occurring on October 1, 2023, through September 30, 2024, based on bills received by CMS through December 31, 2024, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2024 MedPAR file used in calculating the relative weights includes data for approximately 6,860,436 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 2024 update of the FY 2024 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61'', ''62'', ''63'', and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2026 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. In addition, the data exclude Rural Emergency Hospitals (REHs), including hospitals that subsequently became REHs after the period from which the data were taken. We note that the proposed FY 2026 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2024 MedPAR claims data, grouped through the ICD–10 version of the proposed FY 2026 GROUPER (Version 43).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the Healthcare Cost Report Information System (HCRIS). In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this proposed rule, we used the December 2024 update of the FY 2023 HCRIS for calculating the FY 2026 cost-based relative weights. Consistent with our historical practice, for this FY 2026 proposed rule, we are providing the version of the HCRIS from which we calculated these 19 cost-to charge-ratios (CCRs) on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. Click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the proposed FY 2026 relative weights based on 19 CCRs. The methodology we are proposing to use to calculate the FY 2026 MS–DRG cost-based relative weights based on claims data in the FY 2024 MedPAR file and data from the FY 2023 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the proposed FY 2026 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this proposed rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2024 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable

cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, CT scan charges, and MRI charges were also deleted.
- At least 92.6 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.
- Effective October 1, 2008, because hospital inpatient claims include a Present on Admission (POA) field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI Initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services that beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced*. Consistent with our policy for FY 2024, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2025, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2025 IPPS/LTCH PPS final rule, we are also proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS

payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2023 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 proposed national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For this FY 2026 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to the following: MS–DRG 016 and MS–DRG 017, MS–DRG 095 and MS–DRG 096, MS–DRG 504 and MS–DRG 505, MS–DRG 797 and MS–DRG 798. In the supplemental file titled AOR/BOR File, we include statistics for the affected MS–DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2026 relative weights and the changes in relative weights from FY 2025.

b. Relative Weight Calculation for MS–DRG 018

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies. We also finalized our proposal to modify our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs (85 FR 58599 through 58600). Specifically, we stated that clinical trial claims that group to new MS–DRG 018 would not be included when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. We stated that we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the FY 2021 final rule. In addition, we stated that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data.

We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations. We calculate this adjustor by dividing the average cost for cases that we identify as clinical trial cases by the average cost for cases that we identify as non-clinical trial cases, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. We stated that to the best of our knowledge, there were no claims in the historical data used in the calculation of this adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access use immunotherapy cases that group to MS–DRG 018, and indicated that we would provide instructions for identifying these claims in separate guidance. Following the issuance of the FY 2021 IPPS/LTCH PPS final rule, we issued guidance [9] stating that providers may enter a Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim to notify the MAC of expanded access use of CAR T-cell therapy. In this case, the MAC would add payer-only condition code ''ZB'' so that Pricer will apply the payment adjustment in calculating payment for the case. In cases when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the provider may enter a Billing Note NTE02 ''Diff Prod Clin Trial'' on the electronic claim 837I or a remark ''Diff Prod Clin Trial'' on a paper claim. In this case, the MAC would add payer-only condition code ''ZC'' so that the Pricer will not apply the payment adjustment in calculating payment for the case.

In the FY 2022 IPPS/LTCH PPS final rule, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other

[9] *https://www.cms.gov/files/document/r10571cp.pdf.*

immunotherapies (86 FR 44798 through 44806). We also finalized our proposal to continue to use the proxy of standardized drug charges of less than $373,000 (86 FR 44965) to identify clinical trial claims. We also finalized use of this same proxy for the FY 2023 IPPS/LTCH PPS final rule (87 FR 48894).

Following the issuance of the FY 2023 IPPS/LTCH PPS final rule, we issued guidance [10] stating where there is expanded access use of immunotherapy, the provider may submit condition code ''90'' on the claim so that Pricer will apply the payment adjustment in calculating payment for the case. We stated that MACs would no longer append Condition Code 'ZB' to inpatient claims reporting Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim, effective for claims for discharges that occur on or after October 1, 2022.

In the FY 2024 IPPS/LTCH PPS final rule, we explained that the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. We stated that for the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB, and for the FY 2023 MedPAR data and subsequent years, this field will identify whether or not the claim includes condition code 90. We further noted that the MedPAR files now also include a variable that indicates whether the claim includes the payer-only condition code ''ZC'', which identifies a case involving the clinical trial of a different product where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner.

Accordingly, and as discussed further in the FY 2024 IPPS/LTCH PPS final rule, we finalized two modifications to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 (88 FR 58791). First, we finalized to exclude claims with the presence of condition code ''90'' (or, for FY 2024 ratesetting, which was based on the FY 2022 MedPAR data, the presence of condition code ''ZB'') and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we finalized to no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018. Accordingly, we finalized that in calculating the relative weight for MS–DRG 018 for FY 2024, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (2) contain condition code ''ZB'' (or, for subsequent fiscal years, condition code ''90'') would be excluded from the calculation of the average cost for MS–DRG 018. Consistent with this, we also finalized modifications to our calculation of the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs. We refer readers to the FY 2024 IPPS/LTCH PPS final rule for further discussion of these modifications (88 FR 58791).

Consistent with the FY 2025 IPPS/LTCH PPS final rule, in this proposed rule, for FY 2026 we are proposing to continue to use our methodology as modified in the FY 2024 IPPS/LTCH PPS final rule for identifying clinical trial claims and expanded access use claims in MS–DRG 018, with an additional modification as discussed in this section. First, we exclude claims with the presence of condition code ''90'' and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, we no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018.

In section VI.H. of this proposed rule, we discuss our proposal to apply the payment adjustment for clinical trial and expanded access use immunotherapy cases to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. To mirror this proposed change within our relative weight methodology, we are proposing to also exclude claims with standardized drug charges below the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'') when we calculate the average cost for MS–DRG 018. For this proposed rule, based on the December 2024 update of the FY 2024 MedPAR file, we estimate that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'') is $29,819. We are proposing to apply this policy for 2 years (that is, in our relative weight methodology for MS–DRG 018 for FYs 2026 and 2027), until the claims data reflects the addition of the condition code indicating that the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, which then would be able to be used to identify these cases such that they can be identified for exclusion from the calculation of the average cost of MS–DRG 018. We are also proposing, for the purpose of performing this trim, to update the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 based on more recent data for the final rule.

Accordingly, we are proposing that in calculating the relative weight for MS–DRG 018 for FY 2026, in identifying clinical trial claims and expanded access use claims and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'', (2) contain condition code ''90'', or (3) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018 would be excluded from the calculation of the average cost for MS–DRG 018.

With respect to claims that group to MS–DRG 018 and are identified as clinical trials or involve expanded access use of the CAR T-cell therapy or other immunotherapy, we note that there are some cases that appear to include drug charges similar to cases not identified as clinical trials or involving expanded access use. These charges are generally in revenue center 0891, Cell Therapy Drug Charges. We are seeking comments on potential reasons for why claims identified as clinical trials or involving expanded access use, in which the provider would typically receive the product at no cost, would have charges in revenue center 0891, Cell Therapy Drug Charges.

We are also proposing to continue to use the methodology as modified in the FY 2024 IPPS/LTCH PPS final rule to calculate the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs, with the same proposed modification as described previously to identify other cases where the immunotherapy product is not

[10] *https://www.cms.gov/files/document/r11727cp.pdf.*

purchased in the usual manner, such as obtained at no cost:

- Calculate the average cost for cases assigned to MS–DRG 018 that (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'', (b) contain condition code ''90'', or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as applicable clinical trial or expanded access use cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Under our proposal to continue to apply this methodology, with the proposed modification as described, based on the December 2024 update of the FY 2024 MedPAR file used for this proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($88,484) were 23 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($385,147). Accordingly, as we did for FY 2025, we are proposing to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 0.23 to the applicable clinical trial and expanded access use immunotherapy cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, was adjusted by 0.23. As we did for FY 2025, we are applying the same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

d. Cap for Relative Weight Reductions

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. We also finalized a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the permanent 10-percent cap does not result in an increase or decrease of estimated aggregate payments. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion of this policy. In the Addendum to this IPPS/LTCH PPS proposed rule, we present the proposed budget neutrality adjustment for reclassification and recalibration of the FY 2026 MS–DRG relative weights with application of this cap. We are also making available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for FY 2026. For a further discussion of the proposed budget neutrality adjustment for FY 2026, we refer readers to the Addendum of this proposed rule.

3. Development of National Average Cost-To-Charge Ratios (CCRs)

We developed the proposed national average CCRs as follows:

Using the FY 2023 cost report data, we removed CAHs, REHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight. The proposed FY 2026 cost-based relative weights were then normalized by an adjustment factor of 1.92111 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act. We then applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year; specifically for those MS–DRGs for which the relative weight otherwise would have declined by more than 10 percent from the FY 2025 relative weight, we set the proposed FY 2026 relative weight equal to 90 percent of the FY 2025 relative weight. The proposed relative weights for FY 2026 as set forth in Table 5 associated with this proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this cap.

The proposed 19 national average CCRs for FY 2026 are as follows:

NATIONAL AVERAGE CCRS

Group	CCR
Routine Days	0.395
Intensive Days	0.341
Drugs and Cellular Therapies	0.179
Supplies & Equipment	0.304
Implantable Devices	0.265
Inhalation Therapy	0.149
Therapy Services	0.26
Anesthesia	0.074
Labor & Delivery	0.367
Operating Room	0.156
Cardiology	0.087
Cardiac Catheterization	0.100
Laboratory	0.099
Radiology	0.124
MRIs	0.066
CT Scans	0.032
Emergency Room	0.141

NATIONAL AVERAGE CCRS—Continued

Group	CCR
Blood and Blood Products	0.238
Other Services	0.330

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We are proposing to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2026. Using data from the FY 2024 MedPAR file, there were 10 MS–DRGs that contain fewer than 10 cases. For FY 2026, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we are proposing to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2025 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2025 to FY 2026. The crosswalk table is as follows.

LOW-VOLUME MS–DRGS

Low-volume MS–DRG	MS–DRG title	Crosswalk to MS–DRG
010	Pancreas Transplant	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
096	Bacterial and Tuberculous Infections of Nervous System without CC/MCC.	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC.	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate.	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
791	Prematurity with Major Problems	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
792	Prematurity without Major Problems	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
793	Full-Term Neonate with Major Problems	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
794	Neonate with Other Significant Problems	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).
795	Normal Newborn	Final FY 2025 relative weight (adjusted by percent change in average weight of the cases in other MS–DRGs).

E. Add-On Payments for New Services and Technologies for FY 2026

1. Background

Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) the medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d).

We note that section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this proposed rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-On Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. We note that we do not consider a service

or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA marketing authorization, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was market authorized by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2026 are presented in a data file that is available, along with the other data files associated with the FY 2025 IPPS/LTCH PPS final rule, correction notice and interim final action with comment period, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2027 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2026 proposed rule, by clicking on the FY 2026 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the September 7, 2001, final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001, final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR part 160 and subparts A and E of 45 CFR part 164, applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an

improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what services and technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-On Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. To receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, a medical device designated under FDA's Breakthrough Devices Program [11] that has received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received a Breakthrough Device designation, and then received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) for the indication covered by the Breakthrough Device designation, will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d). We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy.

We note that, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive FDA marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high

[11] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69245 through 69252), we finalized an increase in the new technology add-on payment percentage, reflected at § 412.88(a)(2)(ii)(C) and (b)(2)(iv), that for certain gene therapies approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule that are indicated and used specifically for the treatment of sickle cell disease (SCD), effective with discharges on or after October 1, 2024 and concluding at the end of the 2- to 3-year newness period for such therapy, if the costs of a discharge (determined by applying CCRs as described in § 412.84(h)) involving the use of such therapy for the treatment of SCD exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. We noted that these payment amounts would only apply to Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196).

We note that, consistent with the prospective nature of the IPPS, we finalize the new technology add on payment amount for technologies approved or conditionally approved for new technology add-on payments in the final rule for each fiscal year and do not make mid-year changes to new technology add-on payment amounts. Updated cost information may be submitted and included in rulemaking to be considered for the following fiscal year.

Section 503(d)(2) of the MMA (Pub. L. 108–173) provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of the MMA, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization [12] [13] (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request; or approval of a New Drug Application (NDA) or Biologics License Application (BLA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered (85 FR

[12] How to Study and Market Your Device *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device.*

[13] Types of Applications *https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications.*

58742). Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance, or has been granted a De Novo classification request when considering eligibility for the new technology add-on payment.

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments.

As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245), beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance (for a 510k application or De Novo Classification request) or filing (for a PMA, NDA, or BLA) to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245). As we have discussed in prior rulemaking, we consider the application to be complete when the full application has been submitted to FDA and FDA has provided documentation to the applicant indicating that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA. We recognize that FDA processes and documentation may change over time, and the acceptance or filing documentation may vary depending on the type of FDA marketing authorization application the applicant has submitted to FDA. For example, we understand that FDA considers submission of a 510(k) or De Novo Classification request to be accepted for substantive review after the completion of either a refuse to accept (RTA) review or a technical screening process.[14] [15] Submissions of 510(k) and De Novo Classification requests undergo a technical screening process when they are submitted to FDA using the electronic Submission Template And Resource (eSTAR) process; 510(k) and De Novo Classification requests that are not submitted via eSTAR undergo an RTA review. Accordingly, FDA provides applicants using eSTAR with a review assignment notification to indicate that FDA has completed its technical screening process and has determined that the application is sufficiently complete to allow for substantive review. Therefore, new technology add-on payment applicants that have submitted a 510(k) application or De Novo Classification request to FDA through eSTAR must submit a copy of the review assignment notification to CMS (at the time of new technology add-on payment application) to establish the application is sufficiently complete to allow for substantive review by the FDA. We note that PMAs submitted using eSTAR that complete technical screening will still undergo a subsequent filing review by FDA, after which an application is determined to be sufficiently complete to allow for substantive review; therefore, we continue to require documentation of FDA filing for these applications.

In addition, we recognize that FDA does not conduct a new filing review for NDA or BLA applications that were the subject of a Complete Response Letter (CRL) and were subsequently resubmitted to FDA, even though resubmissions are considered a new review cycle.[16] [17] Therefore, beginning with the new technology add-on applications submitted for FY 2027, these new technology add-on payment applicants must provide to CMS a copy of the resubmission acknowledgement letter from FDA that indicates that FDA considers the resubmission to be sufficient to restart a review clock and provides the new goal date for FDA review of the application. We further note that if there are other processes not described here, or if there are further changes to FDA's review processes, consistent with our policy, applicants must provide to CMS the most up-to-date documentation that indicates FDA has determined that the application is sufficiently complete to allow for substantive review by FDA.

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958), we also finalized that, beginning with FY 2025 applications, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA marketing authorization by May 1 (rather than July 1) of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products), as reflected at § 412.87(f)(2) and (3), as amended and redesignated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958, 88 FR 59331).

e. Pharmaceutical & Technology Ombudsman (PTO)

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage with CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS utilizes the Pharmaceutical & Technology Ombudsman as an initial resource for interested parties. This Ombudsman is available to assist with all of the following:

- Help to point interested parties to or provide information and resources

[14] FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. *https://www.fda.gov/media/73507/download.*

[15] FDA and Industry Actions on De Novo Classification Requests: Effect on FDA Review Clock and Goals Guidance for Industry and Food and Drug Administration Staff Document issued on October 3, 2022. *https://www.fda.gov/media/107652/download.*

[16] SOPP 8405.1: Procedures for Resubmissions to an Application or Supplement. Version: 8 Effective Date: November 13, 2022. *https://www.fda.gov/media/84417/download.*

[17] 21 CFR 314.110, Complete response letter to the applicant *https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-D/section-314.110.*

where possible regarding process, requirements, and timelines.

- As necessary, coordinate and facilitate opportunities for interested parties to engage with various CMS components.
- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We receive many questions from parties interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*, we know that there may be additional questions about the application process. Interested parties with further questions regarding Medicare's coverage, coding, and payment processes, and how they can navigate these processes, whether for new technology add-on payments or otherwise, should review the updated resource guide available at: *https://www.cms.gov/medicare/coding-billing/guide-medical-technology-companies-other-interested-parties*. Parties that would like to further discuss questions or concerns with CMS should contact the Pharmaceutical & Technology Ombudsman at *PharmTechOmbud@cms.hhs.gov*.

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2027 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. CMS will review the application based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*.

To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2027, once the application deadline has closed, CMS will post on its website a list of the applications submitted, along with a brief description of each technology as provided by the applicant.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized our proposal to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We also finalized that with the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly, and that we will not post applications that are withdrawn prior to publication of the proposed rule. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) for further information regarding this policy. Beginning with the new technology add-on applications submitted for FY 2027, we intend to include certain cost criterion information in this public posting; however, consistent with our current policy, cost and volume information will not be publicly posted. Consistent with current practice, certain cost and volume information may still be summarized and discussed in the proposed rule, but we intend to provide more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the cost criterion. Specifically, beginning with the FY 2027 applications, the public posting will include the applicant's explanation of the cost analysis methodology, including the step-by-step explanation of the columns used in the cost analysis spreadsheet attachment, any optional comments provided by the applicant, and information about the case weighted threshold and final inflated case weighted standardized charge per case, as is currently subject to discussion in the cost criterion analysis for each eligible application in the proposed rule. The cost analysis spreadsheet attachment and other charge values provided in the applicant's responses would not be included in the public posting. We believe that including the described cost criterion information in the public posting will further improve and streamline our evaluation process, while also further supporting transparency and engagement with interested parties.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347 and has an expiration date of December 31, 2026.

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

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of the MMA, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or technology represents a substantial clinical improvement.
- Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and

technologies for FY 2026 prior to publication of the FY 2026 IPPS/LTCH PPS proposed rule, we published a notice in the September 13, 2024, **Federal Register** (89 FR 74962) and held a virtual town hall meeting on December 11, 2024. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2026 new medical service and technology add-on payment applications before the publication of the FY 2026 IPPS/LTCH PPS proposed rule.

Approximately 200 individuals attended the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*. We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 16, 2024, deadline, in our evaluation of the new technology add-on payment applications for FY 2026 in the development of the FY 2026 IPPS/LTCH PPS proposed rule. In response to the published notice and the December 11, 2024, New Technology Town Hall meeting, we received written comments regarding the applications for FY 2026 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (89 FR 74962 through 74964), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2026. Therefore, we are not summarizing any written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.E.5. of the preamble of this proposed rule, we summarize comments regarding individual applications, or, if applicable, indicate that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

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

In this section of the proposed rule, we discuss the proposed FY 2026 status of 42 technologies approved for 39 new technology add-on payments for FY 2025, as set forth in the tables that follow. Specifically, we present our proposals to continue the new technology add-on payments for FY 2026 for those technologies that were approved for the new technology add-on payment for FY 2025, and which are still considered ''new'' for purposes of new technology add-on payments for FY 2026. We also present our proposals to discontinue new technology add-on payments for FY 2026 for those technologies that were approved for the new technology add-on payment for FY 2025, and which are no longer considered ''new'' for purposes of new technology add-on payments for FY 2026.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year, and, in general, we have extended new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69238 through 69242), we finalized 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, we will extend new technology add-on payments for an additional fiscal year when the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after October 1 of that fiscal year. This change is effective beginning with those technologies that are initially approved for new technology add-on payments in FY 2025 or a subsequent year. For technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered ''new'' for purposes of new technology add-on payments.

Table II.E–01.A lists the technologies that were first approved for new technology add-on payments prior to FY 2025, for which we are proposing to continue making new technology add-on payments for FY 2026 because they are still considered ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs on or after April 1, 2026. This table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

Table II.E–01.B lists the technologies that were first approved for new technology add-on payments in FY 2025, for which we are proposing to continue making new technology add-on payments for FY 2026 because they are still considered ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of

the product's entry onto the U.S. market occurs on or after October 1, 2025. This table also presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We refer readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding, and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We are inviting public comments on our proposals to continue new technology add-on payments for FY 2026 for the technologies listed in Tables II.E.–01.A and II.E.–01.B.

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

Technology	Newness start date	NTAP start date	3-Year anniversary date of entry onto U.S. market	Previous final rule citations	Proposed maximum NTAP amount for FY 2026	Coding used to identify cases eligible for NTAP
1. CYTALUX® (pafolacianine) (lung indication).	06/05/2023	10/01/2023	06/05/2026	88 FR 58810 through 58818. 89 FR 69120 through 69126.	$2,762.50	8E0W0EN, 8E0W3EN, 8E0W4EN, 8E0W7EN, or 8E0W8EN.
2. EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm).	05/19/2023	10/01/2023	05/19/2026	88 FR 58818 through 58835. 89 FR 69120 through 69126.	6,504.07	XW013S9, XW033P9, or XW043P9.
3. Aveir™ AR Leadless Pacemaker.	06/29/2023	10/01/2023	06/29/2026	88 FR 58919 through 58923. 89 FR 69120 through 69126.	10,725.00	X2H63V9.
4. Aveir™ Dual-Chamber Leadless Pacemaker.	06/29/2023	10/01/2023	06/29/2026	88 FR 58923 through 58925. 89 FR 69120 through 69126.	15,600.00	X2H63V9 in combination with X2HK3V9.
5. Ceribell Status Epilepticus Monitor.	05/23/2023	10/01/2023	05/23/2026	88 FR 58927 through 58930. 89 FR 69120 through 69126.	913.90	XX20X89.
6. DETOUR System	06/07/2023	10/01/2023	06/07/2026	88 FR 58930 through 58932. 89 FR 69120 through 69126.	16,250.00	X2KH3D9, X2KH3E9, X2KJ3D9, or X2KJ3E9.
7. DefenCath® (taurolidine/heparin).	11/15/2023	01/01/2024	11/15/2026	88 FR 58942 through 58944. 89 FR 69120 through 69126.	3,656.10	XY0YX28.
8. Phagenyx® System	04/12/2023	10/01/2023	04/12/2026	88 FR 58935 through 58937. 89 FR 69120 through 69126.	3,250.00	XWHD7Q7.
9. REZZAYO™ (rezafungin for injection).	07/19/2023	10/01/2023	07/19/2026	88 FR 58944 through 58946. 89 FR 69120 through 69126.	4,387.50	XW033R9 or XW043R9.
10. TOPS™ System	06/15/2023	10/01/2023	06/15/2026	88 FR 58940 through 58942. 89 FR 69120 through 69126.	11,375.00	XRHB018 in combination with M48.062.
11. XACDURO® (sulbactam/durlobactam).	05/23/2023	10/01/2023	05/23/2026	88 FR 58946 through 58948. 89 FR 69120 through 69126.	13,680.00	XW033K9 or XW043K9 in combination with one of the following: Y95 and J15.61; OR J95.851 and B96.83.

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

Technology	Newness start date	NTAP start date	3-Year anniversary date of entry onto U.S. market	Previous final rule citations	Proposed maximum NTAP amount for FY 2026	Coding used to identify cases eligible for NTAP
1. Annalise Enterprise CTB Triage—OH.	10/10/2023	10/01/2024	10/10/2026	89 FR 69205 through 69208.	$241.39	XXE0X1A.
2. ASTar® System	04/26/2024	10/01/2024	04/26/2027	89 FR 69208 through 69210.	97.50	XXE5X2A.
3. Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™ System").	02/01/2024	10/01/2024	02/01/2027	89 FR 69210 through 69213.	31,850.00	X2RJ3RA.

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

Technology	Newness start date	NTAP start date	3-Year anniversary date of entry onto U.S. market	Previous final rule citations	Proposed maximum NTAP amount for FY 2026	Coding used to identify cases eligible for NTAP
4. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device).	01/12/2024	10/01/2024	01/12/2027	89 FR 69213 through 69215.	47,238.75	X2VE3SA.
5. LimFlow™ System	11/01/2023	10/01/2024	11/01/2026	89 FR 69215 through 69218.	16,250.00	041M3JS, 041N3JS, 041P3JS, 041Q3JS, 041R3JS, 041S3JS, 041T3JS, or 041U3JS.
6. Paradise™ Ultrasound Renal Denervation System.	11/7/2023	10/01/2024	11/07/2026	89 FR 69218 through 69221.	14,950.00	X051329.
7. PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter.	12/13/2023	10/01/2024	12/13/2026	89 FR 69221 through 69225.	6,337.50	02583ZF.
8. Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter.	11/17/2023	10/01/2024	11/17/2026	89 FR 69225 through 69228.	10,400.00	X05133A.
9. TriClip™ G4	04/01/2024	10/01/2024	04/01/2027	89 FR 69228 through 69230.	26,000.00	02UJ3JZ.
10. VADER® Pedicle System	02/26/2024	10/01/2024	02/26/2027	89 FR 69230 through 69236.	28,242.50	XRH60FA, XRH63FA, XRH64FA, XRH70FA, XRH73FA, XRH74FA, XRH80FA, XRH83FA, XRH84FA, XRHA0FA, XRHA3FA, XRHA4FA, XRHB0FA, XRHB3FA, XRHB4FA, XRHC0FA, XRHC3FA, XRHC4FA, XRHD0FA, XRHD3FA, or XRHD4FA in combination with one of the following: M46.20, M46.22, M46.23, M46.24, M46.25, M46.26, M46.27, M46.30, M46.32, M46.33, M46.34, M46.35, M46.36, M46.37, M46.39, M46.40, M46.42, M46.43, M46.44, M46.45, M46.46, M46.47, M46.49, M46.50, M46.51, M46.52, M46.53, M46.54, M46.55, M46.56, M46.57, M46.59, M46.80, M46.82, M46.83, M46.84, M46.85, M46.86, M46.87, M46.89, M46.90, M46.92, M46.93, M46.94, M46.95, M46.96, M46.97, or M46.99.
11. ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications.	04/03/2024	10/01/2024	04/03/2027	89 FR 69236 through 69238.	2,812.50	XW0335A or XW0435A.
12. ZEVTERA™ (ceftobiprole medocaril); SAB indication.	04/03/2024	10/01/2024	04/03/2027	89 FR 69236 through 69238.	8,625.00	XW0335A or XW0435A in combination with R78.81 (in combination with B95.61 or B95.62).
13. CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication.	12/08/2023	10/01/2024	12/08/2026	89 FR 69128 through 69135.	1,650,000.00	XW133J8 or XW143J8 in combination with one of the following: D57.1, D57.20, D57.40, D57.42, D57.44, or D57.80.
14. HEPZATO™ KIT (melphalan for injection/hepatic delivery system).	01/08/2024	10/01/2024	01/08/2027	89 FR 69158 through 69170.	118,625.00	XW053T9 in combination with 5A1C00Z.
15. LYFGENIA™ (lovotibeglogene autotemcel).	12/08/2023	10/01/2024	12/08/2026	89 FR 69188 through 69196.	2,325,000.00	XW133H9 or XW143H9.

Table II.E.–02 lists the technologies that were first approved for new technology add-on payments prior to FY 2025, including technologies determined to be substantially similar to such technologies, for which we are proposing to discontinue making new technology add-on payments for FY 2026 because they are no longer ''new'' for purposes of new technology add-on payments because the 3-year anniversary date of the product's entry onto the U.S. market occurs before April 1, 2026. This table also presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We refer readers to the cited final rules in the following table for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

As discussed in section II.E.6. of the preamble of this proposed rule, BONESUPPORT, Inc. is also seeking new technology add-on payments for CERAMENT® G for FY 2026 for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to open fractures. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48961 through 48966), CERAMENT® G was approved for new technology add-on payments with an indication for use as a bone void filler in skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement (standard treatment approach to a bone infection) as part of the surgical treatment of osteomyelitis in defects in the extremities. For this proposed rule, we are proposing to discontinue new technology add-on payments for FY 2026 for CERAMENT® G when used for bone infections, as the technology will no longer be considered new for this indication. We believe cases involving the use of CERAMENT® G related to bone infections, which would no longer be eligible for new technology add-on payment in FY 2026, would be identified by the ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) in combination with the ICD–10–CM codes in category M86 (Osteomyelitis). We are inviting public comments on the use of these codes to exclude the indication for use of CERAMENT® G related to bone infections, which would not be eligible for the new technology add-on payment for FY 2026, if approved.

We are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2026 for the technologies listed in Table II.E.–02 of the preamble of this proposed rule.

TABLE II.E.–02—PROPOSED DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2025 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2026 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2026

Technology	Newness start date	NTAP start date	3-Year anniversary date of entry onto U.S. market	Previous final rule citations
1. Thoraflex™ Hybrid Device	04/19/2022	10/01/2022	04/19/2025	87 FR 48974 through 48975. 88 FR 58800. 89 FR 69120 through 69126.
2. ViviStim® Paired VNS System	04/29/2022	10/01/2022	04/29/2025	87 FR 48975 through 48977. 88 FR 58800. 89 FR 69120 through 69126.
3. GORE® TAG® Thoracic Branch Endoprosthesis	05/13/2022	10/01/2022	05/13/2025	87 FR 48966 through 48969. 88 FR 58800. 89 FR 69120 through 69126.
4. CERAMENT® G (bone infection indication)	05/17/2022	10/01/2022	05/17/2025	87 FR 48961 through 48966. 88 FR 58800. 89 FR 69120 through 69126.
5. iFuse Bedrock Granite Implant System	05/26/2022	10/01/2022	05/26/2025	87 FR 48969 through 48974. 88 FR 58800. 89 FR 69120 through 69126.
6. CYTALUX® (pafolacianine) (ovarian indication)	04/15/2022	10/01/2023	04/15/2025	88 FR 58804 through 58810. 89 FR 69120 through 69126.
7. Lunsumio™ (mosunetuzumab)	12/22/2022	10/01/2023	12/22/2025	88 FR 58835 through 58845. 89 FR 69120 through 69126.
8. REBYOTA™ (fecal microbiota, live-jslm) and VOWST™ (fecal microbiota spores, live-brpk).	01/23/2023	10/01/2023	01/23/2026	88 FR 58848 through 58868. 89 FR 69120 through 69126.
9. SPEVIGO® (spesolimab)	09/01/2022	10/01/2023	09/01/2025	88 FR 58879 through 58885. 89 FR 69120 through 69126.
10. TECVAYLI™ (teclistamab-cqyv)	11/09/2022	10/01/2023	11/09/2025	88 FR 58885 through 58891. 89 FR 69120 through 69126.
ELREXFIO™ (elranatamab-bcmm) and TALVEY™ (talquetamab-tgvs)		[18] 10/01/2024		89 FR 69149 through 69155.
11. TERLIVAZ® (terlipressin)	10/14/2022	10/01/2023	10/14/2025	88 FR 58891 through 58906. 89 FR 69120 through 69126.
12. EchoGo Heart Failure 1.0	11/23/2022	10/01/2023	11/23/2025	88 FR 58932 through 58935. 89 FR 69120 through 69126.
13. SAINT Neuromodulation System	09/01/2022	10/01/2023	09/01/2025	88 FR 58937 through 58939. 89 FR 69120 through 69126.

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

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our policy to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we are continuing to summarize each application in this proposed rule. However, while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's

[18] As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69149 through 69155), we determined that ELREXFIO™ (elranatamab-bcmm) and TALVEY™ (talquetamab-tgvs) were substantially similar to TECVAYLI® (teclistamab-cqyv), which was first approved for new technology add-on payment in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58885 through 58891). In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for these technologies, November 9, 2022, the date TECVAYLI® became commercially available. As discussed previously in this section, for technologies that were first approved for new technology add-on payments prior to FY 2025, including for technologies we determine to be substantially similar to those technologies, we continue to use the midpoint of the upcoming fiscal year (April 1) when determining whether a technology would still be considered ''new'' for purposes of new technology add-on payments.

assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2026 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2026 new technology add-on payment applications.

We received 19 applications for new technology add-on payments for FY 2026 under the new technology add-on payment traditional pathway. In accordance with the regulations under § 412.87(f), applicants for FY 2026 new technology add-on payments must have received FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958, 89 FR 69242 through 69245). Of the 19 applications received under the traditional pathway, 2 applicants were not eligible for consideration for new technology add-on payment because they did not meet these requirements, and 3 applicants withdrew their applications prior to the issuance of this proposed rule. We are addressing the remaining 14 applications.

a. AUCATZYL® (Obecabtagene Autoleucel)

Autolus Therapeutics, Inc. submitted an application for new technology add-on payments for AUCATZYL® for FY 2026. According to the applicant, AUCATZYL® is a fast off-rate cluster of differentiation 19 (CD19) autologous chimeric antigen receptor (CAR) T-cell therapy with tumor burden-guided dosing designed to improve persistence and reduce immune-mediated toxicity. Per the applicant, AUCATZYL® is indicated for the treatment of adults with relapsed or refractory (R/R) B-cell precursor acute lymphoblastic leukemia (B–ALL).

Please refer to the online application posting for AUCATZYL®, available at *https://mearis.cms.gov/public/publications/ntap/NTP241002GUJHV*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, AUCATZYL® was granted BLA approval from FDA on November 8, 2024, for the treatment of adults with R/R B–ALL. According to the applicant, AUCATZYL® was commercially available immediately after FDA approval. The applicant stated that a single treatment of AUCATZYL® consists of two intravenous infusions (given on Day 1 and Day 10 [±2]) administered via a syringe or gravity-assisted infusion through a central or peripheral venous line over a few minutes. Per the applicant, each infusion is packaged in three or more infusion bags containing a cell dispersion of the target tumor burden-guided dose of 410×10^6 CD19 CAR-positive viable T cells.[19]

[19] The applicant stated that the first dose, infused on Day 1, is determined by the patient's bone marrow disease burden within 7 days prior to lymphodepletion, and the second dose, infused on Day 10 [±2], is tailored for a total dose of 410×10^6 CAR T cells to complete the single treatment of AUCATYZL®.

The applicant stated that, effective October 1, 2024, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of AUCATZYL:® XW0338A (Introduction of obecabtagene autoleucel into peripheral vein, percutaneous approach, new technology group 10) or XW0438A (Introduction of obecabtagene autoleucel into central vein, percutaneous approach, new technology group 10). The applicant stated that C91.00 (Acute lymphoblastic leukemia not having achieved remission), C91.01 (Acute lymphoblastic leukemia, in remission), or C91.02 (Acute lymphoblastic leukemia, in relapse) may be used to currently identify the R/R B–ALL indication for AUCATZYL® under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that AUCATZYL® is not substantially similar to other currently available technologies because it has a distinct immune-modulating mechanism of action and first-in-class tumor burden-guided dosing indicated for the treatment of adults with R/R B–ALL, and that therefore, the technology meets the newness criterion. More specifically, the applicant asserted that AUCATZYL® is the only CAR T-cell therapy constructed using the differentiated 4–1BB co-stimulatory domain with a novel, proprietary low affinity, fast off-rate CAT19 binding domain, and tumor burden-guided dosing. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for AUCATZYL® for the applicant's complete statements in support of its assertion that AUCATZYL® is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	AUCATZYL® is not substantially similar to currently available T-cell therapies indicated for the treatment of adult R/R B–ALL, specifically TECARTUS® (brexucabtagene autoleucel), the only currently available CD19 CAR T-cell therapy for this population. Specifically, AUCATZYL® is designed to model physiological T-cell activation, and its CAR is constructed using the differentiated 4–1BB co-stimulatory domain along with a proprietary and unique CAT19 binding domain, specifically designed to improve potency and persistence and to reduce immune-mediated toxicity. Shorter cell-cell contact resulting from the >40-fold lower affinity of CAT19 (off-rate of 3.7 minutes) compared with the FMC63 antigen-binding domain (off-rate of 2.8 hours) used in currently available CAR T-cell therapy, including TECARTUS®, serves to reduce cytokine release and toxicity, reduces CAR T-cell exhaustion and enhances CAR T-cell persistence. The 4–1BB co-stimulatory domain is also highly differentiated from the CD28 co-stimulatory domain used in TECARTUS®; the 4–1BB distinct signaling pathway results in lower T-cell activation, increased mitochondrial biogenesis, greater oxidative metabolism, and sustained CAR T-cell persistence. AUCATZYL® is also specifically designed to follow a manageable, personalized tumor burden-guided dosing schedule to proactively mitigate risk of cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), addressing the potential for toxicity in older patients and for consideration of patients with higher disease burden. The first-in-class tumor burden-guided dosing of AUCATZYL® tailors administration based on the individual patient's disease burden and corresponding immunotoxicity risk and supports maximal control for the treating physician, while minimizing immune-related toxicities and maximizing treatment effect.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	CMS has made the determination that ICD–10–PCS procedure codes identifying all CAR T-cell therapies will map to Pre-MDC MS–DRG 018 (Chimeric antigen receptor (CAR) T-cell and other immunotherapies), including previously approved TECARTUS® indicated for adult R/R B–ALL. Patient claims for adult R/R B–ALL patients where AUCATZYL® is administered will also be mapped to Pre-MDC MS–DRG 018 and will be identified by unique, AUCATZYL®-specific ICD–10–PCS codes which have been approved by CMS with an effective date of October 1, 2024.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	Inpatient cases involving adults with r/r B–ALL are identified by existing ICD–10–CM diagnosis codes C91.00 (Acute lymphoblastic leukemia not having achieved remission), C91.01 (Acute lymphoblastic leukemia, in remission), and C91.02 (Acute lymphoblastic leukemia, in relapse). These same ICD–10–CM diagnosis codes will identify adult R/R B–ALL patient types eligible for treatment with AUCATZYL®, where the inpatient claims will be identified by unique AUCATZYL® ICD–10–PCS codes, XW0338A or XW0438A, effective October 1, 2024. Importantly, the eligible patient population for treatment with AUCATZYL® is expected to be expanded because of the substantial clinical benefits of its highly differentiated immune-modulating mechanism of action and the first-in-class tumor burden-guided dosing, namely because of a significantly improved safety profile with very low rates of severe CRS and ICANS and high, sustained remissions following the single treatment of AUCATZYL®. The promise of these clinically meaningful results after treatment with AUCATZYL® are especially important for the older Medicare population, the Hispanic population that faces worse survival outcomes than patients of other ethnicities, and others with overall poor health and high disease burden; today, these populations are either considered ineligible for currently available therapies or are at elevated risk following treatment or consolidation with allogenic hemopoietic stem cell transplant (HSCT).

We have the following concerns with regard to the newness criterion. We note that the applicant asserted that AUCATZYL® does not use the same or similar mechanism of action as existing technologies for R/R B–ALL in adults because AUCATZYL®'s co-stimulatory and binding domains differ from those of TECARTUS®, which the applicant stated is the only other currently available CD19-directed CAR T-cell immunotherapy for this population. However, we note that in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41285 through 41291), with regard to the CAR T-cell therapies KYMRIAH® (tisagenlecleucel) and YESCARTA® (axicabtagene ciloleucel), we stated that although the two technologies were not completely the same in terms of manufacturing processes, co-stimulatory domains, and clinical profiles, these differences did not result in different mechanisms of action, and therefore, inferred that the technologies' mechanisms of action were the same. Similarly, we question whether differences in the co-stimulatory and binding domains for AUCATZYL® and TECARTUS® result in the use of a different mechanism of action. In addition, we note that KYMRIAH® is also a CD19-directed CAR T-cell immunotherapy, and it is indicated for the treatment of patients up to 25 years of age with R/R B–ALL. We believe that the mechanism of action for all three therapies is the binding to CD19 by a CAR construct, which results in T-cell activation and killing of malignant cells in the treatment of B–ALL. Furthermore, while the applicant also stated that AUCATZYL®'s personalized tumor burden-guided dosing schedule is first in class and differentiates it from other technologies' mechanisms of action, we are unclear how a technology's dosing schedule is relevant to its mechanism of action. Accordingly, as it appears that AUCATZYL®, TECARTUS®, and KYMRIAH® may use the same or similar mechanism of action to achieve a therapeutic outcome, are assigned to the same MS–DRG, and treat the same or similar patient population and disease, that is, adult patients with R/R B–ALL, we believe that these technologies may be substantially similar to each other. We note that, per our policy, if these technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Therefore, if AUCATZYL® is substantially similar to TECARTUS® and KYMRIAH®, we believe the newness period for this technology would begin on November 22, 2017, the date KYMRIAH® became commercially available.[20] In addition, because the 3-year anniversary date of the KYMRIAH®'s entry onto the U.S. market (November 22, 2020) occurred in FY 2021, AUCATZYL® would no longer be considered new and would not be eligible for new technology add-on payments for FY 2026. We are interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.

We are inviting public comment on whether AUCATZYL® meets the newness criterion, including whether AUCATZYL® is substantially similar to TECARTUS® and KYMRIAH® for purposes of new technology add-on payments.

[20] TECARTUS® received FDA approval on October 1, 2021, for treatment of adult patients with R/R B–ALL. *https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-brexucabtagene-autoleucel-relapsed-or-refractory-b-cell-precursor-acute-lymphoblastic.*

With respect to the cost criterion, the applicant provided two analyses to demonstrate that AUCATZYL® meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

AUCATZYL® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for AUCATZYL®.
Claims identified	Scenario 1: 349 claims mapping to 9 MS–DRGs, with 56.16% of claims mapping to MS–DRG 834 (Acute Leukemia with MCC). Scenario 2: 2,013 claims mapping to 74 MS–DRGs, with 20.22% of claims mapping to MS–DRG 838 (Chemotherapy with Acute Leukemia as Secondary Diagnosis with CC or High Dose Chemotherapy Agent).
Charges removed for prior technology.	Per the applicant, the utilization of AUCATZYL® would replace chemotherapy charges and other CAR–T therapy utilization. The applicant removed 36.2% and 49.4% of radiology charges for cases in scenario 1 and 2, respectively. Per the applicant, these percentages were derived based on an analysis of the revenue center file from the 100% Inpatient SAF in FY 2023, which represent the share of all radiology charges attributable to chemotherapy, based on percentage of charges classified as chemotherapy observed in the SAF when ALL was a diagnosis. In addition, the applicant identified cases with CAR–T therapies and removed an amount equal to the therapy's wholesale acquisition cost (WAC) inflated by its estimated CAR–T cost-to-charge ratio of 0.2643. Finally, the applicant removed all ''Pharmacy Charges'' for claims with ICD–10–PCS codes of 3E03305 (Introduction of other antineoplastic into peripheral vein, percutaneous approach) and 3E04305 (Introduction of other antineoplastic into central vein, percutaneous approach) for other antineoplastics. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 8.406% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the estimated cost of the new technology by its estimated average cost-to-charge ratio of 0.2643 for CAR T-cell therapies. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $1,554,026. Final inflated average case-weighted standardized charge per case: —Scenario 1: $2,315,730. —Scenario 2: $2,131,832.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that AUCATZYL® meets the cost criterion.

We are inviting public comments on whether AUCATZYL® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that AUCATZYL® represents a substantial clinical improvement over existing technologies because the results of the phase IB/II FELIX clinical study demonstrated that the differentiated design of AUCATZYL® and its first-in-class tumor burden-guided dosing drive substantial short- and long-term clinically meaningful improvements in treatment outcomes of adults with R/R B–ALL, with superior immune-mediated toxicity, thereby, reducing the risk of patients experiencing life-threatening toxicities in need for intensive care. The applicant further asserted that AUCATZYL®, as a stand-alone therapy, may be considered standard of care for adults with R/R B–ALL. The applicant provided 3 published, peer-reviewed studies, six unpublished studies or presentations, and the AUCATZYL® prescribing information to support these claims, as well as 4 supplementary attachments and 7 background articles about CD19-directed CAR T-cell therapies, B–ALL-associated survival, and risk factors associated with access to B–ALL treatments.[21] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for AUCATZYL® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[21] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
AUCATZYL® is the first and only autologous CD19 CAR T-cell therapy with a novel, distinct immune-modulating mechanism of action and first-in-class tumor burden-guided dosing indicated for treatment of adult r/r B–ALL.	Jabbour E, et al. Obecabtagene autoleucel (obe-cel) for relapsed/refractory adult B-cell acute lymphoblastic leukemia (r/r B–ALL): impact of chimeric antigen receptor T-cell (CAR T) and tumor burden-guided dosing in the FELIX Phase Ib/II study. Abstract. Society of Hematologic Oncology. 2024a. Jabbour E, et al. Obecabtagene Autoleucel (obe-cel, Auto1) in adults with relapsed/refractory B-cell acute lymphoblastic leukemia: overall survival, event-free survival and the potential impact of chimeric antigen receptor T-cell persistency and consolidative stem cell transplantation in the open-label single-arm FELIX phase Ib/II study. Oral presentation; American Society of Clinical Oncology Annual Meeting, 2024b. Roddie C, et al. Oral #222; American Society of Hematology Annual Meeting, 2023a. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Following the single treatment of AUCATZYL®, adult patients with r/r B–ALL experienced high response rates, with superior immune-mediated toxicity compared to currently available CAR T-cell therapy.	AUCATZYL prescribing information. *www.autolus.com/media/aj4olbsd/aucatzyl-pi-08 nov2024.pdf.* Ghorashian S, et al. Enhanced CAR T cell expansion and prolonged persistence in pediatric patients with ALL treated with a low-affinity CD19 CAR. Nat Med. 2019;25(9):1408–1414. Jabbour, 2024a, *op. cit.* Jabbour, 2024b, *op. cit.* Roddie C, et al. Durable responses and low toxicity after fast off-rate CD19 chimeric antigen receptor-T therapy in adults with relapsed or refractory B-cell acute lymphoblastic leukemia. J Clin Oncol. 2021;39(30):3352–3363. Roddie, 2023a, *op. cit.* Roddie C, et al. Obecabtagene autoleucel in adults with B-cell acute lymphoblastic leukemia. *N Engl J Med* 2024a; DOI:10.1056/NEJMoa2406526. Roddie C, et al. Risk factors associated with sub-optimal outcomes following obecabtagene autoleucel (obe-cel) for relapsed/refractory B-cell acute lymphoblastic leukemia (R/R B–ALL): What we have learned from the FELIX trial ASH Annual Meeting. December 2024b. Shah BD, et al. Healthcare resource utilization and costs associated with managing CRS and ICANS in patients with relapsed/refractory adult B-cell acute lymphoblastic leukemia receiving obecabtagene autoleucel (obe-cel). ASH Annual Meeting. December 2024. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantially improved CAR T persistence following the single treatment of AUCATZYL® leads to high, durable remission rates, without the need for consolidative transplant.	Day W, et al. Droplet digital PCR and flow cytometry sensitivity for measuring CAR T-cell kinetics in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia treated with obecabtagene autoleucel. European Hematology Association Congress. June 2024. Poster. Jabbour, 2024b, *op. cit.* Jabbour E, et al. Obecabtagene autoleucel (obe-cel) for adult B-cell acute lymphoblastic leukemia (R/R B–ALL): deep molecular remission may predict better outcomes. ASH Annual Meeting. December 2024c. Park JH, et al. Obecabtagene autoleucel (obe-cel) for adults with B-cell acute lymphoblastic leukemia (R/R B–ALL) in the open-label, multi-center, global, single-arm, phase Ib/II FELIX study: the impact of bridging therapies on CAR T-cell expansion and persistence. ASH Annual Meeting. December 2024b. Roddie C, et al. Long-term efficacy and safety of obecabtagene autoleucel (obe-cel) in adult patients with relapsed/refractory B-cell acute lymphoblastic leukemia (r/r B–ALL); pooled analysis of ALLCAR19 and FELIX Phase Ib studies) or other B-cell malignancies (ALLCAR19 extension study). Poster 2114. American Society of Hematology Annual Meeting. 2023b. Roddie, 2024a, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
AUCATZYL® may be an important, definitive stand-alone treatment for adult r/r B–ALL versus use as a bridging therapy.	Jabbour, 2024b, *op. cit.* Park JH, et al. Relapsed/refractory B-Cell acute lymphoblastic leukemia (r/r B–ALL) obecabtagene autholeucel (obe-cel) consolidative allogeneic stem cell transplantation. Poster P–008 presented at Lymphoma, Leukemia and Myeloma Congress (LLM 2024). October 2024a. Roddie, 2023b, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for AUCATZYL®.

After review of the information provided by the applicant, we have the following concerns regarding whether AUCATZYL® meets the substantial clinical improvement criterion. First, we question whether there is any patient population with R/R B–ALL that is unresponsive to or ineligible for any of the currently available treatments for the condition. We note that under this assertion, the applicant stated that AUCATZYL® is the first and only autologous CD19-directed CAR T-cell therapy with a novel, distinct immune-modulating mechanism of action and first-in-class tumor burden-guided dosing indicated for the treatment of adult R/R B–ALL, which produces clinically advantageous results for these patients over currently available therapies, which the applicant stated is limited to TECARTUS® as it is the only CAR T-cell therapy approved for patients ≥26 years old. However, the comparison of clinical outcomes does not demonstrate that a technology offers a treatment option for patients who have no other options due to being ineligible for or unresponsive to existing therapies, nor does the type of technology or dosing regimen. We note that the applicant provided three abstracts/presentations describing unpublished results from the phase Ib/II FELIX trial of AUCATZYL® as well as various background studies to support its claim.[22] The FELIX trial is a multi-center, open-label, single-arm study that evaluates the efficacy and safety of AUCATZYL among R/R B–ALL patients, using complete remission (CR)

[22] Jabbour (2024a), *op. cit.;* Jabbour (2024b), *op. cit.;* Roddie (2023a), *op. cit.*

or complete remission with incomplete count recovery (CRi) per independent response review committee (IRRC) as the primary endpoint. In particular, the Jabbour et al. (2024a, 2024b) abstract and oral presentation provided the percent of patients with prior exposure to various existing treatments, and the Roddie et al. (2023b) presentation reported the subgroup analysis of clinical outcomes by prior treatments. However, none of the documents provided described patients who were unresponsive to or ineligible to receive TECARTUS®. Further, we note that being the first CAR T-cell therapy for a particular indication relates to mechanism of action and is not relevant to the demonstration of substantial clinical improvement. We also note that there are other treatments available for adult patients with R/R B–ALL such as Blincyto® (blinatumomab), Besponsa® (inotuzumab ozogamicin), and allogeneic stem cell transplant (allo-SCT), as well as KYMRIAH® which is FDA-approved in adults 18–25. Therefore, we are unclear which R/R B–ALL patients eligible for AUCATZYL® are unresponsive to or ineligible for treatment with any of these existing treatment options.

We also question the applicant's assertion that following the single treatment of AUCATZYL®, adult patients with r/r B–ALL experienced high response rates, with superior immune mediated toxicity compared to TECARTUS®. We note that the applicant provided the published FELIX trial which demonstrated overall remission [Complete Response (CR)/ Complete Response with incomplete recovery (CRi)] rate of 77 percent and CR of 55 percent in the efficacy-evaluable pivotal cohort 2A of (n=94) as well as unpublished presentations/ abstracts of the trial which included pooled data for all cohorts, different follow up periods, and subgroup analyses. The applicant stated that the response rates for AUCATZYL® were at least comparable to that reported for TECARTUS®, and provided the phase 2 single-arm, open-label ZUMA–3 trial of TECARTUS®, which demonstrated an overall remission rate and CR of 71 percent and 56 percent, respectively (n=55). The applicant also stated that the response rates seen with AUCATZYL® were achieved with superior immune-mediated toxicity with low rates of Grade ≥3 CRS (2 percent) and/or ICANS (7 percent) compared to TECARTUS®, where Grade ≥3 CRS and ICANS have been observed in 24 percent and 25 percent of patients, respectively, in clinical studies and 7 percent and 38 percent, respectively, in real-world studies. However, we question the use of historical controls for comparing the clinical outcomes of AUCATZYL® and TECARTUS® without adjustments for the differences between the clinical trials for the two technologies. For example, there were several differences in baseline demographic and clinical attributes between FELIX, the pivotal trials for AUCATZYL®, and ZUMA–3, the pivotal trial for TECARTUS®. These differences could confound the relationship between the intervention and clinical outcomes and reduce the validity of the results if they are not taken into account in the analysis of the findings. For example, AUCATZYL® recipients were in general older (median age: FELIX: 47 years; ZUMA–3: 40 years), had a higher percent Philadelphia chromosome positive (FELIX: 33 percent; ZUMA–3: 27 percent), had extramedullary disease at screening (FELIX: 25 percent; ZUMA–3: 11 percent); and had a lower tumor burden (median BM blast percent at screening: FELIX: 25 percent; ZUMA–3: 60 percent). AUCATZYL® recipients included a higher proportion of those previously treated with inotuzumab ozogamicin [23] (FELIX: 31 percent; ZUMA–3: 22 percent), or allo-SCT (FELIX: 58 percent; ZUMA–3: 42 percent), but a lower proportion of those previously exposed to blinatumomab (FELIX: 39 percent; ZUMA–3: 45 percent).[24] [25] We question whether these baseline patient attributes in the trials could have impacted outcomes to the extent that differences between these attributes would impact comparisons in clinical outcomes between AUCATZYL® and TECARTUS®.

With regard to the applicant's claim that AUCATZYL® may be an important, definitive stand-alone treatment for adult r/r B–ALL versus use as a bridging therapy, we note that among the 99 patients in the FELIX study who achieved CR or CRi, 40 (40 percent) experienced ongoing remission with subsequent stem cell transplant (SCT) or other therapy; 18 (18 percent) received subsequent SCT during remission, five (5 percent) started new anti-cancer therapy, and the remaining 36 patients (36 percent) either relapsed or died.[26] We are unclear why AUCATZYL® was not a stand-alone treatment for the 23 percent of patients who underwent SCT or anti-cancer therapy subsequently. We are interested in the criteria that were used to determine whether a patient in remission should undergo subsequent SCT or not. Per the applicant, 17 percent of the patients at high risk for immune effector cell-associated hematotoxicity (HT), the most common side effect of CAR T therapy, and 21 percent of those at lower risk for HT proceeded to undergo allogeneic SCT (allo-SCT).[27] We welcome information about factors besides HT that may also be used to inform decisions about the need for subsequent allo-SCT.

We are also concerned about potential confounders introduced by pooling the data from two independent trials with different study designs, and how those confounders might impact the validity of the findings related to AUCATZYL®'s impact on clinical outcomes. According to the applicant, Roddie et al. (2023b) pooled data from the ALLCAR19 (N=20) and FELIX trials (N=16).[28] Per the applicant, the former was a multicenter, non-randomized open-label Phase 1 study in patients aged 16 years or older with B-cell malignancies, including B–ALL. The latter was a global, open-label, single-arm Phase Ib/II study enrolling patients ages 18 years or older with R/R B–ALL. We are interested in the differences between the ALLCAR19 and FELIX trials in terms of eligibility criteria, patients' prior exposure to B–ALL treatments, co-morbidities, and reasons for attrition. We question whether, and how, differences were accounted for in the analysis of clinical outcomes associated with AUCATZYL®.

Moreover, we are concerned about the availability of evidence on AUCATZYL's effects on the outcomes of the Medicare population of those age 65 years or older. According to a study using National Cancer Institute's Surveillance, Epidemiology, and End Result (SEER) database, which drew its data from population-based cancer registries covering 48 percent of the US population,[29] between 1980 and 2017, while the majority (57 percent) of B–ALL patients were under the age of 15 years, 13 percent were 60 years of age or older.[30] We note that the patient sample in Ghorashian et al. (2019) included those age 19 years or younger,

[23] Jabbour (2024b), *op. cit.*

[24] Jabbour (2024a), *op. cit.*

[25] Shah (2021), *op. cit.*

[26] Jabbour (2024b), *op. cit.*

[27] Roddie (2024b), *op. cit.*

[28] Roddie (2023b), *op. cit.*

[29] National Cancer Institute. Division of Cancer Control & Population Sciences. Surveillance, Epidemiology, and End Results (SEER) Surveillance Research Program (*chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://seer.cancer.gov/about/factsheets/SEER_Overview.pdf*, accessed 1/23/2025).

[30] Sasaki K, Jabbour E, and Short NJ et al. Acute lymphoblastic leukemia: A population-based study of outcome in the United States based on the surveillance, epidemiology, and end results (SEER) database, 1980–2017. *American Journal of Hematology* 2021:96:650.

and the patient sample in Roddie et al. (2021) were age 16 years or older (median: 41.5 years, range: 17 to 62). We also note that the applicant's substantial clinical improvement claims for AUCATZYL® are specific to adults (18 years or older) with R/R B–ALL. However, the estimated five-year survival of B–ALL patients decreased from 85 percent for those under the age of 15, to 19 percent for those between the age of 60 and 69 years, and further to six percent for those age 70 years or older.[31] We welcome evidence about the clinical outcomes of R/R B–ALL patients age 65 years or older who received AUCATZYL®.

In addition, we are unclear whether the CD19-targeting CAR T therapy discussed in Ghorashian et al. (2019) was identical to AUCATZYL® or an earlier version of it. We note that Ghorashian et al. (2019) discussed a novel CD19 CAR (CAT–41BBz CAR),[32] and Roddie et al. (2021) stated that they developed a novel second generation CD19–CAR (CAT19–41BB–Z) with a fast off rate.[33] We welcome information about how the technology in Ghorashian et al. (2019) compares with AUCATZYL®.

With regard to the applicant's assertion that AUCATZYL® represents a substantial clinical improvement because it substantially improves CAR T-cell persistence, we note that this relates to surrogate endpoints rather than clinical outcomes. The applicant provided the Day presentation (2024) which examined the association between CAR T-cell persistence and event-free survival among patients who received AUCATZYL® at six month post infusion.[34] However, we note that while the applicant stated persistence of CAR T-cells is associated with improved event-free survival, CAR T-cell persistence is a surrogate measure and does not assess a clinical outcome as described under the regulations at § 412.87(b)(1)(ii)(C).

In addition, we note that the applicant only asserted improved outcomes for AUCATZYL® over TECARTUS®, and we did not receive any evidence comparing AUCATZYL® with other currently available treatments for adults with R/R B–ALL such as KYMRIAH® (approved in adults 18–25), as well as non-CAR T-cell therapies described previously, to demonstrate improved clinical outcomes. We welcome additional information comparing these therapies with AUCATZYL® in order to demonstrate that it provides a substantial clinical improvement over existing therapies.

We are inviting public comments on whether AUCATZYL® meets the substantial clinical improvement criterion.

b. AURLUMYN™ (Iloprost Injection)

SERB Pharmaceuticals submitted an application for new technology add-on payments for AURLUMYN™ for FY 2026. According to the applicant, AURLUMYN™ is an intravenous form of iloprost associated with immediate generalized vasodilation, immunomodulation, and anti-inflammation indicated for the treatment of severe frostbite in adults to reduce the risk of digit amputations.

Please refer to the online application posting for AURLUMYN™, available at *https://mearis.cms.gov/public/publications/ntap/NTP241007QK29V*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, FDA granted NDA approval for AURLUMYN™ on February 13, 2024, for the treatment of severe frostbite in adults to reduce the risk of digit amputations. Per the applicant, the commercial launch of AURLUMYN™ was delayed until the NDA sponsor could secure a capable commercial partner. Per the applicant, it acquired AURLUMYN™ globally on October 18, 2024, and prepared for launch aligned with the beginning of the winter season. The applicant stated that the technology became available for sale on November 12, 2024. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, including additional details about the preparation for launch that aligned with the beginning of the winter season.

According to the applicant, AURLUMYN™ is administered as a continuous intravenous (IV) infusion over 6 hours per day, increased in increments up to a maximum dose of 2 ng/kg/minute, for up to a maximum of 8 consecutive days. The applicant expects that AURLUMYN™ will be dosed in the inpatient setting for 8 consecutive days using a total of eight single-use vials (one per day).

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify AURLUMYN™. We note that the applicant submitted a request for a unique ICD–10–PCS procedure code for AURLUMYN™ beginning in FY 2026. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for AURLUMYN™ under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that AURLUMYN™ is not substantially similar to other currently available technologies because it is the first-ever FDA-approved treatment for frostbite of any grade and is specifically indicated for the treatment of severe frostbite in adults to reduce the risk of finger or toe amputation, and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for AURLUMYN™ for the applicant's complete statements in support of its assertion that AURLUMYN™ is not substantially similar to other currently available technologies.

[31] Sasaki (2021), *op. cit.*

[32] Ghorashian (2019), *op. cit.*

[33] Roddie (2021), *op. cit.*

[34] Day (2024), *op. cit.*

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	AURLUMYN™ is the only IV form of iloprost available in the U.S. AURLUMYN™ is a stable synthetic analog of PGI2 and is a potent prostacyclin receptor agonist. Upon binding to the prostacyclin receptor, prostacyclin inhibits platelet activation and acts as a vasodilator. AURLUMYN™ is associated with immediate generalized vasodilation, immunodulation, and anti-inflammation. AURLUMYN™ has been associated with reductions in neutrophil adhesion and chemotaxis as well as downregulation of intracellular expression of IL–6 and TNF alpha in human monocytes. In addition, AURLUMYN™ has been shown to enhance fibrinolysis, increase red cell deformability, and reduce white cell adhesion to endothelial cells. AURLUMYN™ has also demonstrated activity with respect to increasing cAMP levels in human platelets via stimulation of adenylate cyclase, with resultant inhibition of platelet aggregation. AURLUMYN™ inhibits arachidonic acid-induced vasoconstriction, which may be explained by its ability to counteract thromboxane. As a result of these properties, AURLUMYN™ may mitigate vasoconstriction and microthrombosis to limit frostbite injury. Previously, access to medical frostbite treatment in the U.S. has been limited to agents not specifically studied or approved for frostbite. AURLUMYN™ is not substantially similar to those agents used in case study and anecdotal reports, including nonsteroidal anti-inflammatory drugs, heparin, antibiotics, dextran, tetanus toxoid, immune globulin, antiplatelet agents, and anticoagulant therapy. AURLYMN™ is also significantly differentiated from VENTAVIS® (iloprost) inhalation solution approved in 2004, and since discontinued, for the chronic treatment of pulmonary arterial hypertension and intended to be chronically administered.
Is the technology assigned to the same MS–DRG as existing technologies?	No	The 2023 MedPAR file contains no patient cases assigned to any MS–DRG representing frostbite cases treated with an FDA-approved therapy for severe frostbite. AURLUMYN™ is the first-ever FDA-approved treatment for frostbite of any grade. It is expected AURLUMYN™ administration cases will map to MS–DRGs based on the MS–DRG assignment logic for the case-specific diagnosis or procedural codes.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	AURLUMYN™ is the first-ever FDA-approved treatment for frostbite of any grade and is specifically approved for the treatment of severe frostbite in adults to reduce the risk of finger or toe amputation.

We note that the applicant asserted that AURLUMYN™ is not assigned to the same MS–DRG as existing technologies. However, as the applicant also stated that AURLUMYN™ will map to MS–DRGs based on diagnosis/procedure codes, we believe that the use of AURLUMYN™ will not change the MS–DRG assignment and will, therefore, map to the same MS–DRGs as other treatments for severe frostbite. In addition, while the applicant asserted that AURLUMYN™ does not treat the same or similar type of disease and the same or similar patient population as existing treatments because it is the first-ever FDA-approved treatment for frostbite, we note that there are other severe frostbite treatments that are commonly used including rapid rewarming, fasciotomy, thrombolysis, and sympathectomy.

We are inviting public comments on whether AURLUMYN™ is substantially similar to existing technologies and whether AURLUMYN™ meets the newness criterion.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that AURLUMYN™ meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

AURLUMYN™ COST ANALYSIS

Inclusion/exclusion criteria ...	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for AURLUMYN™.
Claims identified	Scenario 1: 103 claims mapping to nine MS–DRGs, with none of the MS–DRGs exceeding 13.59% of the total identified cases. Scenario 2: 159 claims mapping to 11 MS–DRGs, with 22.64% of claims mapping to MS–DRG 923 (Other Injury, Poisoning and Toxic Effect Diagnoses without CC).
Charges removed for prior technology.	The applicant stated that no charges were removed for a prior technology as a result of using AURLUMYN™, and that there were no indirect charges related to a prior technology to be removed.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 8.4% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	For both scenarios 1 and 2, the applicant added charges for the new technology by dividing the average cost of the new technology per inpatient stay by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

AURLUMYN™ COST ANALYSIS—Continued

Cost analysis results	Scenario 1: —Average case-weighted threshold amount: $87,166. —Final inflated average case-weighted standardized charge per case: $353,509. Scenario 2: —Average case-weighted threshold amount: $73,762. —Final inflated average case-weighted standardized charge per case: $328,186.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that AURLUMYN™ meets the cost criterion.

We are inviting public comments on whether AURLUMYN™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that AURLUMYN™ represents a substantial clinical improvement over existing technologies because AURLUMYN™ substantially lowers the risk of digit amputation in severe frostbite cases. Additionally, the applicant claimed that, by reducing the risk of finger and toe amputations in adults with severe frostbite, AURLUMYN™ mitigates debilitating, lifelong health-related, functional, and work-related impacts associated with digit amputation. The applicant provided four documents, including two studies and clinical practice guidelines to support these claims, as well as two background articles about a classification system for frostbite severity and the prevention and clinical treatment of frostbite.[35] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for AURLUMYN™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
AURLUMYN™ is the first-ever medical treatment for frostbite approved by the FDA and is specifically approved for treatment of severe frostbite to reduce the risk of digit amputations.	Cauchy E, et al. A controlled trial of a prostacyclin and rt-PA in the treatment of severe frostbite. N Engl J Med 2011;364, 189–190. Crooks S, et al. Effectiveness of intravenous prostaglandin to reduce digital amputations from frostbite: an observational study. Canadian Journal of Emergency Medicine 2022;24, 622–629. McIntosh SE, et al. Wilderness Medical Society Clinical Practice Guidelines for the Prevention and Treatment of Frostbite. 2019 Update. Wilderness & Environmental Medicine 2019;30, S19–S32. McIntosh SE, et al. Wilderness Medical Society Clinical Practice Guidelines for the Prevention and Treatment of Frostbite: 2024 Update. Wilderness & Environmental Medicine 2024;35(2) 183–197. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
AURLUMYN™ reduces the risk of amputation of fingers and toes in adults with severe frostbite, mitigating debilitating, lifelong health-related, functional and work-related impacts of digit amputation.	Cauchy, 2011, *op. cit.* Crooks, 2022, *op. cit.* McIntosh, 2019, *op. cit.* McIntosh, 2024, *op. cit.*

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for AURLUMYN™.

After review of the information provided by the applicant, we have the following concerns regarding whether AURLUMYN™ meets the substantial clinical improvement criterion. With respect to the claim that AURLUMYN™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that the applicant stated that AURLUMYN™ is the first-ever FDA-approved medical treatment for severe frostbite to reduce the risk of digit amputations, but did not identify a patient group that is unresponsive to, or ineligible for, the standard-of-care treatment, where AURLUMYN™ does offer a treatment option.

The applicant provided two published studies that used AURLUMYN™ to support this claim (Cauchy et al., 2011; Crooks et al., 2022). Cauchy et al. (2011), which was published as a letter to the editor, is a single site, open-label trial which randomized 47 healthy patients (aged 18 to 55 years) with severe frostbite after mountain rescue in France to receive either buflomedil, AURLUMYN™, or AURLUMYN™ plus recombinant tPA (rtPA), and assessed treatment efficacy based on bone scan scintigraphy to determine risk of amputation. The second study (Crooks et al., 2022) was a retrospective cohort study consisting of a medical records review in Calgary, Canada, a large city inclusive of an unhoused population. The study excluded patients due to superficial or grade 1 frostbite, resulting in 90 patients

[35] Background articles are not included in the following table but can be accessed via the online posting for the technology.

with an interquartile age range of 31 to 53 years old. For frostbite treatment, these patients received either AURLUMYN™ or the standard of care, which consisted of the local best practice without AURLUMYN™. While these two studies compared treatment of patients with severe frostbite using AURLUMYN™ to other treatments, neither study described a patient group that is unresponsive to, or ineligible for, existing treatment options where AURLUMYN™ offers treatment. We further note that while the applicant also cited the Wilderness Medical Society Practice Guidelines (McIntosh et al., 2024) which included a strong recommendation for iloprost as the first-line treatment for severe (grades 3 and 4) frostbite less than 48 hours after thawing, and possibly for up to 72 hours post-thawing,[36] the full statement in the Guidelines is that intravenous iloprost should be considered first-line therapy for grade 3 and 4 frostbite <72 hours after injury, when tPA is contraindicated, and in austere environments where tPA infusion is considered risky or evacuation to a treatment facility will be delayed. Additionally, the guidelines include other recommendations for treatments such as sympathectomy, fasciotomy, and hydrotherapy. Therefore, it appears that there are other treatment options for frostbite other than AURLUMYN™. We would appreciate any additional information regarding which patient population AURLUMYN™ can treat for severe frostbite, for which other existing treatments could not be used.

With respect to the claim that AURLUMYN™ significantly improves clinical outcomes relative to services or technologies previously available, the applicant stated that AURLUMYN™ reduces the risk of amputation of fingers and toes in adults with severe frostbite, mitigating debilitating, lifelong health-related, functional, and work-related impacts of digit amputation. To support this claim, the applicant provided the two published studies and Wilderness Medical Society Practice Guidelines previously discussed (Cauchy et al., 2011; Crooks et al., 2022; McIntosh et al., 2024). The Cauchy et al. (2011) study found that the 16 patients treated with AURLUMYN™ without rtPA resulted in no amputations, whereas the risk of amputation was greater in patients treated with buflomedil (60 percent, 9 of 15 patients) and patients treated with AURLUMYN™ plus rtPA (19 percent, 3 of 16 patients). The Crooks et al. (2022) study found that 18 percent of grade 3 frostbite injuries and 46 percent of grade 4 frostbite injuries treated with AURLUMYN™ resulted in digital amputation, compared to the standard of care groups where 44 percent of grade 3 frostbite injuries and 95 percent of grade 4 frostbite injuries resulted in amputations. However, we question whether the composition of the AURLUMYN™ and standard of care treatment groups in these two published studies were sufficiently comparable and, consequently, whether outcomes demonstrated are clinically significant. Specifically, we question the accuracy of severity grading determinations and the resulting randomization process used to group patients in both studies due to the subjective nature of grading frostbite injuries that can evolve over time, and being that the grading of frostbite injuries in Crooks et al. (2022) was conducted using photographs and clinician health descriptions in the local electronic health record. We also note that, in Crooks et al. (2022), no patients in the control group were treated with tPA, despite tPA and heparin being available for severe injuries during the period of treatment with standard frostbite care. The absence of tPA in the control group raises questions about the adequacy of the comparator, given that the Wilderness Medical Society Practice Guidelines recommend tPA for select severe frostbite cases where timely administration is feasible. We also question the extent to which the quality of frostbite care in the control group may have varied, prior to the implementation of the protocol that implemented 5-day iloprost infusion. In addition, while the utility of recommendations in establishing evidence of clinically improved outcomes is limited, we further note that neither study provided direct comparison with therapies that are also strongly recommended by the Wilderness Medical Society, such as fasciotomy and hydrotherapy, or with other therapies that may have limited data availability, such as sympathectomy and hyperbaric oxygen therapy.

We also have concerns about the generalizability of the Cauchy et al. (2011) and Crooks et al. (2022) studies to the Medicare population. We note that Cauchy et al. (2011) studied AURLUMYN™ treatment in patients in France, whose mean age was 33.1 years and who had no notable medical or surgical history. As noted in the Crooks et al. (2022) study, which studied patients from a large Canadian city with a substantial unhoused population, the effects may not be as dramatic as results in other studies, owing to the differences in medical and social comorbidities in the study population. Similarly, the Medicare population may have significant differences from the Cauchy et al. (2011) study population, in physical and mental health and social complexities. We also question whether efficacy data from Cauchy et al. (2011) is generalizable to the Medicare population due to the study's location, small patient population, and patients' age. We note that these two published studies assessing AURLUMYN™ were both conducted outside of the U.S and primarily included patients under the age of 55 years (range: 18 to 55 and 29 to 54 years, respectively). As noted in the AURLUMYN™ prescribing information, clinical studies included insufficient numbers of patients aged 65 years and older to determine whether they respond differently than younger subjects.[37]

We are inviting public comments on whether AURLUMYN™ meets the substantial clinical improvement criterion.

c. BREYANZI® (Lisocabtagene Maraleucel)

Bristol Myers Squibb submitted an application for new technology add-on payments for BREYANZI® for FY 2026. According to the applicant, BREYANZI® is a CD19-directed, autologous CAR T-cell immunotherapy comprised of individually formulated CD8 and CD4 CAR T-cells, and it is indicated for the treatment of adult patients with relapsed/refractory (R/R) chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received two or more prior lines of therapy (LOTs), including a Bruton tyrosine kinase inhibitor (BTKi) and a B-cell lymphoma 2 protein inhibitor (BCL2i). We note that BREYANZI® is also indicated for the treatment of adult patients with R/R large B-cell lymphoma, for which the applicant submitted an application for new technology add-on payments for FY 2021 and FY 2022, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44996 through 45008).

Please refer to the online application posting for BREYANZI®, available at *https://mearis.cms.gov/public/*

[36] McIntosh, S.E., Freer, L., Grissom, C.K., Rodway, G.W., Giesbrecht, G.G., McDevitt, M., Imray, C.H., Johnson, E.L., Pandey, P., Dow, J., & Hackett, P.H. (2024). Wilderness Medical Society Clinical Practice Guidelines for the Prevention and Treatment of Frostbite: 2024 Update. Wilderness & Environmental Medicine, 35(2). *https://doi.org/10.1177/10806032231222359.*

[37] Eicos Sciences, Inc. Prescribing Information for *AURLUMYN™ (iloprost) injection, for intravenous use* (revised 5/2024), section 8.5 Geriatric Use. Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/217933s000lbl.pdf.*

publications/ntap/NTP24100722KTJ, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, BREYANZI® was granted accelerated approval for its supplemental Biologics License Application (sBLA) by FDA on March 14, 2024 for the treatment of adult patients with R/R CLL or SLL who have received two or more prior LOTs including a BTKi and a BCL2i.[38] According to the applicant, BREYANZI® was commercially available immediately after FDA marketing authorization for the CLL/SLL indication. Per the applicant, for this indication, patients receive a one-time intravenous infusion of BREYANZI®, which contains 90 to 110 $\times 10^6$ CAR-positive viable T-cells consisting of 1:1 CAR-positive viable T-cells of the CD8 and CD4 components, with each component supplied separately in one or more single-dose vials.

The applicant stated that, effective October 1, 2021, the following ICD–10–PCS codes could be used to uniquely describe procedures involving the use of BREYANZI®: XW033N7 (Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein) or XW043N7 (Transfusion of lisocabtagene maraleucel immunotherapy into central vein). The applicant provided the following list of codes may be used to currently identify the R/R SLL/CLL indication for BREYANZI® under the ICD–10–CM coding system:

ICD–10–CM code	Description
C83.00	Small cell B-cell lymphoma, unspecified site.
C83.01	Small cell B-cell lymphoma, lymph nodes of head, face, and neck.
C83.02	Small cell B-cell lymphoma, intrathoracic lymph nodes.
C83.03	Small cell B-cell lymphoma, intra-abdominal lymph nodes.
C83.04	Small cell B-cell lymphoma, lymph nodes of axilla and upper limb.
C83.05	Small cell B-cell lymphoma, lymph nodes of inguinal region and lower limb.
C83.06	Small cell B-cell lymphoma, intrapelvic lymph nodes.
C83.07	Small cell B-cell lymphoma, spleen.
C83.08	Small cell B-cell lymphoma, lymph nodes of multiple sites.
C83.09	Small cell B-cell lymphoma, extranodal and solid organ sites.
C91.10	Chronic lymphocytic leukemia of B-cell type not having achieved remission.
C91.12	Chronic lymphocytic leukemia of B-cell type in relapse.

We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the indication of R/R SLL or CLL for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that BREYANZI® is not substantially similar to other currently available technologies because BREYANZI® does not use the same or similar mechanism of action as other therapies approved for the treatment of R/R CLL/SLL, is not assigned to the same MS–DRG as other therapies currently approved for the treatment of R/R CLL/SLL, and does not involve treatment of the same or similar type of disease and patient population as other CAR T-cell therapies, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for BREYANZI® for the applicant's complete statements in support of its assertion that BREYANZI® is not substantially similar to other currently available technologies.

[38] Breyanzi. United States Prescribing Information (USPI), (revised 5/2024). According to the applicant, FDA has also approved BREYANZI® for several other indications, including for the treatment of adults with (1) R/R follicular lymphoma (FL) who have received two or more prior LOT (approved on 5/15/2024); (2) R/R mantle cell lymphoma (MCL) who have received at least two prior LOT, including a BTKi (approved on 5/30/2024); (3) R/R large B-cell lymphoma (LBCL) after two or more LOT, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal LBCL, and FL grade 3B (approved on 2/5/2021); and (4) LBCL, including DLBCL, not otherwise specified (including DLBCL arising from indolent lymphoma), high-grade B-cell lymphoma, primary mediastinal LBCL, and FL grade 3B, who have either refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplant (HSCT) due to comorbidities or age (approved on 6/24/2022). (*https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/breyanzi-lisocabtagene-maraleucel*, accessed 3/27/2025).

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	BREYANZI® is the first CAR T-cell therapy indicated for the treatment of R/R CLL/SLL. This mechanism of action is not similar to any existing technology indicated for the treatment of R/R CLL/SLL. Existing therapies include BTKis and BCL2is either alone or in combination with CD20 monoclonal antibodies. These classes of therapies are typically sequenced with BTKi as the first line of therapy, then BCL2i as the second line or therapy or vice versa depending on the preference of the patient and treating physician. Patients who experience intolerance to or disease progression after a BTKi and a BCL2i are limited to treatment via recycling of previous agents (unless refractory), chemoimmunotherapy, non-covalent BTKi, or phosphatidylinositol 3-kinase inhibitors (PI3Ki). BTKis, including ibrutinib, acalabrutinib, zanubrutinib, pirtobrutinib, work by inhibiting the B-cell receptor signaling pathway through the Bruton Tyrosine Kinase protein. BCL2is, including venetoclax, work by binding to the BCL2 protein in the mitochondria leading to apoptosis sensitization. Used in combination with CD20 monoclonal antibodies, such as rituximab, obinutuzumab, the two drugs synergize to induce direct induction of apoptosis, antibody-dependent cell-mediated cytotoxicity and complement-dependent lysis. Chemoimmunotherapy works through a variety of mechanisms that disrupt cellular replication leading to cell death. PI3Kis (idelalisb, duvelisib) work through the inhibition of the PI3K signaling pathway which regulates multiple downstream cellular pathways and is often associated with the development of malignancies. In contrast, BREYANZI® is a CAR T-cell therapy. A CAR is an artificial construct introduced into the DNA of a patient's T cells. The patient's T cells will then transcribe and translate this DNA into a protein, which resides at the surface of the T cell, with the extracellular/targeting domain on the outside of the cell and the costimulatory and signaling domains, required for T-cell activation, on the inside of the cell. When the targeting domain binds to its target. CD19 in the case of BREYANZI®, a signal is transmitted from the activation and costimulatory domain, that initiates proliferation of the T cell and secrete compounds that direct the immune system to kill the cell that is expressing the target. CAR binding to CD19 expressed in CLL/SLL cells induces activation and proliferation of CAR T cells, release of pro-inflammatory cytokines, and cytotoxic killing of target cells. No other therapy indicated for the treatment of R/R CLL/SLL has this mechanism of action.
Is the technology assigned to the same MS–DRG as existing technologies?	No	ICD–10–PCS codes XW033N7 (Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein) and XW043N7 (Transfusion of lisocabtagene maraleucel immunotherapy into central vein) are assigned to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and Other Immunotherapies). No other therapies indicated for the treatment of patients with R/R CLL/SLL are assigned to MS–DRG 018. Thus, BREYANZI® is anticipated to be the only technology indicated for R/R CLL/SLL assigned to MS–DRG 018.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	BREYANZI® is the first CAR T-cell therapy approved for the treatment of R/R CLL/SLL. Other approved CAR T-cell therapies treat other myelomas or lymphomas but are not sufficiently analogous to R/R CLL/SLL to be considered the same or a similar disease or patient population, as described below. Because BREYANZI® is the first CAR T-cell therapy, regardless of target, indicated for the treatment of R/R CLL/SLL, it does not involve treatment of the same or similar type of disease and patient population when compared to existing CAR T-cell therapies.

We note that the applicant asserted that because BREYANZI® is the first CAR T-cell therapy, regardless of target, indicated for the treatment of R/R CLL/SLL, it does not involve treatment of the same or similar type of disease and patient population as existing technologies. However, there are other existing (non-CAR T-cell) treatments for patients with R/R CLL/SLL who have received two or more prior LOTs including a BTKi and a BCL2i, such as noncovalent BTKis, PI3Kis, or allogeneic HSCT, and therefore, we question whether BREYANZI® treats a different type of disease or patient population than existing technologies.

We are inviting public comments on whether BREYANZI® is substantially similar to existing technologies and whether BREYANZI® meets the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that BREYANZI® meets the cost criterion. The analysis followed the order of operations summarized in the following table.

BREYANZI® COST ANALYSIS

Inclusion/exclusion criteria ...	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for BREYANZI®.
Claims identified	550 claims mapping to 11 MS–DRGs, with 30.00% of claims mapping to MS–DRG 840 (Lymphoma and Non-Acute Leukemia with MCC).

BREYANZI® COST ANALYSIS—Continued

Charges removed for prior technology.	Per the applicant, it is possible that BREYANZI® could replace other drug therapies during some patients' inpatient stays. The applicant removed 100% of drug charges from the identified cases, as it is difficult to identify the exact differences in drug regimens BREYANZI® patients would receive, both before and in conjunction with administration of BREYANZI®. The applicant stated this removal likely over-estimates charges for drugs that would be replaced by BREYANZI®, as patients may receive some ancillary drug treatments in conjunction with their BREYANZI® administration. The applicant did not remove indirect charges related to prior therapies.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $1,554,026. Final inflated average case-weighted standardized charge per case: $2,759,094.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that BREYANZI® meets the cost criterion.

We are inviting public comments on whether BREYANZI® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that BREYANZI® demonstrates a substantial clinical improvement because R/R CLL/SLL patients who have received a prior BTKi and BCL2i have limited treatment options and outcomes are extremely poor. The applicant also asserted that BREYANZI® is the first and only CAR T-cell therapy indicated for this population, and in clinical studies, 20 percent of patients treated with BREYANZI® achieved complete response or remission (CR) and remained in CR through 22.4 months of follow-up. The applicant provided one article and two conference presentations regarding one clinical trial, and the BREYANZI® package insert to support these claims, as well as 11 background articles about CLL, SLL, and current treatment options.[39] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for BREYANZI® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
BREYANZI® is the first and only CAR T-cell therapy specifically approved for the treatment of R/R CLL and SLL patients who have received a prior covalent BTKi and BCL2i.	BREYANZI® (lisocabtagene maraleucel) Prescribing Information. 2024. Siddiqi, T., Maloney, D.G., Kenderian, S.S., Brander, D.M., Dorritie, K., Soumerai, J., Riedell, P.A., Shah, N.N., Nath, R., Fakhri, B., Stephens, D.M., Ma, S., Feldman, T., Solomon, S.R., Schuster, S.J., Perna, S.K., Tuazon, S.A., Ou, S.S., Papp, E., Peiser. L., Chen, Y., & Wierda, W.G. (2023a, August 19). Lisocabtagene maraleucel in chronic lymphocytic leukaemia and small lymphocytic lymphoma (TRANSCEND CLL 004): a multicentre, open-label, single-arm, phase 1–2 study. *The Lancet, 402*(10402), 641–654. *https://doi.org/10.1016/S0140-6736(23)01052-8.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
R/R CLL and SLL patients who received a prior BTKi and BCL2i have limited treatment options.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
R/R CLL/SLL patients who have received a prior BTKi and BCL2i experience poor outcomes on existing therapy.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
BREYANZI® is anticipated to significantly improve clinical outcomes in R/R CLL/SLL patients who have received prior BTKi and BCL2i therapy.	BREYANZI® (lisocabtagene maraleucel) Prescribing Information. 2024. Siddiqi, 2023a, *op. cit.* Siddiqi T, Maloney DG, Kenderian SS, et al. Lisocabtagene Maraleucel in Relapsed or Refractory Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma: 24-Month Median Follow-up of TRANSCEND CLL 004. Abstract presented at: 2023 ASH Annual Meeting; December 9–12, 2023b; San Diego, CA. Siddiqi T, Gauthier J, Kenderian SS, et al. Lisocabtagene Maraleucel (liso-cel) in Patients (pts) with Relapsed or Refractory (R/R) Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Updated Follow-up of Transcend CLL 004. Abstract presented at: 2024 ASH Annual Meeting; December 7–10, 2024; San Diego, CA.

[39] Background articles are not included in the following table but can be accessed via the online posting for the technology.

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for BREYANZI®, which we are summarizing in this section.

Comment: The applicant submitted a public comment in response to questions posed at the Town Hall meeting. With regard to a question asking about the discrepancy in the number of patients in the full efficacy set of the TRANSCEND CLL 004 trial in *The Lancet* article (Siddiqi et al., 2023a) versus the American Society of Hematology (ASH) conference slides (Siddiqi et al., 2023b), the applicant stated that, in the Siddiqi et al. article (2023a), the conforming status of CAR T-cell product for one patient was unavailable at data cutoff (September 29, 2022); therefore, the product for this patient was considered non-conforming, and the patient was excluded in the efficacy and safety analyses that required the receipt of conforming product. The applicant further explained that after data cutoff, the patient received conforming product, and thus, the ASH conference slides (Siddiqi et al., 2023b) included this patient in its safety and efficacy analyses.

With regard to a question asking the applicant to speak to the issue of CR and how the applicant thinks about CR with minimal residual disease (MRD) versus nodal response, the applicant stated that the TRANSCEND CLL 004 study in the Siddiqi et al., article (2023a) assessed participant responses using the 2018 International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria, which are the regulatory standard and based on nodal response and hematopoietic recovery and do not include MRD. The applicant further explained that with CLL, patients may have bulky lymph nodes, where with treatment, these patients may see resolution of nodal burden, but it may not resolve to <1.5 cm, which would qualify as a partial response (PR), and not CR per the 2018 iwCLL criteria. The applicant stated that there may be no evidence of residual disease based on blood or bone marrow measures in these patients.

With regard to a question inquiring how efficacy (overall response rate (ORR) and progression-free survival (PFS)) with BREYANZI® compares to other existing therapies (such as Jaypirca® (pirtobrutinib)), and how the applicant considered treatment-emergent adverse events (TEAEs) for BREYANZI® versus other treatments for CLL/SLL, the applicant stated that there is limited real-world data using other agents in the post-BTKi and -BCL2i treatment setting. Per the applicant, these limited data suggest poor outcomes, details of which are included in the BREYANZI® application for new technology add-on payments. The applicant referred to the Siddiqi (2024) presentation slides, which discussed the effects of BREYANZI on the outcomes of all the TRANSCEND CLL 004 subjects (full population) and a subset of those with progression on a previously BTKi and venetoclax failure (referred to as the primary efficacy analysis set, or PEAS, in the rest of this review). According to the applicant, Siddiqi et al. (2024) reported the IRC-assessed CR rate of 20 percent and ORR of 48 percent for the full population treated with BREYANZI® at DL2, and the IRC-assessed CR of 20 percent and ORR of 44 percent for patients in the PEAS cohort. The applicant also noted that the Siddiqi (2024) presentation slides reported the median PFS (mPFS) of 18 months for the full population and 11.9 months for the PEAS cohort. The applicant stated that of the patients who achieved CR or incomplete count recovery (CRi), the mPFS was not reached (NR) for both the full population and the PEAS population. The applicant noted that this efficacy was a result of a single-dose, one-time infusion of BREYANZI®, rather than a continuous treatment, and that this resulted in favorable long-term outcomes. Regarding toxicities, the applicant stated that cytokine response syndrome (CRS) and neurological adverse events are unique to cellular therapies and were overall well-managed in the TRANSCEND CLL 004 study (Siddiqi et al., 2023a), as previously described. The applicant added that no new safety signals were observed in CLL patients. Per the applicant, other common toxicities with cellular therapy include hematologic toxicities, which are also inherent with other targeted agents and were managed with supportive care.

According to the applicant, Jaypirca® (pirtobrutinib), a non-covalent BTKi, is the other FDA-approved agent for patients with CLL/SLL who have received two or more prior LOTs, including a BTKi and BCL2i. Per the applicant, in the phase I–II Jaypirca® trial, the IRC-assessed ORR was reported as 70 percent, the CR rate reported as 0 percent, and the mPFS reported as 16.8 months.[40] According to the applicant, the trial reported any grade adverse events including fatigue (31.5 percent), bleeding (42.6 percent), infections (71.0 percent), and neutropenia (32.5 percent), which are characteristic of this type of targeted agent.

With regard to a question about the breakdown between rates of CR and CRi in the TRANSCEND CLL 004 study (Siddiqi et al., 2023a), the applicant stated that the study's primary analysis, which had a data cutoff of September 29, 2022, reported that the CR rate was 18.4 percent (in 9 of 49 patients) and that among the nine patients who achieved CR/CRi, eight were in CR and one was in CRi.

The applicant also reiterated that patients with R/R CLL/SLL who have failed prior BTKi and BCL2i treatment experience poor outcomes on existing therapy, and BREYANZI® substantially improved clinical outcomes for these patients. The applicant added that BREYANZI®'s outcomes were even more significant when considering the established safety profile and the fact that it is a one-time infusion treatment rather than continuous treatment.

Response: We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether BREYANZI® meets the substantial clinical improvement criterion. First, we question whether there is a particular subpopulation for which BREYANZI® offers a treatment option that is unresponsive to or ineligible for other existing therapies. While the applicant asserted that BREYANZI® is the first and only CAR T-cell therapy for this indication, it also stated that there are other treatment options for this patient population, including non-covalent BTKis, such as Jaypirca®, and PI3Ks, such as COPIKTRA®.[41] We note that being the first CAR T-cell therapy for a particular indication relates to mechanism of action and is not relevant to the demonstration of substantial clinical improvement.

[40] Mato, A.R., Woyach, J.A., Brown, J.R., Ghia, P., Patel, K., Eyre, T.A., Munir, T., Lech-Maranda, E., Lamanna, N., Tam, C.S., Shah, N.N., Coombs, C.C., Ujjani, C.S., Fakhri, B., Cheah, C.Y., Patel, M.R., Alencar, A.J., Cohen, J.B., Gerson, J.N., Flinn, I.W., Ma, S., Jagadeesh, D., Rhodes, J.M., Hernandez-Ilizaliturri, F., Zinzani, P.L., Seymour, J.F., Balbas, M., Nair, B., Abada, P., Wang, C., Ruppert, A.S., Wang, D., Tsai, D.E., Wierda, W.G., & Jurczak, W. (2023b, July 6). Pirtobrutinib after a Covalent BTK Inhibitor in Chronic Lymphocytic Leukemia. *New England Journal of Medicine, 389*(1), 33–44. *https://doi.org/10.1056/NEJMoa2300696.*

[41] National Comprehensive Cancer Network. (2024, October 1). *NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®): Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma. https://www.nccn.org/professionals/physician_gls/pdf/cll.pdf.*

Secondly, while the applicant stated that BREYANZI® is anticipated to significantly improve clinical outcomes in R/R CLL/SLL patients who have received prior BTKi and BCL2i therapy, we have questions regarding the evidence provided in support of this claim. The applicant provided several studies based on the results of the TRANSCEND CLL 004 trial, including one published article (Siddiqi et al., 2023a), two conference presentations (Siddiqi et al., 2023b; Siddiqi et al., 2024), and the BREYANZI® package insert (2024). We note that the TRANSCEND CLL 004 trial was a single-arm study in which no historical controls were used to compare the effects of BREYANZI® on clinical outcomes. We also note that the applicant acknowledged the caveats inherent with direct cross-study comparisons due to differences between patient populations, baseline comorbidities, and the number and type of prior treatment regimens that subjects have received. In addition, the applicant stated that no head-to-head studies exist comparing BREYANZI® in CLL to currently available treatments. At the same time, the applicant asserted that BREYANZI®'s median time to next therapy was considerably longer than that observed in a real-world study of patients with CLL/SLL after prior treatment with a BTKi and B-cell lymphoma 2 inhibitors (6.6 months [95 percent CI, 3.6–10.a].[42] Also, the applicant noted that patients with prior BTKi exposure who were venetoclax-naïve would have improved outcomes had they received BREYANZI® earlier, before other early-line treatments.[43] We are concerned about the validity of comparing the clinical outcomes of BREYANZI® and existing therapies to the extent those clinical outcomes were results of trials with different designs, and the patients in those studies were selected based on different inclusion/exclusion criteria and may have different baseline clinical characteristics. These differences may have an impact on clinical outcomes that was independent of BREYANZI® or the comparator treatments. Moreover, we note the differing results between BREYANZI® and other existing therapies in terms of the clinical outcomes cited by the applicant. For example, as previously described, BREYANZI® demonstrated a CR rate of 20 percent and ORR of 44 percent for patients in the PEAS cohort. According to the applicant, in a trial in which patients with R/R CLL/SLL received Jaypirca®, the CR rate and ORR was 0 percent and 70 percent respectively.[44] Furthermore, according to the applicant, BREYANZI® resulted in PFS of 11.9 months for patients in the PEAS cohort in the TRASNCEND CLL 004 trial. However, we note that in the trial in which patients with R/R CLL/SLL received Jaypirca®, the PFS was 16.8 months.[45] We question how these mixed findings support the claim that BREYANZI® represents a substantial clinical improvement, given the higher values with respect to the existing therapies for particular outcome results.

In addition, with respect to the applicant's claims that R/R CLL/SLL patients who received prior BTKi and BCL2i therapies have limited treatment options, and that patients with R/R CLL/SLL have poor outcomes on existing therapy, we question whether these claims support that BREYANZI® improves clinical outcomes for this patient population.

We are inviting public comments on whether BREYANZI® meets the substantial clinical improvement criterion.

d. COBENFY™ (Xanomeline and Trospium Chloride)

Bristol Myers Squibb submitted an application for new technology add-on payments for COBENFY™ for FY 2026. According to the applicant, COBENFY™ is an oral combination drug consisting of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, that is indicated for the treatment of schizophrenia in adults. Please refer to the online application posting for COBENFY™, available at *https://mearis.cms.gov/public/publications/ntap/NTP241007U99FM*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, COBENFY™ was granted NDA approval from FDA on September 26, 2024, for the treatment of schizophrenia in adults. The applicant stated that COBENFY™ became commercially available on October 9, 2024, and stated the delay in availability was due to a ramp-up period associated with distribution. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, such as additional information about the ramp-up period for distribution.

COBENFY™ has 3 approved dose strengths (50 mg/20 mg, 100 mg/20 mg, and 125 mg/30 mg) in capsule form. The recommended starting dosage is one 50 mg/20 mg capsule orally twice daily for at least 2 days. The dosage is increased to one 100 mg/20 mg capsule orally twice daily for at least 5 days and may be increased thereafter to one 125 mg/30 mg capsule orally twice daily based on patient tolerability and response. The applicant stated the per day treatment cost is the same across all dosages and the average length of stay for patients taking COBENFY™ is 7.5 days.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify COBENFY™. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for COBENFY™ beginning in FY 2026. The applicant provided the following list of diagnosis codes that may be used to currently identify the indication for COBENFY™ under the ICD–10–CM coding system: F20.0 (Paranoid schizophrenia), F20.1 (Disorganized schizophrenia), F20.3 (Undifferentiated schizophrenia), F20.89 (Other schizophrenia), F20.9 (Schizophrenia, unspecified), F25.0 (Schizoaffective disorder, bipolar type), F25.1 (Schizoaffective disorder, depressive type), F25.8 (Other schizoaffective disorders), and F25.9 (Schizoaffective disorder, unspecified).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that COBENFY™ is not substantially similar to other currently available technologies because it is the first treatment for schizophrenia to target muscarinic receptors instead of dopamine. Per the applicant, COBENFY™ combines xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, which work together to stimulate muscarinic receptors in the brain while minimizing peripheral side effects; and its efficacy, safety, and tolerability have been established in acute and long-term trials providing a new option for patients; and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for COBENFY™ for the applicant's complete statements in support of its assertion that COBENFY™ is not

[42] Siddiqi (2023b), *op.cit.*

[43] Siddiqi (2024), *op.cit.*

[44] Mato (2023b), *op.cit.*

[45] Mato (2023b), *op.cit.*

substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	COBENFY™ targets muscarinic receptors as opposed to dopamine receptors, which has long been the standard of care. This novel mechanism marks a significant breakthrough in schizophrenia treatment. COBENFY™ is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. Per the FDA label, the efficacy of COBENFY™ is thought to be due to xanomeline's agonist activity at M1 and M4 muscarinic acetylcholine receptors in the central nervous system. Meanwhile, trospium chloride antagonizes the muscarinic receptors primarily in the peripheral tissues and does not measurably cross the blood brain barrier. In contrast, typical and atypical antipsychotics antagonize the dopamine receptors as pure antagonists or partial agonists and antagonists. With its unique mechanism of action, COBENFY™ represents the first treatment in a distinct class of drugs for schizophrenia.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The use of COBENFY™ should not impact the MS–DRG assignment and COBENFY™ should be assigned to the same MS–DRG as existing products.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	While COBENFY™ treats the same condition, schizophrenia in adults, as other available technologies, COBENFY™ stands apart due to the distinct patient population that could benefit from it. While the current standard of care can be effective in managing symptoms of schizophrenia, studies have shown that approximately 40% of people with schizophrenia do not respond to therapy, and up to 60% experience a partial or inadequate improvement or intolerable side effects during therapy. Side effects from existing antipsychotics can include sedation, vision impairments, seizures, neuroleptic malignant syndrome, and motor disturbances, such as tremors and rigidity. Similarly, atypical antipsychotics are associated with significant weight gain, hyperlipidemia, insulin resistance/diabetes, heart-rate corrected QT interval (QTc) prolongation, extrapyramidal symptoms, tardive dyskinesia, and sexual dysfunction due to prolactin elevation. Breaking this cycle of trial and error is critical and highlights the urgent need for new treatment options. COBENFY™'s unique mechanism of action and clinical profile provide a new therapeutic option for patients, many of whom have not responded to prior treatments. Its efficacy, safety, and tolerability have been demonstrated across both acute and long-term studies. In all placebo-controlled clinical trials, COBENFY™ demonstrated statistically significant reductions in schizophrenia symptoms compared to placebo as measured by the Positive and Negative Syndrome Scale (PANSS) total score, the primary endpoint in the trial. While common adverse reactions of COBENFY™ included nausea and dyspepsia, more severe gastrointestinal issues were rare. Additionally, COBENFY™ does not have atypical antipsychotic class warnings and precautions and does not have a boxed warning. COBENFY™'s favorable side effect profile, coupled with its efficacy, positions it as a valuable alternative for patients, including those who are unable or unwilling to take typical or atypical antipsychotics due to adverse events.

We are inviting public comments on whether COBENFY™ is substantially similar to existing technologies and whether COBENFY™ meets the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that COBENFY™ meets the cost criterion. The analysis followed the order of operations summarized in the following table.

COBENFY™ COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for COBENFY™.
Claims identified	24,817 claims mapping to 9 MS–DRGs, with 93.45% of claims mapping to MS–DRG 885 (Psychoses).
Charges removed for prior technology.	The applicant did not remove direct or indirect charges related to the prior technology. Per the applicant, patients admitted to the hospital for schizophrenia treatment need to be stabilized. The applicant anticipated that patients will continue to receive their traditional treatments to maintain consistent care and that COBENFY™ will be an additive treatment during a switching period where prescribers transition from traditional treatments to COBENFY™ as a monotherapy.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the average cost of the new technology per inpatient stay (treatment cost per day multiplied by an average 7.5 days per inpatient stay) by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

COBENFY™ COST ANALYSIS—Continued

Cost analysis results	Average case-weighted threshold amount: $43,788. Final inflated average case-weighted standardized charge per case: $44,511.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that COBENFY™ meets the cost criterion.

We are inviting public comments on whether COBENFY™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that COBENFY™ represents a substantial clinical improvement over existing technologies because it is a first-in-class muscarinic agonist offering a new approach to treating schizophrenia by selectively targeting muscarinic receptors in the brain without targeting dopamine. The applicant further asserted that COBENFY™ has the potential to improve outcomes by addressing both positive and negative symptoms, which current drugs often inadequately manage, and that its unique mechanism reduces the risk of dopamine-related side effects, such as tardive dyskinesia (TD). The applicant stated that for these reasons, COBENFY™ offers a treatment option for adult patients with schizophrenia who are unresponsive to, or ineligible for, currently available treatments and significantly improves clinical outcomes relative to existing treatments. The applicant provided six articles regarding five studies to support these claims. We also note that two additional articles (Cornett et al., 2017 and Lieberman et al., 2005) [46] submitted as supporting evidence would more appropriately be characterized as background articles because they do not directly assess the use of COBENFY™.[47] [48] Instead, Cornett, et al. (2017) is a literature review of medication-induced TD, and Lieberman, et al. (2005) is a study reviewing the efficacy and side effect profile of other antipsychotic drugs in chronic schizophrenia. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for COBENFY™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
COBENFY™'s proven efficacy and side effect profile make it a valuable option for patients who respond inadequately to current treatments.	Amy Claxton, George Konis, Inder Kaul, Andrew C. Miller, Steven M. Paul, Stephen K. Brannan, Ronald Marcus (2024). Long-Term Metabolic Outcomes Associated With KarXT (Xanomeline and Trospium): Interim Results From Pooled, Long-Term Safety Studies EMERGENT–4 and EMERGENT–5. Presentation at the 2024 Annual Conference of the Schizophrenia International Research Society (SIRS), April 3–7, 2024, Florence, Italy. Kaul I, Sawchak S, Correll CU, Kakar R, Breier A, Zhu H, Miller AC, Paul SM, Brannan SK. Efficacy and safety of the muscarinic receptor agonist KarXT (xanomeline-trospium) in schizophrenia (EMERGENT–2) in the USA: results from a randomised, double-blind, placebo-controlled, flexible-dose phase 3 trial. Lancet. 2024a Jan 13;403(10422):160–170. doi: 10.1016/S0140–6736(23)02190–6. Epub 2023 Dec 14. Erratum in: Lancet. 2024a Jun 1;403(10442):2380. doi: 10.1016/S0140–6736(24)01041–9. PMID: 38104575. Kaul I, Sawchak S, Walling DP, Tamminga CA, Breier A, Zhu H, Miller AC, Paul SM, Brannan SK. Efficacy and Safety of Xanomeline-Trospium Chloride in Schizophrenia: A Randomized Clinical Trial. JAMA Psychiatry. 2024b Aug 1;81(8):749–756. doi: 10.1001/jamapsychiatry.2024.0785. Erratum in: JAMA Psychiatry. 2024 Aug 1;81(8):846. doi: 10.1001/jamapsychiatry.2024.2002. PMID: 38691387; PMCID: PMC11063924.
COBENFY™, due to its distinctive mechanism of action, may be an effective treatment option for patients experiencing disruptive negative symptoms.	Brannan SK, Sawchak S, Miller AC, Lieberman JA, Paul SM, Breier A. Muscarinic Cholinergic Receptor Agonist and Peripheral Antagonist for Schizophrenia. N Engl J Med. 2021 Feb 25;384(8):717–726. doi: 10.1056/NEJMoa2017015. PMID: 33626254; PMCID: PMC7610870. Kaul, 2024a, *op. cit.* Kaul, 2024b, *op. cit.* Weiden PJ, Breier A, Kavanagh S, et al. Antipsychotic efficacy of xanomeline – trospium: post hoc analysis of Positive and Negative Syndrome Scale categorical response rates, time course of response, and symptom domains of response in a phase 2 study. J Clin Psychiatry. 2022;83(3):21m14316.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
COBENFY™ improves clinical outcomes by demonstrating a long-term reduction in positive and negative symptoms of schizophrenia and a persistently well-tolerated side-effect profile after a year.	Scott Vuocolo, William P. Horan, Amy Claxton, Steven D. Targum, Inder Kaul, Sharon Sawchak, Andrew C. Miller, Steven M. Paul, Stephen K. Brannan. (2024, May). Efficacy of KarXT on Negative Symptoms in Acute Schizophrenia: An Analysis of Pooled Data From 3 Trials. In Annual Meeting of the World Congress Collegium Internationale Neuro-Psychopharmacologicum (CINP).

[46] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[47] Cornett, E.M., Novitch, M., Kaye, A.D., Kata, V., Kaye, A.M. Medication-Induced Tardive Dyskinesia: A Review and Update. Ochsner J. 2017 Summer;17(2):162–174. PMID: 28638290; PMCID: PMC5472076.

[48] Lieberman, J.A., Stroup, T.S., McEvoy, J.P., Swartz, M.S., Rosenheck, R.A., Perkins, D.O., . . . & Hsiao, J.K. (2005). Effectiveness of antipsychotic drugs in patients with chronic schizophrenia. The New England Journal of Medicine, 353(12), 1209–1223. *https://doi.org/10.1056/NEJMoa051688.*

Applicant statements in support	Supporting evidence provided by the applicant
COBENFY™ offers a side-effect profile that addresses a significant gap in antipsychotic treatment and has the potential to enhance outcomes by improving tolerability and expanding treatment options.	Kaul, 2024a, *op. cit.* Kaul, 2024b, *op. cit.*
COBENFY™ has the potential to improve clinical outcomes due to its demonstrated efficacy in addressing both negative and positive symptoms of schizophrenia.	Brannan, 2021, *op. cit.* Kaul, 2024a, *op. cit.* Kaul, 2024b, *op. cit.* Weiden, 2022, *op. cit.*
COBENFY™ demonstrates statistically significant and clinically meaningful reductions in the severity of illness, as measured by the Clinical Global Impressions-Severity scale (CGI–S), compared to placebo.	Brannan, 2021, *op. cit.* Kaul, 2024b, *op. cit.*

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for COBENFY™, which we are summarizing in this section.

Comment: The applicant submitted a public comment in response to questions posed at the Town Hall meeting and provided additional information.

With regard to a question asking whether there was a statistically significant degree of long-term improvement for patients treated with COBENFY™ compared to placebo, the applicant referenced EMERGENT–4, a 52-week phase III outpatient, open-label extension clinical trial included with its application. The applicant stated that participants in this trial previously completed the treatment period of either the EMERGENT–2 or EMERGENT–3 trial, two 5-week, double-blind, placebo-controlled, phase III inpatient clinical trials and regardless of which treatment patients received in the EMERGENT–2 or EMERGENT–3 trial, all patients received COBENFY™ after week 5 during the open-label extension period (EMERGENT–4). The applicant noted that the EMERGENT–4 trial found that long-term treatment with COBENFY™ was associated with improvements in schizophrenia symptoms, regardless of participants' initial group during EMERGENT–2 and EMERGENT–3, and improvements were maintained throughout the study period. The applicant stated that, therefore, it expected no differences in symptom reduction between the two groups during the EMERGENT–4 study period. The applicant stated that the publication manuscript is currently in development with planned submission to a clinical journal in early 2025.

With regard to a request for clarification as to the source of effect size data referenced during the Town Hall meeting, the applicant stated there are two large meta-analyses that report effect size ranges for first-generation (typical) and second-generation (atypical) antipsychotics, and that in these analyses, the effect size of commonly used antipsychotics in the U.S. ranges from 0.3 to 0.56.[49] [50] We note that effect size in these studies refer to treatments' mean differences, standardized mean differences, or risk ratios with 95 percent CIs in comparison to placebo.

With regard to a question asking for additional information as to the clinical significance of a 1.0-point improvement in PANSS negative subscale, the applicant stated it is generally accepted that a mean reduction of 15 points or greater from baseline on the PANSS total score, which evaluates positive and negative symptoms of schizophrenia, is considered clinically meaningful. The applicant also stated that across EMERGENT–1, EMERGENT–2, and EMERGENT–3 clinical trials, patients treated with COBENFY™ demonstrated statistically significant improvements in symptoms compared to placebo, with a mean PANSS total score reduction of ≥15 points from baseline. Further, the applicant stated that all three trials evaluated the change in PANSS negative score from baseline as a secondary efficacy endpoint, and while there is less consensus regarding a clinically meaningful threshold for the PANSS negative subscale score, COBENFY™ demonstrated statistically significant PANSS negative subscale score reductions compared to placebo in the EMERGENT–1 and EMERGENT–2 clinical trials, with a least squares mean difference of -2.3 ($p<0.001$) and -1.8 ($p=0.0055$), respectively. The applicant noted that none of the three studies enrolled a patient population enriched for negative symptoms, and currently, there are no FDA-approved medications for the specific treatment of negative schizophrenia symptoms.

With regard to an inquiry for additional information on long-term medication adherence in adult patients treated with COBENFY™ compared to other schizophrenia treatments, the applicant stated that it will initiate a real-world, prospective, patient registry study to understand COBENFY™ usage patterns and COBENFY™'s potential impacts among U.S. adults with schizophrenia.

Response: We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether COBENFY™ meets the substantial clinical improvement criterion. We note that the applicant did not identify a patient population for which

[49] Leucht, S., Cipriani, A., Spineli, L., Mavridis, D., Örey, D., Richter, F., Samara, M., Barbui, C., Engel, R.R., Geddes, J.R., Kissling, W., Stapf, M.P., Lässig, B., Salanti, G., & Davis, J.M. (2013). Comparative efficacy and tolerability of 15 antipsychotic drugs in schizophrenia: a multiple-treatments meta-analysis. *The Lancet, 382*(9896), 951–962. *https://doi.org/10.1016/s0140-6736(13)60733-3.*

[50] Huhn, M., Nikolakopoulou, A., Schneider-Thoma, J., Krause, M., Samara, M., Peter, N., Arndt, T., Bäckers, L., Rothe, P., Cipriani, A., Davis, J., Salanti, G., & Leucht, S. (2019). Comparative Efficacy and Tolerability of 32 Oral Antipsychotics for the Acute Treatment of Adults with multi-episode schizophrenia: a Systematic Review and Network meta-analysis. *The Lancet, 394*(10202). *https://doi.org/10.1016/s0140-(19)31135-3.*

COBENFY™ could be used that is unresponsive to or ineligible for other available treatments. The applicant asserted that COBENFY™'s efficacy and side effect profile make it a valuable option for patients who respond inadequately to current treatments and that COBENFY™ may be an effective treatment option for patients experiencing disruptive negative symptoms. To support these assertions, we note that the applicant provided data on COBENFY™ from three 5-week, randomized, double-blind trials (EMERGENT–1, EMERGENT–2, and EMERGENT–3) that compared COBENFY™ to placebo and from two unpublished 52-week open-label trials (EMERGENT–4 and EMERGENT–5). While the exclusion criteria are unknown for EMERGENT–5, we note that the other trials excluded patients with a history of treatment resistance to schizophrenia medications, and we therefore question how the trials demonstrate that COBENFY™ can treat patients unresponsive to other therapies. In addition, we did not receive data indicating that other antipsychotics cannot manage negative symptoms. We also note that if a patient experiences a side effect on one antipsychotic, they may not experience the same side effect on another antipsychotic. Similarly, if one antipsychotic does not work for a patient, it does not necessarily mean another typical or atypical antipsychotic would not work for that patient. Therefore, we question if COBENFY™ is the only treatment option for patients with inadequate response to current treatments or for those experiencing negative symptoms.

The applicant also asserted that COBENFY™ significantly improves outcomes relative to previously available therapies. To support this assertion, the applicant provided data from three 5-week clinical trials (EMERGENT–1, EMERGENT–2, and EMERGENT–3) that compared COBENFY™ to placebo and a literature review on TD (Cornett et al., 2017). However, COBENFY™ was compared to placebo in these trials, and data was not provided comparing COBENFY™ to currently available therapies. We note that, per the applicant, there are more than 20 FDA-approved therapies for schizophrenia, and we are interested in additional information comparing clinical outcomes with COBENFY™ to these therapies, such as with regard to reduction in symptoms of schizophrenia and/or side effects, improved medication adherence, or other outcomes described under the regulations at § 412.87(b)(1)(ii)(C), to inform an assessment of whether COBENFY™ provides a substantial clinical improvement over existing treatment options.

In addition, with respect to the claim that COBENFY™ offers a side-effect profile that has the potential to enhance outcomes by improving tolerability and expanding treatment options, the applicant stated that the provided literature review on TD (Cornett et al., 2017) supports the theory that blockade of dopamine receptors by dopamine antagonists contributes to the development of TD, which COBENFY™ does not affect. We note that the study stated that typical antipsychotics are the most likely to cause TD while atypical antipsychotics may be associated with a decreased prevalence of TD, and we, therefore, are unclear if the applicant is stating that COBENFY™ may reduce the prevalence of TD only compared to typical antipsychotics. We also note that this literature review only discussed TD, which is one potential side effect of some schizophrenia treatments, and no other provided evidence related to rates of other potential side effects seen with existing schizophrenia treatment options such as cardiac arrhythmias, metabolic syndrome, and tremor were compared to the rates for COBENFY™. We would appreciate further information comparing the overall benefit-risk profile of COBENFY™ to previously available antipsychotics in order to assess if COBENFY™ provides a substantial clinical improvement over other available therapies. We also note that the applicant stated that the EMERGENT trials demonstrated that COBENFY™ is well-tolerated and that measures of extrapyramidal symptoms, weight gain, and somnolence were similar between groups. However, given that the trials were only 5 weeks in duration and some side effects, such as tardive dyskinesia, can take longer to occur, we question whether these rates of adverse events may increase over time. For these reasons, we question the assertion that COBENFY™ improves tolerability and side-effects relative to previously available therapies.

The applicant claimed that COBENFY™ demonstrates statistically significant and clinically meaningful reductions in the severity of illness compared to placebo, as measured by the Clinical Global Impression-Severity (CGI–S) scale. According to the applicant, the CGI–S is a global assessment tool used to rate the overall severity of a patient's illness, and rather than being specific to positive, negative, or cognitive symptoms, it instead gives an overall sense of how severe schizophrenia is perceived to be at a given time. However, we question long-term efficacy, given that the only data submitted for this claim was from two 5-week trials (EMERGENT–1 and EMERGENT–3).

We are inviting public comments on whether COBENFY™ meets the substantial clinical improvement criterion.

e. DuraGraft® (Vascular Conduit Solution)

Marizyme, Inc. submitted an application for new technology add-on payments for DuraGraft® for FY 2026. Per the applicant, DuraGraft® is a first-in-class product used during coronary artery bypass grafting surgery (CABG) in adult patients to protect the vascular endothelia of harvested vascular grafts during the ischemic graft storage interval. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26795), Somahlution, Inc., acquired by Marizyme, Inc. in 2020, submitted and withdrew applications for new technology add-on payments for DuraGraft® for FY 2018 and FY 2019. The applicant also submitted an application for new technology add-on payments for FY 2020 and FY 2024, as summarized in the FY 2020 and FY 2024 IPPS/LTCH PPS proposed rules (84 FR 19305 through 19312, 88 FR 26795 through 26803), that it withdrew prior to the issuance of the FY 2020 and FY 2024 IPPS/LTCH PPS final rules (84 FR 42194, 88 FR 58804), respectively. The applicant also submitted an application for new technology add-on payments for FY 2025, but its application was not approved in the FY 2025 IPPS/LTCH PPS final rule because we were unable to determine that DuraGraft® represents a substantial clinical improvement over existing therapies (89 FR 69149).

Please refer to the online application posting for DuraGraft® available at *https://mearis.cms.gov/public/publications/ntap/NTP241007PUDEH*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, DuraGraft® was granted De Novo classification from FDA on October 4, 2023, as a solution indicated for adult patients undergoing CABG and is intended for flushing and storage of the saphenous vein grafts from harvesting through grafting for up to 4 hours. The applicant also stated that it received clearance from FDA for a labeled storage temperature change from refrigerated to controlled room temperature for DuraGraft® through a Special 510(k) in May 2024 so that it

could be stored in the OR. The applicant stated that it chose to launch the DuraGraft® product upon this label change, and that DuraGraft® will become commercially available on March 31, 2025. The applicant stated the refrigerated product was not placed on the US market, nor will it be, as only the controlled room temperature DuraGraft® product will be placed on the market. The applicant further explained that manufacturing with the updated labels could not begin until new labels were allowed by FDA, ordered from suppliers, and accepted into the Contract Manufacturing Organization Quality Management System (CMO QMS), which, per the applicant, is a process that takes 3 to 4 months. We would appreciate additional information regarding the cause for any delay in the technology's commercial availability.

The applicant stated that, effective October 1, 2017, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of DuraGraft®: XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for DuraGraft® under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that DuraGraft® is not substantially similar to other currently available technologies because DuraGraft® is a first-in-class product for use in adult patients undergoing CABG surgery and received FDA marketing authorization via a De Novo pathway. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for DuraGraft® for the applicant's complete statements in support of its assertion that DuraGraft® is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	DuraGraft® is a first-in-class product and there is no product that is similar with similar mechanism of action. Also, the response to FY2025 NTAP application concurred that DuraGraft met the Newness Criterion and since then there are still no other technologies or products that have been introduced into the market that are similar or with similar mechanism of action.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	MS–DRGs used during CABG surgery are aligned to the same MS–DRGs for which DuraGraft® is indicated.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	DuraGraft® is used in the CABG patient population; however, there are no existing products with the same indication as DuraGraft® nor are there existing products similar to DuraGraft® used during CABG surgery.

We note that in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69142 through 69143), we agreed that DuraGraft® has a unique mechanism of action compared to other vein graft storage solutions because it creates a reducing environment for vascular grafts to prevent oxidative damage which occurs during ischemic storage of grafts.

We are inviting public comments on whether DuraGraft® is substantially similar to existing technologies and whether DuraGraft® meets the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that DuraGraft® meets the cost criterion. The analysis followed the order of operations summarized in the following table.

DURAGRAFT® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for DuraGraft®.
Claims identified	32,602 claims mapping to 65 MS–DRGs, with none exceeding more than 22.69% of the total identified cases.
Charges removed for prior technology.	The applicant removed 100% of blood charges and 25% of the charges associated with medical/surgical supplies for each case. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of DuraGraft® by the national average cost-to-charge ratio of 0.297 for Supplies & Equipment from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $245,963. Final inflated average case-weighted standardized charge per case: $312,912.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that DuraGraft® meets the cost criterion.

We are inviting public comments on whether DuraGraft® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that DuraGraft® represents a substantial clinical improvement over existing technologies because DuraGraft® significantly improves clinical outcomes including reducing long-term adverse events and mortality, improving myocardial protection and event-free survival, and reducing vein graft wall thickness compared to other intraoperative vein-graft preservation solutions. The applicant provided six documents to support these claims, including five studies and a pre-publication version of one of the studies, as well as a supplemental attachment providing responses to CMS's concerns and decision regarding the applicant's FY 2025 application for new technology add-on payments for DuraGraft®, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69147 through 69149). The applicant also provided 44 background articles.[51] Please see the online posting for DuraGraft® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Reduced Long-term Repeat Revascularization.	Haime, M, McLean RR, and Kurgansky KE, et al (2018). Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting, *Expert Review of Cardiovascular Therapy,* 16:12, 963–970. DOI: 10.1080/14779072.2018.1532289. Lopez-Menendez J, Castro-Pinto M, Fajardo E, Miguelena J, Martin M, Munoz R, Rodriguez-Roda J. Vein graft preservation with anendothelial damage inhibitor in isolated coronary artery bypass surgery: an observational propensity score-matched analysis. *J Thorac Dis* 2023;15(10):5549–5558. Marizyme, Inc. Substantial Clinical Improvement Discussion. The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
Reduced 12 mo. Overall Mean Wall Thickness (Whole Graft Analysis).	Perrault, LP, Carrier, M, and Voisine, P, et al (2021). Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting. *Journal of Thoracis and Cardiovascular Surgery.* Jan. 2021, Vol. 161, Number 1, 96–106. *https://doi.org/10.1016/j.jtcvs.2019.10.115*.
Improved Myocardial Protection	Szalkiewicz, P, Emmert, MY, and Heinisch, PP, et al (2022). Graft Preservation confers myocardial protection during coronary artery bypass grafting. *Frontiers in Cardiovascular Medicine,* July 2022, pp 1–10. DOI 10.3389/fcvm.2022.922357.
Reduction of long-term major adverse cardiovascular events (MACE).	Haime, 2018, *op. cit.* Lopez-Menendez, 2023, *op. cit.*
Reduced Mortality for at Least 3 Years post-CABG.	Caliskan E, Misfeld M, Sandner, S, et al. Transatlantic analysis of patient profiles and mid-term survival after isolated coronary artery bypass grafting: a head-to-head comparison between the European DuraGraft Registry and the US STS Registry. *Frontiers in Cardiovascular Medicine,* Sept 2024, DOI 10.3389\fcmv.2024.1366460. Marizyme (2023) Internal Study Report Safety of DuraGraft: A Comparison to Standard of Care Graft Storage Solutions in Isolated CABG Patients in the Largest Worldwide CABG Registry 3-Year Follow-up Post-Market DuraGraft Registry vs. Standard of Care CABG in the STS Database. Unpublished.
Significantly Better Event-free Survival in Diabetic Patients and Those with Two or More SVGs.	Lopez-Menendez, 2023, *op. cit.*
Decreased Rate of Change from 1–12 months for Maximum Graft Narrowing (Focal Stenosis).	Perrault, 2021, *op. cit.*
Reduced Long-term Non-fatal myocardial infarction (MI).	Haime, 2018, *op. cit.*

We received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for DuraGraft®, which we summarize in this section.

Comment: The applicant submitted a public comment to address questions raised at the Town Hall meeting. In response to questions asking about why DuraGraft® has an impact at 36-months and about results observed within 15 minutes post flushing and storage, the applicant referred to a peer-reviewed journal article by Pachuk et al. (2019) study, which compared the viability of human saphenous vein (HSV) segments flushed and submerged in either (a) DuraGraft® for one hour or heparinized saline (b) one hour, (c) 15 minutes or (d) 30 minutes and then stained for viability.[52] The applicant submitted this article as background information as part of its FYs 2024, 2025, and 2026 new technology add-on payment applications. Per the applicant, the data showed that storage in saline resulted in loss of cell viability within 15 minutes and almost complete loss of viability following 30 minutes exposure to saline. The applicant noted that in contrast, viability of HSV segments is maintained following one hour storage/flushing with DuraGraft® (and even after several hours), which means that the vein segments must also have been viable earlier at 15 and 30 minutes; a time at which vein segments were dying or dead in saline. Per the applicant, it is therefore concluded that DuraGraft® provides a benefit even at 15–30 minutes of storage and flushing. The applicant also clarified how a single intraoperative exposure to DuraGraft®

[51] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[52] Pachuk, CJ, Rushton-Smith SK, & Emmert MY (2019). Intraoperative storage of saphenous vein grafts in coronary artery bypass grafting. *Expert review of medical devices, 16*(11), 989–997. *https://doi.org/10.1080/17434440.2019.1682996.*

can affect clinical outcomes years later. The applicant explained that DuraGraft® mitigates oxidative damage during bypass surgery, thereby reducing ischemia reperfusion injury (IRI) and its long-term effects.[53] [54] The applicant noted that IRI, characterized by oxidative stress and inflammation, leads to vein graft disease (VGD), which progresses through stages of intimal hyperplasia, stenosis, and occlusion.[55] [56] The applicant stated that clinical studies, which were included in its application and discussed in further detail later in this section, such as the Perrault et al. (2019) study, demonstrated that DuraGraft®-treated veins showed reduced wall thickening and lumen narrowing at 12 months. Additionally, the applicant stated that the Haime et al. (2018) study and the Caliskan et al. (2024) study [57] indicated improved clinical outcomes and lower mortality rates in DuraGraft® patients.

In response to our request for additional details on the study highlighting the impact of storage solutions on vein graft failure rates, based on a sub-analysis of the data from PREVENT IV trial (*ClinicalTrials.gov: NCT00042081*),[58] the applicant explained that the PREVENT IV study was a large-scale prospective trial aimed at assessing the safety and efficacy of edifoligide in preventing vein graft failure (VGF) after CABG by inhibiting neointimal hyperplasia (Alexander et al., 2005). The applicant noted that the sub-analyses of the study data revealed that the intraoperative graft storage solution had the most significant correlation with VGF, with buffered saline solutions like Plasmalyte, Normasol, or Lactated Ringer reducing failure rates by 28 percent compared to blood and saline.[59] [60] [61] The applicant stated that, despite this improvement, these solutions do not prevent ischemic or oxidative damage, as they merely maintain pH balance.[62] The applicant asserted that, in contrast, DuraGraft® offers a unique mechanism by creating a reducing environment to prevent oxidative damage during ischemic storage, using L-glutathione and L-Ascorbic acid, which has been associated with reduced graft wall thickening and a significant three-year mortality benefit, and therefore, in no way should these liquids be compared to or considered similar to DuraGraft®.

Response: We thank the applicant for its comment. After review of the information provided by the applicant and the public comment received in response to the new technology add-on payment town hall meeting, we continue to have concerns regarding whether DuraGraft® meets the substantial clinical improvement criterion, as described in the FY 2025 IPPS/LTCH final rule (89 FR 69144 through 69149). First, with regard to comparison with currently available treatments, as previously stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69148), we are unclear how improvements demonstrated by use of DuraGraft® as compared to saline controls demonstrate substantial clinical improvement over other existing technologies without an assessment of comparative outcomes to the other vein graft preservation solutions. We note that all of the studies provided compared DuraGraft® to saline controls and not to other intraoperative buffered vein graft solutions such as PlasmaLyte, Normoscol, and Ringer's solution with respect to vein graft patency or clinical outcomes.[63] We note that in its response to this concern from the FY 2025 IPPS/LTCH PPS final rule, the applicant stated that it tested against saline as it is still the most preferred wetting solution amidst dozens used as wetting solutions by surgeons in the United States according to the result of a survey published in *JAMA*.[64] The applicant also stated that DuraGraft® was tested against other wetting solutions in preclinical and non-clinical studies with no difference seen in the results of mechanism compared to when saline was used as the control.[65] However, we note that according to the same survey, among the 100 top-performing medical centers that conduct CABG, 40 percent reported using pH-buffered solution (commercially available or homegrown), compared to 28.9 percent reporting the use of saline, and 25.6 percent autologous blood. In addition, we are unclear how the lack of differences in the mechanism in pre-clinical and non-clinical studies relates to a demonstration of substantial clinical improvement over those therapies in Medicare patients undergoing CABG. While the applicant stated in its Town Hall comment that Ringers Lactate, Plasmalyte or Normosol buffered solutions are only used to keep grafts from drying out between harvesting and implantation and should not be compared to or considered similar to DuraGraft®, as we noted in the FY 2025 IPPS/LTCH PPS final rule, studies have shown that vein graft storage solutions have differing effects on graft endothelium. We further note that previous studies have shown that saline alone is acidic and not beneficial for grafts, and that buffered solutions, such as PlasmaLyte, Normoscol, and Ringer's solution, are associated with lower VGF rates as compared to saline.[66] We note that whether or not these other buffered solutions are the same or similar to DuraGraft® does not determine if their use is part of the standard of care for

[53] Shuhaiber, J.H., Evans, A.N., Massad, M.G., & Geha, A.S. (2002). Mechanisms and future directions for prevention of vein graft failure in coronary bypass surgery. *European journal of cardio-thoracic surgery: official journal of the European Association for Cardio-thoracic Surgery, 22*(3), 387–396. *https://doi.org/10.1016/s1010-7940(02)00253-1.*

[54] Osgood, M.J., Hocking, K.M., Voskresensky, I.V., Li, F.D., Komalavilas, P., Cheung-Flynn, J., & Brophy, C.M. (2014). Surgical vein graft preparation promotes cellular dysfunction, oxidative stress, and intimal hyperplasia in human saphenous vein. *Journal of vascular surgery, 60*(1), 202–211. *https://doi.org/10.1016/j.jvs.2013.06.004.*

[55] Murphy, G.J., & Angelini, G.D. (2004). Insights into the pathogenesis of vein graft disease: lessons from intravascular ultrasound. *Cardiovascular ultrasound, 2,* 8. *https://doi.org/10.1186/1476-7120-2-8.*

[56] Schwartz S.M. (1997). Smooth muscle migration in atherosclerosis and restenosis. *The Journal of clinical investigation, 100*(11 Suppl), S87–S89.

[57] The EU DuraGraft Registry is an ongoing European post-market study designed to support an international CABG registry database used to assess patients receiving DuraGraft® during CABG surgery.

[58] Alexander, J.H., Hafley, G., Harrington, R.A., Peterson, E.D., Ferguson, T.B., Lorenz, T.J., Goyal, A., Gibson, M., Mack, M.J., Gennevois, D., Bowman, S.D., & Jennings, L.K. (2005). Prevention of autogenous vein graft failure in coronary artery bypass procedures: Results of a multicenter trial of edifoligide for the prevention of vein graft failure in coronary artery bypass grafting (PREVENT IV). *The Journal of the American Medical Association, 294*(19), 2446–2454. *https://doi.org/10.1001/jama.294.19.2446.*

[59] Harskamp, R.E., Lopes, R.D., Baisden, C.E., de Winter, R.J., & Alexander, J.H. (2013). Saphenous vein graft failure after coronary artery bypass surgery: pathophysiology, management, and future directions. *Annals of surgery, 257*(5), 824–833. *https://doi.org/10.1097/SLA.0b013e318288c38d.*

[60] Murphy, G.J., & Angelini, G.D. (2004). Insights into the pathogenesis of vein graft disease: lessons from intravascular ultrasound. *Cardiovascular ultrasound, 2,* 8. *https://doi.org/10.1186/1476-7120-2-8.*

[61] Hess, C.N., Lopes, R.D., Gibson, C.M., Hager, R., Wojdyla, D.M., Englum, B.R., Mack, M.J., Califf, R.M., Kouchoukos, N.T., Peterson, E.D., & Alexander, J.H. (2014). Saphenous vein graft failure after coronary artery bypass surgery: insights from PREVENT IV. *Circulation, 130*(17), 1445–1451. *https://doi.org/10.1161/CIRCULATIONAHA.113.008193.*

[62] Hess, 2014, *op. cit.*

[63] Marizyme (2023) *op. cit.*

[64] William SE, Harskamp RE, and Bose S (2015). The Preservation and Handling of Vein Grafts in Current Surgical Practice: Findings of a Survey Among Cardiovascular Surgeons of Top-Ranked US Hospitals | Surgery | JAMA Surgery | JAMA Network.

[65] Marizyme (2023), *op. cit.*

[66] Harskamp RE, Alexander JH, Schulte PJ, Brophy CM, Mack MJ, Peterson ED, Williams JB, Gibson CM, Califf RM, Kouchoukos NT, Harrington RA, Ferguson TB Jr, Lopes RD. Vein Graft Preservation Solutions, Patency, and Outcomes After Coronary Artery Bypass Graft Surgery Follow-up From PREVENT IV Randomized Clinical Trial. *JAMA Surg.,* 2014;149(8):798–805.

purposes of assessing whether DuraGraft® represents a substantial clinical improvement as compared to existing technologies. We welcome comments on the comparison of DuraGraft® to saline alone versus other storage solutions used in contemporary CABG standards of care in the U.S. As these other solutions are also existing vein graft storage options, we would appreciate evidence comparing DuraGraft® to these currently available standard of care options to demonstrate post-CABG clinical improvement.

Second, regarding interim or surrogate endpoints, as in previous years, the applicant stated that the use of DuraGraft® leads to reduced 12 month overall mean wall thickness and a decreased rate of change from 1 to 12 months (focal stenosis) for maximum graft narrowing (Perrault et al., 2021), and improved myocardial protection with lower troponin (hs-Tnl) values from 3 to 6 hours and up to 4 days (Szalkiewicz et al., 2022). However, as discussed previously in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69148), early anatomical changes associated with the development of VGD (such as changes in wall thickness and graft narrowing) are surrogate endpoints, and we similarly note that that hs-Tnl levels are also surrogate measure for peri-operative MI, and, therefore, they do not demonstrate a clinical outcome as described under the regulations at § 412.87(b)(1)(ii)(C).

We also remain concerned about the effects on the evidence provided of potential confounders that have not been taken into account in the study designs. We note that SVG failure is the result of a complex process involving multiple risk factors. Surgical risk factors other than the use of DuraGraft® may also contribute to post-CABG clinical outcomes. Thus, evidence about the effects of DuraGraft® on VGF may be confounded by factors related to pre-operative care (such as aspirin), intra-operative procedures and techniques (such as no touch harvesting, appropriate length of vein, vein graft storage, or transit time flow measurement, and post-CABG care management (such as lipid-lowering therapies and $P2Y_{12}$ inhibitors). For example, we are concerned about whether the Haime study (2018) accounted for potential confounding effects of risk factors such as whether patients received beta-blockers before surgery, were on ventilation support for more than 12 hours, developed pneumonia or post-operative atrial fibrillation,[67] were in pre-operative renal failure on dialysis or had a lower estimated glomerular filtration rate,[68] or the type of post-acute care facility that patients were referred to,[69] which may impact post-CABG outcomes. Similarly, we question whether the results of the Szalkiewicz (2022) study, based on a single-center study conducted in Austria, and the Lopez-Mendez (2023) study, based on a single-center study in Spain, could have been confounded by site-specific factors or by standard of CABG care specific to those two countries.

We also note that the only new study provided by the applicant in its application for FY 2026 was the Caliskan et al. (2024) study,[70] which is the published version of the Marizyme Internal Study Report (2023) that was also provided in its FY 2025 application. The applicant stated that this study demonstrates a three-year mortality benefit associated with the use of DuraGraft®. Per the applicant, the Caliskan et al. (2024) study compares patients in the European DuraGraft Registry (DuraGraft® cohort) who underwent isolated CABGs and were exposed to DuraGraft® between 2016 and 2019 to randomly selected patients in the U.S. Society of Thoracic Surgeons (STS) National Database™ (US Cohort) for the same period. Using a propensity score model (PSM), the authors examined the mortality rate of 2,400 patients matched from each registry at 30-day,
12-, 24-, and 36-month post CABG. However, we question whether any results seen may have been affected by potential confounders. According to Caliskan et al. (2024), more than 95 percent of the U.S. hospitals performing CABG surgery report data to the STS, which captured almost all (98 percent) of the CABG surgeries in the U.S. We are interested in similar information about the European DuraGraft Registry, including its clinical site-selection standards and patient inclusion and exclusion criteria. We question whether these factors may have confounded the relationship between DuraGraft® and post-CABG mortality. In addition, we note that due to data availability, intra-operative risk factors, like the use of Transit Time-Flow Measurement,[71] on-pump status, endoscopic harvest, and post-operative therapies known to minimize SVG failure, were not accounted for in the Caliskan (2024) study. The use of post-procedural therapies may also confound the effects of DuraGraft® on post-CABG outcomes. For example, SVG failure is up to five times more frequent in patients who are not treated with aspirin postoperatively, and lipid-lowering therapies, such as statin therapies, reduce SVG occlusion rates as well as adverse events after CABG.[72] Additionally, we note that according to Lopez-Menendez et al. (2023), every CABG patient in its institution is discharged home with dual antiplatelet therapy for a duration of three months, along with high-dose statins and that the study groups adhered to this institutional protocol, with a 100 percent completion rate. We question whether post-surgical protocols like this might have confounded the treatment effects of DuraGraft® on mortality rates, especially those after 30-day post CABG. We also question the Caliskan team's finding (2024) that DuraGraft® had significant effects on all-cause mortality rates at 36-month post-CABG but not at 30-day, 12-, or 24-months. Per the applicant, the 36-month all-cause mortality estimate for the DuraGraft® cohort was 7.37 percent [95 percent, CI 6.36 to 8.53], compared to 9.65 percent [95 percent, CI 8.37 to 11.10] for the US cohort (log-rank p-value = 0.016). However, there was no significant difference in survival between the DuraGraft® and U.S. cohorts throughout 2 years post-CABG. We therefore question whether mortality at 36 months post-CABG may be associated with risk factors that emerged long after the CABG surgery. Moreover, we note that in Lopez-Menendez et al. (2023), in which 90 CABG patients whose veins were treated with DuraGraft® were matched with another 90 whose veins were treated with saline solution, the three-year mortality rate of the DuraGraft® group was not significantly different from that of the saline group. We welcome information about the mixed evidence from the Caliskan et al. (2024) and Lopez-Menendez et al. (2023) studies.

[67] Ibrahim KS, Kheirallah KA, Rahman A, et al. Factors affecting duration of stay in the intensive care unit after coronary artery bypass surgery and its impact on in-hospital mortality: a retrospective study. *Journal of Cardiothoracic Surgery* February 2024. 19(45).

[68] Chua TK, GAO F, Chia SY, et al. Long-term mortality after isolated coronary artery bypass grafting and risk factors for mortality. *Journal of Cardiothoracic Surgery* July 2024. 19(429).

[69] Sultana I, Errguntla M, Kum HC, et al. The interrelationships between the length of stay, readmission, and post-acute care referral in cardiac surgery patients. *Health Analytics* November 2022. Volume 2.

[70] Per the applicant, Caliskan et al. (2024) is based on the Marizyme internal study report.

[71] Lopez-Menendez (2023), *op. cit.*

[72] Willemsen, L, Janssen, P, Klein, P, Berg, JM, Therapies to improve vein graft patency after CABG, American College of Cardiology, February 8, 2021: Therapies to Improve Vein Graft Patency After CABG—American College of Cardiology.

Furthermore, the Caliskan study used all-cause mortality, rather than cardiac-related mortality, to represent clinical outcomes resulting from the use of DuraGraft®, which may include deaths by other acute or chronic conditions and cannot be attributed to the quality of CABG-related care, including the use of DuraGraft®. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69149), we expressed concern that the Marizyme Internal Study (2023), which has the same content as Caliskan et al. (2024), only reported all-cause mortality and does not specify how many patients had mortality due to other causes that could not be attributed to use of a vein preservation solution other than DuraGraft®. We continue to have the concern that all-cause mortality may include deaths resulting from other conditions rather than heart diseases. We remain unclear whether DuraGraft® was the only factor that contributed to the differences in all-cause mortality rates between the treatment (DuraGraft®) and control groups. We also remain unclear in what ways the results demonstrated how DuraGraft® brought about the reduction in all-cause mortality. While we acknowledge that the use of all-cause mortality as a clinical outcome may be the result of data availability, it is unclear that DuraGraft® was the only differing factor between the arms, and how this demonstrates that it was DuraGraft® that effected this difference in mortality, rather than some other factor. We welcome information about the choice of this outcome as an indicator of the effects of DuraGraft® on clinical outcome improvement.

We also note regarding the attrition rate for the DuraGraft® registry that, according to Caliskan et al. (2019),[73] patients were contacted via mail, email, or telephone at one month, one year, and annually thereafter up to five years post CABG to determine whether cardiac-related adverse events and/or hospitalizations have occurred. We are unclear about the number of patients who were lost to follow up, the reasons for dropping out, and how these reasons were mapped to the definition of clinical outcomes. We also welcome information about how attrition impacted the number of patients in the treatment (DuraGraft®) and control groups at prespecified points of the follow-up period.

We are inviting public comments on whether DuraGraft® meets the substantial clinical improvement criterion.

f. FIBRYGA® (Fibrinogen (Human))

Octapharma USA, Inc. submitted an application for new technology add-on payments for FIBRYGA® for FY 2026. According to the applicant, FIBRYGA® is a concentrated form of human fibrinogen, indicated for fibrinogen supplementation in bleeding patients with acquired fibrinogen deficiency and the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. We note that the applicant is seeking new technology add-on payments for FIBRYGA® for FY 2026 specific to the 2024 supplemental Biologics License Application (sBLA) indicated for the fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency.

Please refer to the online application posting for FIBRYGA®, available at *https://mearis.cms.gov/public/publications/ntap/NTP241007YU8UR*, for additional detail describing the technology and acquired fibrinogen deficiency.

With respect to the newness criterion, according to the applicant, FIBRYGA® was granted supplemental BLA approval from FDA on July 31, 2024, expanding its previous BLA indication to include the fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency indication and to update the U.S. prescribing information to include this indication.[74] According to the applicant, FIBRYGA® became commercially available immediately after FDA approval for this expanded indicated use. The applicant stated that FIBRYGA® is administered intravenously with a recommended dose of 4g for adults per inpatient stay.

According to the applicant, there are currently no ICD–10–PCS procedure codes to identify FIBRYGA®. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for FIBRYGA® beginning in FY 2026. The applicant stated that D68.4 (Acquired coagulation factor deficiency) and O72.3 (Postpartum coagulation defects) may be currently used to identify the indication for FIBRYGA® under the ICD–10–CM coding system. We believe the relevant ICD–10–CM code to identify the indication of fibrinogen supplementation in bleeding adult and pediatric patients with acquired fibrinogen deficiency that is relevant to this new technology add-on payment application would be D68.4 (Acquired coagulation factor deficiency). We are inviting public comments on the use of this ICD–10–CM diagnosis code to identify this indication for purposes of the new technology add-on payment, if approved.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that FIBRYGA® is not substantially similar to other currently available technologies because it is the only FDA-approved therapy available to treat acquired fibrinogen deficiency in bleeding patients. According to the applicant, in patients experiencing a major bleeding event, acquired fibrinogen deficiency often goes untreated because cryoprecipitate cannot be delivered fast enough. The applicant further explained that FIBRYGA®'s storage and preparation characteristics allow it to be readily available, giving patients reliable access to therapy that is potentially lifesaving, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for FIBRYGA® for the applicant's complete statements in support of its assertion that FIBRYGA® is not substantially similar to other currently available technologies.

[73] Caliskan E, Sandner S, and Misfeld M, et al (2019) A novel endothelial damage inhibitor for the treatment of vascular conduits in coronary artery bypass grafting: protocol and rationale for the European, multicentre, prospective, observational DuraGraft registry. *Journal of Cardiothoracic Surgery https://doi.org/10.1186/s13019-019-1010-z.*

[74] Previous FDA approvals for FIBRYGA®: In 2017, FDA granted FIBRYGA® approval under a BLA application for the treatment of acute bleeding episodes in adults and adolescents ≥12 years of age with congenital fibrinogen deficiency, including afibrinogenemia and hypofibrinogenemia. On December 23, 2020, FDA granted FIBRYGA® approval under a sBLA application for on-demand treatment of acute bleeding episodes to pediatric patients <12 years of age with congenital fibrinogen deficiency.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	Yes	FIBRYGA® works by providing a source of fibrinogen the body can use to form blood clots to stop bleeding. This is the same mechanism used by cryoprecipitate; however, FIBRYGA® provides a faster, safer, and more consistent dosage as compared to cryoprecipitate.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	It is not expected that the use of FIBRYGA® will affect the MS–DRG assignment.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	FIBRYGA® is currently the only FDA-approved therapy for treating acquired fibrinogen deficiency as a result of major bleeding. Fibrinogen is a key component in blood clot formation and levels in the body drop fast and early during an emergent major bleeding event. Low levels of fibrinogen can lead to impaired blood clot formation which is life threatening. Cryoprecipitate, the current standard of care, requires long processing times and transport to the point of care. Because of this, patients suffering from acquired fibrinogen deficiency during this early, critical period of a major bleed are often not treated as clinicians do not have a quickly available option to supplement declining fibrinogen levels. This potentially leads to adverse outcomes ranging from longer ICU stays to exsanguination. FIBRYGA® can be stored at room temperature and reconstituted quickly. These two properties allow it to be stored near the point of care and delivered quickly to bleeding patients who might otherwise not have received therapy. For the first time, FIBRYGA® offers an FDA-approved rapid treatment option for acquired hypofibrinogenemia in emergent bleeds.

We note the following concerns with regard to the newness criterion. While the applicant asserted that FIBRYGA® is currently the only FDA-approved therapy for treating acquired fibrinogen deficiency as a result of major bleeding, we note that INTERCEPT® Fibrinogen Complex, which is the pathogen reduced cryoprecipitated fibrinogen complex (PRCFC) produced by the INTERCEPT® Blood System, is FDA-approved for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. The applicant further asserted that FIBRYGA® can be stored at room temperature, allowing it to be delivered quickly to bleeding patients and offering an FDA-approved rapid treatment option for acquired hypofibrinogenemia in emergent bleeds. However, we note that INTERCEPT® Fibrinogen Complex has a 5-day shelf life at room temperature and is immediately available in a ready-to-transfuse form as a fibrinogen source.[75] [76] Therefore, we question whether FIBRYGA® and INTERCEPT® Fibrinogen Complex involve the treatment of the same or similar type of disease and the same or similar patient population. In addition, we note that the applicant asserted that FIBRYGA® has the same mechanism of action used by cryoprecipitate and works by providing a source of fibrinogen the body can use to form blood clots to stop bleeding. We also note that INTERCEPT® Fibrinogen Complex provides a source of fibrinogen, and therefore, we question whether FIBRYGA® and INTERCEPT® Fibrinogen Complex have the same mechanism of action. We also note that the applicant asserted that use of FIBRYGA® is not expected to change the MS–DRG assignment for cases of acquired hypofibrinogenemia, and we therefore believe it would map to the same MS–DRGs as INTERCEPT® Fibrinogen Complex.

Therefore, as it appears that FIBRYGA® and INTERCEPT® Fibrinogen Complex may use the same or similar mechanism of action to achieve a therapeutic outcome, are assigned to the same MS–DRGs, and treat the same or similar patient population and disease, we believe that these technologies may be substantially similar to each other. We note that, per our policy, if these technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Therefore, if FIBRYGA® is substantially similar to INTERCEPT® Fibrinogen Complex, we believe the newness period for this technology would begin on May 5, 2021, the date INTERCEPT® Fibrinogen Complex became commercially available.[77] In addition, because the 3-year anniversary date of the INTERCEPT® Fibrinogen Complex's entry onto the U.S. market (May 5, 2024) occurred in FY 2024, FIBRYGA® would not be considered new and would not be eligible for new technology add-on payments for FY 2026. We are interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.

We are inviting public comment on whether FIBRYGA® meets the newness criterion, including whether FIBRYGA® is substantially similar to INTERCEPT® Fibrinogen Complex for purposes of new technology add-on payments.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that FIBRYGA® meets the cost criterion. The analysis followed the order of operations summarized in the following table.

FIBRYGA® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for FIBRYGA®.

[75] Cerus Corporation. INTERCEPT® Blood System for Cryoprecipitation Package Insert For the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex. (Revised 5/2024). Available at: *www.fda.gov/media/143996/download.*

[76] *https://intercept-usa.com/products/intercept-fibrinogen-complex/#:~:text=INTERCEPT%C2%AE%20Fibrinogen%20Complex%20is,day%20post%2Dthaw%20shelf%20life.*

[77] INTERCEPT® Blood System received FDA approval on November 24, 2020, to produce PRCFC; however, as noted in FY 2022 IPPS/LTCH PPS final rule (86 FR 45149), the manufacturers stated that it was not available for sale until May 5, 2021.

FIBRYGA® COST ANALYSIS—Continued

Claims identified	18,037 claims mapping to 468 MS–DRGs, with none exceeding more than 12.55% of the total identified cases.
Charges removed for prior technology.	The applicant did not remove any direct or indirect charges related to the prior technology. Per the applicant, FIBRYGA® is expected to be additive to current treatments and no charges were removed from the claims used in the analysis.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.246 for Blood and Blood Products from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $105,002. Final inflated average case-weighted standardized charge per case: $188,525.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that FIBRYGA® meets the cost criterion.

We are inviting public comments on whether FIBRYGA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that FIBRYGA® represents a substantial clinical improvement over existing technologies because FIBRYGA® is the only currently available, FDA-approved, pharmaceutical-grade therapy for the treatment of acquired fibrinogen deficiency, and it provides a faster, more precise treatment option for patients with life-threatening bleeding. Additionally, the applicant asserted that patients receiving FIBRYGA® have better clinical outcomes relative to technologies previously available. The applicant provided four documents and the FIBRYGA® package insert to support these claims, as well as 17 background articles about the safety and efficacy of existing treatment options for fibrinogen supplementation. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for FIBRYGA® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
FIBRYGA® is the only FDA approved therapy for the treatment of acquired fibrinogen deficiency.	FIBRYGA® Package Insert: *https://www.fda.gov/media/105864/download#:~:text=FIBRYGA%20is%20a%20human%20fibrinogen%20concentrate.*
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Pathogen inactivation makes FIBRYGA® a potentially safer source for fibrinogen supplementation in the treatment of bleeding.	Callum J, Farkouh ME, Scales DC, Heddle NM, Crowther M, Rao V, Hucke HP, Carroll J, Grewal D, Brar S, Bussières J, Grocott H, Harle C, Pavenski K, Rochon A, Saha T, Shepherd L, Syed S, Tran D, Wong D, Zeller M, Karkouti K; FIBRES Research Group. Effect of Fibrinogen Concentrate vs Cryoprecipitate on Blood Component Transfusion After Cardiac Surgery: The FIBRES Randomized Clinical Trial. JAMA. 2019 Nov 26; 322(20):1966–1976. doi: 10.1001/jama.2019.17312. PMID: 31634905; PMCID: PMC6822637. FIBRYGA® Package Insert. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
As compared to cryoprecipitate, the current standard of care, FIBRYGA® permits rapid correction of low serum fibrinogen levels in bleeding patients.	Roy A, Stanford S, Nunn S, Alves S, Sargant N, Rangarajan S, Smith EA, Bell J, Dayal S, Cecil T, Tzivanakis A, Kruzhkova I, Solomon C, Knaub S, Moran B, Mohamed F. Efficacy of fibrinogen concentrate in major abdominal surgery—A prospective, randomized, controlled study in cytoreductive surgery for pseudomyxoma peritonei. J Thromb Haemost. 2020 Feb;18(2):352–363. doi: 10.1111/jth.14665. Epub 2019 Nov 26. PMID: 31654548; PMCID: PMC7027898. FIBRYGA® Package Insert. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
FIBRYGA® decreases the use of allogeneic blood products which are associated with higher rates of adverse events post-transfusion.	Lunde J, Stensballe J, Wikkelsø A, Johansen M, Afshari A. Fibrinogen concentrate for bleeding—a systematic review. Acta Anaesthesiol Scand. 2014 Oct;58(9):1061–74. doi: 10.1111/aas.12370. Epub 2014 Jul 24. PMID: 25059813. Callum, 2019, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
FIBRYGA® is highly purified and has consistent levels of fibrinogen, permitting precise serum fibrinogen correction without delivering unneeded components associated with adverse reactions.	Schulz PM, Gehringer W, Nöhring S, Müller S, Schmidt T, Kekeiss-Schertler S, Solomon C, Pock K, Römisch J. Biochemical characterization, stability, and pathogen safety of a new fibrinogen concentrate (fibryga®). Biologicals. 2018 Mar;52:72–77. doi: 10.1016/j.biologicals.2017.12.003. Epub 2018 Jan 12. PMID: 29336864. FIBRYGA® Package Insert. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for FIBRYGA®.

After review of the supporting evidence provided by the applicant, we have the following concerns regarding whether FIBRYGA® meets the substantial clinical improvement criterion. While the applicant asserted that FIBRYGA® is the only FDA-approved technology for the treatment of acquired fibrinogen deficiency, we note that there are other available treatments, including cryoprecipitate and INTERCEPT® Fibrinogen Complex, which is FDA-approved for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency, including those with acquired fibrinogen deficiency.[78] We therefore question the assertion that FIBRYGA® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.

With respect to the assertion that FIBRYGA® significantly improves clinical outcomes relative to services or technologies previously available, we note that the applicant claimed that pathogen inactivation makes FIBRYGA® a potentially safer source for fibrinogen supplementation, FIBRYGA® permits rapid correction of fibrinogen levels, and FIBRYGA® has consistent levels of fibrinogen which allow for precise serum fibrinogen correction without delivering unneeded components associated with adverse reactions, and that these claims demonstrate that FIBRYGA® improves outcomes. However, while for each of these three claims the applicant inferred that they potentially improve safety or outcomes, it did not provide data that tested or demonstrated improvements. Therefore, we are unclear how these claims relate to a demonstration of substantial clinical improvement over existing technologies because they do not pertain to clinical outcomes described at § 412.87(b)(1)(ii)(C), such as a reduction in mortality or a decreased rate of at least one subsequent diagnostic or therapeutic intervention. For example, with regard to pathogen inactivation, while the applicant stated that the overall reduction in viral titers achieved with INTERCEPT® Fibrinogen Complex is lower than those achieved with FIBRYGA®'s manufacturing process, we note that the background studies that were provided discussed why pathogen activation is important but did not demonstrate reduced pathogen transmission as compared to existing options such as INTERCEPT® Fibrinogen Complex or cryoprecipitate in order to demonstrate improved outcomes. We further note that the FIBRES study, a randomized controlled trial of 827 patients requiring blood component transfusion after cardiac surgery at 11 Canadian hospitals, did not report differences between the FIBRYGA® and cryoprecipitate groups' adverse events associated with bloodborne pathogens, which may include fever, chills, nausea, vomiting, hypotension, tachycardia, abdominal pain, back pain, or disseminated intravascular coagulation, and we question if the length of patient follow-up (28 days) is sufficient to assess for bloodborne infection transmission.[79] [80] With regards to the claim that FIBRYGA® allows for precise serum fibrinogen correction without delivering unneeded components associated with adverse reactions, while the applicant provided a biochemical analysis of FIBRYGA® by Schulz et al. to demonstrate that FIBRYGA®'s manufacturing process leads to consistent levels of fibrinogen and low levels of von Willebrand factor, as well as background documents discussing levels of fibrinogen and other factors for cryoprecipitate and INTERCEPT® Fibrinogen Complex, these documents did not demonstrate precise fibrinogen correction using FIBRYGA® compared to other available treatment options. Also, while the applicant further stated that FIBRYGA®'s manufacturing process removes agents responsible for allergic transfusion reactions and transfusion related lung injury, the evidence provided did not assess these outcomes or otherwise demonstrate reduced incidence of these outcomes as compared to available standard of care treatments for the patient population.

In addition, we note that none of the studies submitted demonstrated improvements in clinical outcomes, such as treatment emergent adverse events (TEAEs), length of ICU stay, and duration of hospitalization between FIBRYGA® and cryoprecipitate study treatment groups. We note the FIBRES study found that TEAEs (acute kidney injury, hepatobiliary disorders, and thromboembolic adverse events) were similar between both groups and found no differences in clinical outcomes between the groups (duration of mechanical ventilation, duration of ICU stay, and duration of hospitalization). We further note that the study authors disclosed several limitations of the FIBRES study, including the lack of standardized transfusion protocols, lack of strict timing of laboratory assessments, and the variability in the amount of fibrinogen in cryoprecipitate that make it difficult to interpret true differences in clinical outcomes between the two groups. Regarding the FORMA–05 study, a single-center, prospective, randomized control phase 2 study of 45 patients undergoing cytoreductive surgery for peritoneal malignancy, we note that this study did not demonstrate any differences in clinical outcomes for the FIBRYGA® arm over the cryoprecipitate arm. Rather, per the study, the median durations of surgery, artificial ventilation in the ICU, ICU stay, hospitalization, and intraoperative blood loss were comparable between groups, and there was no bleeding in

[78] Cerus Corporation. INTERCEPT® Blood System for Cryoprecipitation Package Insert For the manufacturing of Pathogen Reduced Cryoprecipitated Fibrinogen Complex. (Revised 5/2024). Available at: *https://www.fda.gov/media/143996/download.*

[79] Association for the Advancement of Blood & Biotherapies. (2024). *Circular of information for the use of human blood and blood components.* American Red Cross, America's Blood Centers, Armed Services Blood Program. Retrieved on November 14, 2024, from *https://www.aabb.org/docs/default-source/default-document-library/resources/circular-of-information-watermark.pdf.*

[80] Bloch, E.M. (2024). Transfusion-transmitted bacterial infection. *UpToDate.* Retrieved December 16, 2024, from *https://www.uptodate.com/contents/transfusion-transmitted-bacterial-infection.*

patients in either treatment group post-operatively through the assessments at 24 and 48 hours. We also note that both studies were conducted outside of the U.S., and the study populations were specific groups of surgical patients, which may impact the generalizability of these results to broader, more diverse clinical use cases for FIBRYGA® in the U.S. Medicare patient population. In addition, both studies compared FIBRYGA® with cryoprecipitate, and no studies comparing to the currently available INTERCEPT® Fibrinogen Complex were provided. While the applicant included the INTERCEPT® package insert, it contains only in vitro data and does not offer clinical comparisons. We are interested in information on clinical outcomes of FIBRYGA® in comparison to INTERCEPT® Fibrinogen Complex in order to evaluate whether the use of FIBRYGA® significantly improves clinical outcomes compared to available treatments.

We also note regarding the applicant's claim that FIBRYGA® permits rapid correction of low serum fibrinogen levels in bleeding patients compared to cryoprecipitate, while the applicant stated that the FORMA–05 study demonstrated that FIBRYGA® was delivered to the patient 46 minutes faster than cryoprecipitate (0.90 hours (±0.23) versus 1.30 hours (±0.33), $p<0.0001$), this value does not measure the time to correction of fibrinogen levels. We further note that, in the study, the difference between arms decreased from 46 minutes to 24 minutes with regard to time to when the intervention was administered (2.02 hours ± 0.22 for FIBRYGA® and 2.42 hours ± 0.33 for cryoprecipitate), and the study did not measure time to correction of fibrinogen levels, though as noted, this is a surrogate measure and not a clinical outcome as described under the regulations at § 412.87(b)(1)(ii)(C). Further, while the applicant also provided background studies to demonstrate the correlation between low serum fibrinogen and poor patient outcomes, and that faster replenishment is important, as noted, the FORMA–05 study did not demonstrate any differences in clinical outcomes between arms. We also note that the applicant stated that FIBRYGA® allows for more rapid availability due to its powder form which allows long-term storage at room temperature in proximity to patients, while INTERCEPT® Fibrinogen Complex, which can be also stored at room temperature for up to 5 days, must be kept in regulated blood bank storage distant from the patient even when thawed. However, no data was provided to demonstrate that time to administration of FIBRYGA®, or time to serum fibrinogen correction with FIBRYGA®, is faster than that of INTERCEPT® Fibrinogen Complex.

In regard to the applicant's fourth claim that FIBRYGA® decreases the use of allogeneic blood products, which the applicant asserted are associated with higher rates of adverse events post-transfusion, we question whether the Lunde et al. (2014) and FIBRES studies provided in support of this claim showed that FIBRYGA® resulted in lower rates of post-transfusion adverse events. We note that Lunde et al. (2014) study was a systematic review of six RCTs that evaluated fibrinogen concentrate broadly to determine the evidence for its use and efficacy, but the studies included were varied in choice of comparator, including fresh frozen plasma (FFP), cryoprecipitate, or no comparator. We are also unclear whether the fibrinogen concentrate included in the study refers specifically to FIBRYGA®, and therefore question whether the study provides evidence that FIBRYGA® demonstrates improved outcomes compared to cryoprecipitate. We further note that the study authors determined that data on continuous outcomes such as quantity of FFP, RBC or platelet transfused were statistically skewed, often with the median equaling zero, and that the comparison of fibrinogen concentrate to any comparator with respect to adverse events was not statistically significant. We also note that the six RCTs that the study is based on are more than 10 years old, and thus, we question whether the findings adequately represent the current standard of care for this patient population that may have evolved over the last decade. We further note that, although the FIBRES study was provided to demonstrate that FIBRYGA® decreases the use of allogeneic blood products, the study did not specifically report transfusion-related adverse events. We would be interested in additional data regarding transfusion-related adverse events, such as urticaria, wheezing, hypotension, tachycardia, nausea, vomiting and/or diarrhea, abdominal pain, severe dyspnea, pulmonary and/or laryngeal edema, and bronchospasm and/or laryngospasm.[81]

We are inviting public comments on whether FIBRYGA® meets the substantial clinical improvement criterion.

[81] Association for the Advancement of Blood & Biotherapies, 2024, *op. cit.*

g. GRAFAPEX™ (Treosulfan)

Medexus Pharma, Inc. submitted an application for new technology add-on payments for GRAFAPEX™ for FY 2026. According to the applicant, GRAFAPEX™ is a novel conditioning agent for use in combination with fludarabine as a preparative regimen for allogeneic hematopoietic stem cell transplantation (allo-HSCT) in adult and pediatric patients one year of age and older with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). We note that Medexus Pharma, Inc. submitted an application for new technology add-on payments for GRAFAPEX™ for FY 2023 under the name treosulfan, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28296 through 28302), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

Please refer to the online application posting for GRAFAPEX™, available at *https://mearis.cms.gov/public/publications/ntap/NTP241007WE8D6*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, GRAFAPEX™ was granted NDA approval from FDA on January 21, 2025, for use in combination with fludarabine as a preparative regimen for allo-HSCT in adult and pediatric patients one year of age and older with either AML or MDS. The applicant stated that GRAFAPEX™ became commercially available on February 20, 2025, because the applicant required time after FDA marketing authorization to build inventory and stock the third-party logistic wholesalers prior to commercial launch. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, such as additional information about building inventory and stocking logistic wholesalers.

According to the applicant, GRAFAPEX™ is administered via intravenous infusion in conjunction with fludarabine from either a 1g or 5g vial after reconstitution with a 20mL or 100mL solution. Per the package insert,[82] the recommended dosage of GRAFAPEX™ is 10g/m^2 body surface area per day, given as a 2-hour intravenous infusion on 3 consecutive days (day -4, -3, -2) in conjunction with fludarabine before hematopoietic stem cell infusion on day 0. Per the

[82] Oncotec Pharma Produktion GmbH. GRAFAPEX™ [package insert]. (Revised 2/2025). Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/214759s001lbl.pdf.*

applicant, based on the estimated average body size for Medicare patients being treated with GRAFAPEX™ and the labeling for a 3-day treatment, the estimated average dose per inpatient stay is 54g.

According to the applicant, effective October 1, 2022, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of GRAFAPEX™: XW04388 (Introduction of treosulfan into central vein, percutaneous approach, new technology group 8) or XW03388 (Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for GRAFAPEX™ under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that GRAFAPEX™ is not substantially similar to other currently available technologies because GRAFAPEX™ is a new chemical entity with a unique structure and unique mechanism of action that permits it to be metabolized without the liver, resulting in reduced toxicity while still delivering effective treatment, including for older and/or more comorbid patients who are ineligible for myeloablative conditioning (MAC) and face higher relapse risk if reduced intensity conditioning (RIC) is used. The applicant stated that GRAFAPEX™ addresses the unmet need in this patient population and is the only FDA-approved allo-HSCT conditioning agent for AML and MDS, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for GRAFAPEX™ for the applicant's complete statements in support of its assertion that GRAFAPEX™ is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	As a prodrug, GRAFAPEX™ is activated under normal physiological conditions with its own distinct cytotoxic activity toward hematopoietic precursor cells. GRAFAPEX™ has a unique mechanism of action that permits it to bypass the liver when it metabolizes, resulting in reduced toxicity while still delivering effective treatment, including for older patients and/or patients with significant comorbidities who are ineligible for MAC. Other alkylating agents used to date in allo-HSCT conditioning—for example, busulfan, melphalan, cyclophosphamide—are all metabolized by the liver, which results in higher toxicity and leads to excess regimen-related morbidity and mortality observed in older and comorbid patients. GRAFAPEX™'s mechanism of action differs from other agents in this class because no other alkylating agent has a mechanism of action that bypasses treated patients' liver. GRAFAPEX™ also has a unique chemical structure resulting from two hydroxide (OH) bonds not present in other alkylating agents. Due to these OH bonds, GRAFAPEX™'s mechanism of alkylation is entirely different compared to busulfan and other alkylating agents. Its distinct structure and unique mechanism of alkylation further distinguish GRAFAPEX™'s mechanism of action. GRAFAPEX™'s activity is due to the spontaneous, pH-dependent conversion into a monoepoxide intermediate and diepoxybutan that bypasses liver metabolism. These epoxides alkylate and crosslink nucleophilic centers of DNA and other biological molecules involved in various physiological functions and are responsible for its stem cell depleting, immunosuppressive, and antineoplastic effects. Because GRAFAPEX™ uniquely bypasses liver metabolism, it reduces treatment-related toxicity compared to other alkylating agents used to date for allo-HSCT conditioning.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	Medexus anticipates that inpatient cases involving administration of GRAFAPEX™ typically will be assigned to MS–DRG 014—Allogeneic Bone Marrow Transplant—because, in a majority of cases, it is anticipated that a patient would undergo GRAFAPEX™-based conditioning during the same inpatient admission as allo-HSCT itself. It is Medexus's understanding that other conditioning treatments prior to allo-HSCT also would typically be assigned to MS–DRG 014. Some cases also may be assigned to MS–DRG 004.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	GRAFAPEX™ offers a critical new treatment option for allo-HSCT conditioning for a different patient population compared to existing technologies. Many patients—especially older patients and/or patients with significant comorbidities who have AML or MDS—are ineligible for MAC and face higher relapse risk with RIC. Multiple studies discuss the unmet need for this patient population based on previously available regimens and show that GRAFAPEX™-based regimens are particularly well-suited and provide significant clinical benefits for this patient population. If approved, GRAFAPEX™ will be the only FDA-approved allo-HSCT conditioning agent for AML and MDS. A landmark multicenter RCT discusses how allo-HSCT conditioning regimens available to date are not suitable for all patients, especially older and/or more comorbid patients—an important population for Medicare. The limits of MAC and RIC create an unmet medical need particularly for the growing number of older or comorbid AML and MDS transplantation candidates. Peer-reviewed studies confirm GRAFAPEX™ addresses the unmet need for this patient population, including studies comparing GRAFAPEX™-based regimens to busulfan-, melphalan-, cyclophosphamide-, and TBI-based regimens. GRAFAPEX™-based conditioning thus involves treatment of a different patient population compared to previously existing conditioning regimens.

With respect to the substantial similarity criteria, we note that GRAFAPEX™ is an alkylating agent like other drugs used in conditioning, such as busulfan and melphalan. While the applicant stated that GRAFAPEX™ has a unique mechanism of action and unique structure that allows it to bypass liver metabolism, reducing toxicity, we question whether bypassing liver metabolism is the mechanism of action of a conditioning agent, or if it instead relates to clinical outcomes, such as the side effect profile of GRAFAPEX™. In regard to whether GRAFAPEX™ treats the same or similar type of disease and the same or similar patient population compared to existing technologies, we question whether GRAFAPEX™ treats a new patient population since MAC, nonmyeloablative conditioning (NMA), and RIC are all options for patients. Additionally, while MAC may not be preferred for older or comorbid patients, RIC and NMA may still be options for these patients.

We are inviting public comments on whether GRAFAPEX™ is substantially similar to existing technologies and whether GRAFAPEX™ meets the newness criterion.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that GRAFAPEX™ meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

GRAFAPEX™ COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for GRAFAPEX™.
Claims identified	Scenario 1: 713 claims mapping to 2 MS–DRGs, with 98.46% of claims mapping to MS–DRG 014 (Allogeneic Bone Marrow Transplant) and 1.54% of claims mapping to MS–DRG 004 (Tracheostomy With MV >96 Hours Or Principal Diagnosis Except Face, Mouth And Neck Without Major O.R. Procedures). Scenario 2: 466 claims mapping to two MS–DRGs, with 97.64% of claims mapping to MS–DRG 014 (Allogeneic Bone Marrow Transplant) and 2.36% of claims mapping to MS–DRG 004 (Tracheostomy With MV >96 Hours Or Principal Diagnosis Except Face, Mouth And Neck Without Major O.R. Procedures).
Charges removed for prior technology.	The applicant removed 100% of charges associated with drugs and cellular therapies (revenue centers 025x, 026x, and 063x), as an estimate of the percentage of total charges that the technology would replace could not be determined. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Scenario 1: —Average case-weighted threshold amount: $368,736. —Final inflated average case-weighted standardized charge per case: $559,537. Scenario 2: —Average case-weighted threshold amount: $368,795. —Final inflated average case-weighted standardized charge per case: $559,369.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that GRAFAPEX™ meets the cost criterion.

We are inviting public comments on whether GRAFAPEX™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that GRAFAPEX™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments because GRAFAPEX™ offers a critical new treatment option and addresses an unmet need for allo-HSCT conditioning for older and/or more comorbid patients who have AML or MDS and are ineligible for currently available MAC regimens and face higher relapse risk if a RIC regimen is used. Additionally, per the applicant, GRAFAPEX™ significantly improves clinical outcomes relative to existing technologies because GRAFAPEX™-based conditioning has shown superiority in survival (in terms of overall and event-free survival) and non-relapse mortality, as well as significant reductions in adverse events, such as graft-versus-host disease (GVHD), veno-occlusive disease (VOD), and infections, compared to previously available regimens. The applicant provided 10 studies to support these claims, as well as 1 background article that, per the applicant, indicates that many patients with AML or MDS, especially those who are older and/or have significant comorbidities, are ineligible for MAC regimens, and face higher risk of relapse with RIC regimens.[83] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for GRAFAPEX™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
GRAFAPEX™ offers a treatment option for allo-HSCT conditioning for older and/or more comorbid patients who have AML or MDS, who are ineligible for currently available MAC regimens.	Beelen DW, Iacobelli S, Koster L, et al. Fludarabine-treosulfan versus fludarabine-melphalan or busulfan-cyclophosphamide conditioning in older AML or MDS patients—A clinical trial to registry data comparison. Bone Marrow Transplant. 2024;59(5):670–679. Wedge E, Sengeløv H, Hansen JW, et al. Improved Outcomes after Allogenic Hematopoietic Stem Cell Transplantation with Fludarabine/Treosulfan for Patients with Myelodysplastic Syndromes. Biol Blood Marrow Transplant. 2020;26(6):1091–1098. Fraccaroli A, Stauffer E, Haebe S, et al. Treosulfan-Versus Melphalan-Based Reduced Intensity Conditioning in HLA-Haploidentical Transplantation for Patients ≥ 50 Years with Advanced MDS/AML. Cancers (Basel). 2024;16(16):2859. Bug G, Labopin M, Niittyvuopio, R, et al. Fludarabine/TBI 8 Gy versus fludarabine/treosulfan conditioning in patients with AML in first complete remission: a study from the Acute Leukemia Working Party of the EBMT. Bone Marrow Transplant. 2023;58(6):710–716. Nagler A, Labopin M, Beelen D, et al. Long-term outcome after a treosulfan-based conditioning regimen for patients with acute myeloid leukemia: A report from the Acute Leukemia Working Party of the European Society for Blood and Marrow Transplantation. Cancer. 2017;123(14):2671–2679. Gavriilaki E, Sakellari Ioanna, Labopin, et al. Survival advantage of treosulfan plus fludarabine (FT14) compared to busulfan plus fludarabine (FB4) in active acute myeloid leukemia post allogeneic transplantation: an analysis from the European Society for Blood and Marrow Transplantation (EBMT) Acute Leukemia Working Party (ALWP). Bone Marrow Transplant. 2023;58(10):1084–1088. Pasic I, Moya TA, Remberger Mats, et al. Treosulfan- Versus Busulfan-based Conditioning in Allogeneic Hematopoietic Cell Transplantation for Myelodysplastic Syndrome: A Single-center Retrospective Propensity Score-matched Cohort Study. Transplant Cell Ther. 2024;30(7):681.e1–681.e11. Chichra A, Nayak L, Kothari R, et al. Fludarabine melphalan versus fludarabine treosulfan for reduced intensity conditioning regimen in allogeneic hematopoietic stem cell transplantation: a retrospective analysis. Int J Hematol. 2024;119(1):71–79. Beelen DW, Stelljes M, Reményi P, et al. Treosulfan compared with reduced-intensity busulfan improves allogeneic hematopoietic cell transplantation outcomes of older acute myeloid leukemia and myelodysplastic syndrome patients: Final analysis of a prospective randomized trial. Am J Hematol. 2022;97(8):1023–1034. Shimoni A, Robin M, Iacobelli S, et al. Allogeneic hematopoietic cell transplantation in patients with myelodysplastic syndrome using treosulfan based compared to other reduced-intensity or myeloablative conditioning regimens. A report of the chronic malignancies working party of the EBMT. Br J Haematol. 2021;195(3):417–428. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

[83] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
GRAFAPEX™-based conditioning has shown superior outcomes for event-free survival (EFS), overall survival (OS), and non-relapse mortality (NRM), and significant reductions in several adverse events.	Beelen, 2024, *op. cit.* Wedge, 2020, *op. cit.* Fraccaroli, 2024, *op. cit.* Bug, 2023, *op. cit.* Nagler, 2017, *op. cit.* Gavriilaki, 2023, *op. cit.* Pasic, 2024, *op. cit.* Chichra, 2024, *op. cit.* Beelen, 2022, *op. cit.* Shimoni, 2021, *op. cit.*

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for GRAFAPEX™, which we summarize in this section.

Comment: The applicant submitted a public comment summarizing the claims from its application regarding why it believes GRAFAPEX™ meets the substantial clinical improvement criterion. Additionally, the applicant provided additional information related to questions raised at the Town Hall meeting. With regard to a question asking for clarification with respect to whether any of the studies cited by the applicant compared GRAFAPEX™-based conditioning to other reduced-toxicity conditioning (RTC) regimens, the applicant stated the classification concept of MAC and RIC regimens was defined around 2009. According to the applicant, Spyridonidis et al. (2020) introduced a new tool for measuring conditioning regimen intensity, called transplant conditioning intensity (TCI).[84] The applicant quoted Spyridonidis et al. (2020) and stated that TCI ''provides an improvement of the RIC/MAC classification'' and ''enable[s] the identification of a distinct subgroup of RIC and MAC conditioning regimens with an intermediate TCI [2.5–3.5] score that had identical outcomes and which are frequently referred [to] as 'reduced toxicity conditioning'.'' The applicant further noted that Spyridonidis et al. (2020) developed the TCI scoring tool to address limitations of the currently used RIC/MAC classification scheme. The applicant suggested that other conditioning regimens could also be categorized as RTC regimens based on this publication's TCI scoring methodology and classification system.[85] The applicant noted that although a number of publications continued to use the MAC/RIC classification system, rather than incorporating RTC terminology or other nomenclature reflecting the TCI scoring classification system, Spyridonidis et al. (2020) reflects a new paradigm shift in conditioning regimen classification. Based on the TCI scoring methodology, the applicant provided examples of peer-reviewed publications from its application where both the GRAFAPEX™ plus fludarabine arm and comparator arm in the study were conditioning regimens that the applicant believed would likely be scored as intermediate-intensity or RTC regimens, that is regimens with a TCI score of 2.5–3.5. The applicant provided the following three examples.

First, the applicant calculated TCI scores for the regimens compared in Gavriilaki et al. (2023) based on dosage and the Spyridonidis et al. (2020) methodology: fludarabine <160mg/m2 (0.5 TCI score) plus GRAFAPEX™ 42g (3 TCI score) equates to a TCI score of 3.5; fludarabine <160mg/m2 (0.5 TCI score) plus busulfan 12.8mg/kg (3 TCI score) equates to a TCI score of 3.5. The applicant reiterated that Gavriilaki et al. (2023) found that the GRAFAPEX™-based conditioning demonstrated superiority in overall survival (44.4 percent vs. 34 percent (p = 0.009)) and was similar in non-relapse mortality compared to the busulfan-based conditioning treatment in patients with relapsed or refractory AML.

Second, the applicant calculated TCI scores for the regimens compared in Pasic et al. (2024) based on dosage and the Spyridonidis et al. (2020) methodology: fludarabine 35mg/m2 x 4 (0.5 TCI score) plus GRAFAPEX™ (2 or 3 TCI score) (depending on dose) equals a TCI score of 2.5 or 3.5 (depending on the GRAFAPEX™ dosage); fludarabine 35mg/m2 x 4 (0.5 TCI score) plus busulfan 3.2mg/kg x 2 (1 TCI score) plus total body irradiation 2Gy (1 TCI score) equals a TCI score of 2.5. The applicant reiterated the results from this study, noting that the GRAFAPEX™-based conditioning regimen demonstrated superiority in overall survival, event-free survival, and non-relapse mortality at 2 years follow-up, 2-year superiority in GVHD relapse-free survival (GRFS), and a lower percentage of patients requiring at least one hospital readmission at 1 year compared to the comparison group (fludarabine+busulfan+total body irridation).

Third, the applicant calculated TCI scores for the regimens compared in Chichra et al. (2023) based on dosage and the Spyridonidis et al. (2020) methodology: fludarabine 30mg/m2 x 4 (0.5 TCI score) plus GRAFAPEX™ 12–14g/m2 (2 or 3 TCI) (depending on dose) equals a TCI score of 2.5 or 3.5 (depending on the GRAFAPEX™ dosage); fludarabine (0.5 TCI score) plus melphalan 140mg/m2 (2 TCI score) equals a TCI score of 2.5. The applicant restated the study's results, including that the GRAFAPEX™-based conditioning group had fewer acute toxicities and fewer cases of severe mucositis and diarrhea compared to the melphalan-based conditioning group.

The applicant also provided information related to the following three points from its slide presentation at the new technology add-on payment Town Hall: (1) previously available allo-HSCT conditioning agents and regimens create an unmet need for conditioning treatment that minimizes toxicity while maximizing efficacy, especially for older patients and/or those with significant comorbidities; (2) other conditioning agents used to date are all metabolized

[84] Spyridonidis, A., Labopin, M., Savani, B.N., Niittyvuopio, R., Blaise, D., Craddock, C., Socié, G., Platzbecker, U., Beelen, D., Milpied, N., Cornelissen, J.J., Ganser, A., Huynh, A., Griskevicius, L., Giebel, S., Brissot, E., Malard, F., Esteve, J., Peric, Z., Baron, F., . . . Mohty, M. (2020). Redefining and measuring transplant conditioning intensity in current era: a study in acute myeloid leukemia patients. *Bone Marrow Transplantation, 55*(6), 1114–1125. *https://doi.org/10.1038/s41409-020-0803-y.*

[85] See Figure 1b in Spyridonidis et al. (2020) for additional regimens with transplant conditioning intensity scores of 2.5–3.5 (intermediate/RTC range).

by the liver, which results in higher toxicity and leads to ''excess regimen-related morbidity and mortality observed in older and comorbid patients;'' [86] and (3) GRAFAPEX™ reduces treatment-related toxicity because it uniquely bypasses liver metabolism. The applicant restated information from its application, specifically citing the Beelan et al. (2022) study in which 27 percent of patients were ages 65 to 74 years. The applicant noted that this study did not analyze the liver metabolism of conditioning agents but that it found a GRAFAPEX™ and fludarabine conditioning regimen performed better than a busulfan and fludarabine conditioning regimen in regards to event-free survival, overall survival, and non-relapse mortality. The applicant also stated that other alkylating agents used to date in allo-HSCT conditioning, such as busulfan, melphalan, cyclophosphamide, are all metabolized by the liver and that such metabolism by the liver results in higher toxicity.[87]

Response: We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether GRAFAPEX™ meets the substantial clinical improvement criterion. The applicant stated GRAFAPEX™ offers a conditioning treatment regimen option for older and/or more comorbid patients with AML or MDS who are ineligible for currently available MAC regimens due to their high toxicity and higher relapse risk with RIC regimens. The applicant provided 11 studies which it stated show that GRAFAPEX™-based regimens reduce the toxicity, non-relapse related mortality, and treatment related mortality associated with MAC without resulting in the increased incidence of relapse associated with RIC. However, we note that in two studies provided by the applicant comparing a GRAFAPEX™-based regimen to RIC, there was a higher rate of relapse with the GRAFAPEX™-based regimen. Specifically, in Fraccaroli et al. (2024), patients treated with a GRAFAPEX™ regimen demonstrated a higher cumulative incidence of relapse compared to the melphalan treatment group (24 percent vs. 0 percent, p=0.006). Similarly, we note that Bug et al. (2023) found that a fludarabine plus GRAFAPEX™ conditioning regimen had a higher cumulative incidence of relapse (34.7 percent) compared to a fludarabine plus fractionated total body irradiation conditioning regimen (18.3 percent, p = 0.018).

Additionally, as the applicant noted in its Town Hall comment, GRAFAPEX™-based regimens are not the only intermediate-intensity or RTC regimens. Specifically, the applicant mentioned three additional RTC regimens in addition to GRAFAPEX™-based regimens: fludarabine <160mg/m2 plus busulfan 12.8mg/kg, fludarabine 35mg/m2 x 4 plus busulfan 3.2mg/kg x 2 plus total body irradiation 2Gy, and fludarabine plus melphalan 140mg/m2. We also note that RIC and NMA are additional options for these patients. Therefore, we question if GRAFAPEX™-based regimens are the only treatment options for patients ineligible for MAC.

With respect to the assertion that GRAFAPEX™ significantly improves clinical outcomes relative to services or technologies previously available, the applicant stated that GRAFAPEX™-based conditioning has shown superior outcomes for event-free survival, overall survival, and non-relapse mortality, as well as significant reductions in several adverse events. To support its statements, the applicant provided 1 randomized trial for GRAFAPEX™ and 9 retrospective studies, which were also cited in support of the prior claim. However, we question the generalizability of these studies to the Medicare population. First, none of the studies assessing GRAFAPEX™ evaluated the treatment in a U.S. population; rather, all of the studies were conducted outside the U.S, and we question whether differences in treatment guidelines and regimens between countries could affect generalizability to the Medicare population. Second, we note that, of the submitted studies directly assessing GRAFAPEX™, 7 had a majority of participants in the GRAFAPEX™ treatment arm under 65 years and 1 study (Wedge et al., 2020) did not include any participants over 66 years of age in the GRAFAPEX™ treatment group, and we therefore question whether outcomes seen in these studies are generalizable to the Medicare population. Third, relative to the number of Medicare patients with AML or MDS who may be eligible for allo-HSCT, two studies (Chichra et al., 2023; Fraccaroli et al., 2024) included small sample sizes among the GRAFAPEX™ treatment arms. In particular, Chichra et al. (2023) only contained 11 patients in the matched sibling donor/matched unrelated (MRD/MUD) donor fludarabine plus GRAFAPEX™ group and 16 patients in the haploidentical (Haplo) donor fludarabine plus GRAFAPEX™ group. Fraccaroli et al. (2024) included only 21 patients in the melphalan group and 21 patients in the GRAFAPEX™ group. Given these small sample sizes, we question whether these studies would be generalizable to the Medicare population due to the potential influence of confounding variables. We also note that in Beelen et al. (2024), about half of the data was missing for the comorbidity index and over half of the data was missing regarding the disease risk, which are characteristics that could impact efficacy, making it difficult to fully compare the treatment groups.

We further note that while some studies showed improved overall survival, a lower NRM, and reduced adverse events with the GRAFAPEX™-based regimen, there were some conflicting results across studies. First, while the applicant stated GRAFAPEX™-based regimens have shown improved overall survival (OS), we note that in Bug et al. 2023, Chichra et al. 2023, and Fraccaroli et al. 2024, OS was similar between the GRAFAPEX™-based regimen and RIC. Specifically, 2-year OS was 67.8 percent in the GRAFAPEX™-based regimen in Bug et al. 2023 and 66.9 percent in the fludarabine/TBI group (HR 1.08 (95 percent CI, 0.67–1.75)). In Chichra et al. 2023, 5-year OS was 53 percent in those treated with a GRAFAPEX™-based regimen (Flu-Treo) and 62 percent in those treated with fludarabine/melphalan (Flu-Mel) in the MRD/MUD transplant group (p=0.694) and 28 percent in Flu-Treo and 41 percent in Flu-Mel in the Haplo transplant group (p=0.770). In Fraccaroli et al. (2024), the 2-year survival was 66 percent in both the fludarabine-cyclophosphamide-melphalan and fludarabine-cyclophosphamide-GRAFAPEX™ groups (p=0.8).

Second, the applicant asserted superior outcomes for GRAFAPEX™ in non-relapse mortality (NRM). However, multiple studies showed that GRAFAPEX™ had a NRM rate that was higher than or similar to other technologies. Per Chichra et al. (2023), the 2-year NRM was similar between Flu-Treo and Flu-Mel in the MRD/MUD and Haplo groups, although the specific numbers were not provided in the

[86] Beelen, 2022, *op. cit.*

[87] Scheulen, M.E., Hilger, R.A., Oberhoff, C., Casper, J., Freund, M., Josten, K.M., Bornhäuser, M., Ehninger, G., Berdel, W.E., Baumgart, J., Harstrick, A., Bojko, P., Wolf, H.H., Schindler, A.E., & Seeber, S. (2000). Clinical phase I dose escalation and pharmacokinetic study of high-dose chemotherapy with treosulfan and autologous peripheral blood stem cell transplantation in patients with advanced malignancies. *Clinical Cancer Research, 6*(11), 4209–16. *https://aacrjournals.org/clincancerres/article/6/11/4209/199579/Clinical-Phase-I-Dose-Escalation-and.*

study. In Gavriilaki et al. (2023), NRM was similar between fludarabine/GRAFAPEX™ (FT14) (20.8 percent) and fludarabine/busulfan (FB4) (22.6 percent) (p=0.46). Shimoni et al. (2021) found that 5-year NRM was statistically highest among patients who received MAC (34 percent) followed by those who received fludarabine and GRAFAPEX™ (30 percent) and lowest among those who received RIC (27 percent) (p=0.008). In Wedge et al. (2020), 3-year NRM was not statistically different (p=0.425) with a NRM of 13.6 percent for fludarabine/GRAFAPEX™, 33.3 percent for standard myeloablative (SMA) conditioning, and 17.9 percent for nonmyeloablative (NMA) conditioning.

Third, the applicant claimed a significant reduction in several clinically significant adverse events and complications that often lead to treatment-related mortality (TRM), such as graft-versus-host disease (GVHD), veno-occlusive disease (VOD), life-threatening infections, and organ toxicities. However, some studies showed similar or higher rates of adverse effects with the GRAFAPEX™-based regimen. Specifically, Fraccaroli et al. (2024) reported a similar frequency of GVHD and renal failure, with no cases of VOD in either group and no statistical comparison of infection rates presented. Per Beelen et al. (2022), the frequencies of treatment-emergent adverse events and serious adverse events were equally distributed between the study arms. The incidence of acute GVHD and chronic GVHD was similar between treatment groups or higher with the GRAFAPEX™-based regimen in Chichra et al. (2023), Bug et al. (2023), Gavriilaki et al. (2023), and Pasic et al. (2024). In Shimoni et al. (2021), there was no statistical difference in chronic GVHD among the treatment groups and in Wedge et al. (2020), acute GVHD was similar between FluTreo and NMA.

We are inviting public comments on whether GRAFAPEX™ meets the substantial clinical improvement criterion.

h. IMDELLTRA™ (Tarlatamab-Dlle)

Amgen, Inc. submitted an application for new technology add-on payments for IMDELLTRA™ for FY 2026. According to the applicant, IMDELLTRA™ is a novel, first-in-class bispecific T-cell engager (BiTE®) molecule for the treatment of adult patients with extensive stage small cell lung cancer (ES–SCLC) with disease progression on or after platinum-based chemotherapy. According to the applicant, IMDELLTRA™ works by binding to the delta-like ligand 3 (DLL3) antigen expressed on the surface of SCLC tumor cells and the cluster of differentiation 3 (CD3) co-receptor expressed on the surface of T cells, causing T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells.

Please refer to the online application posting for IMDELLTRA™, available at *https://mearis.cms.gov/public/publications/ntap/NTP241007BQ3UB*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, IMDELLTRA™ was granted accelerated approval of its BLA from FDA on May 16, 2024, for the treatment of adult patients with ES–SCLC with disease progression on or after platinum-based chemotherapy. According to the applicant, IMDELLTRA™ was commercially available immediately after FDA approval. The applicant stated that the first dose of IMDELLTRA™ is 1 mg and all subsequent doses are 10 mg, with all doses administered by a healthcare provider as a 1-hour intravenous (IV) infusion. Per the applicant, the average inpatient dose is 7.3 mg based on available data. The applicant noted the only inpatient data available is for patients who experience cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS) after IMDELLTRA™ and it is unknown how many patients without these adverse events would receive IMDELLTRA™ on an inpatient basis.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify IMDELLTRA™. We note that the applicant submitted a request for approval for unique ICD–10–PCS procedure codes for IMDELLTRA™ beginning in FY 2026. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for IMDELLTRA™ under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM (and PCS) codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that IMDELLTRA™ is not substantially similar to other currently available technologies because it has a unique mechanism of action as a BiTE® that simultaneously binds DLL3 on SCLC cells and CD3 on T cells and because it is the only therapy specifically studied and shown to improve outcomes for patients who are relapsed or refractory to two or more other therapies and those with treated, stable brain metastases, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for IMDELLTRA™ for the applicant's complete statements in support of its assertion that IMDELLTRA™ is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	IMDELLTRA™ has a unique mechanism of action as the first and only approved BiTE® therapy targeting DLL3 across all patient populations and as the only BiTE® therapy approved for SCLC. IMDELLTRA™'s mechanism of action involves simultaneously binding the DLL3 antigen on a SCLC cell and the CD3 antigen on the patient's own T cells. The binding of IMDELLTRA™ results in the formation of a synapse between T cells and DLL3-expressing cells, including tumor cells, leading to T-cell activation causing the release of inflammatory cytokines and lysis of DLL3-expressing cells. Thus, IMDELLTRA™ is unique as the only T-cell directed immunotherapy approved for ES–SCLC. In contrast, other approved ES–SCLC treatments are cytotoxic chemotherapies that work by interfering with the ability of rapidly dividing cells to replicate and divide, which can lead to cell death in both cancerous and noncancerous cells. Lurbinectedin is an alkylating drug that binds to DNA, forming adducts that perturb the cell cycle and cause cell death in dividing cells. Topotecan and irinotecan are topoisomerase-1 inhibitors that bind topoisomerase-1–DNA complex and inhibit the repair of double-strand breaks in DNA in dividing cells. IMDELLTRA™ has a novel mechanism of action targeting DLL3 for the treatment of ES–SCLC and is differentiated from existing ES–SCLC treatments due to the uniqueness of both this target and its tissue expression profile, which results in activation of the T cell and lysis of DLL3-expressing SCLC cells.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The use of IMDELLTRA™ to treat ES–SCLC is not expected to change the MS–DRG assignment of the case.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	IMDELLTRA™ does not involve the treatment of the same or similar type of disease or the same or similar patient population when compared to existing technology because IMDELLTRA™ is the first and only BiTE® therapy available for the treatment of patients with ES–SCLC who have had disease progression on or after platinum-based chemotherapy. Furthermore, although IMDELLTRA™ is indicated to treat patients after relapsing on first line (1L) platinum-based chemotherapy, for the subset of these patients who have become relapsed or refractory (R/R) to two or more therapies, IMDELLTRA™ is the only therapy that is approved by FDA and has been specifically studied and demonstrated improvements in this population. IMDELLTRA™ also is the only FDA-approved second line therapy (2L) that has been studied in SCLC patients with treated, stable brain metastases.

We note that while the applicant asserted that IMDELLTRA™ does not involve the treatment of the same or similar disease or patient population because it is the first BiTE® therapy for patients with ES–SCLC who have had disease progression on or after platinum-based chemotherapy, per the applicant, other FDA-approved therapies for the treatment of the same patient population (patients who have ES–SCLC with disease progression on or after platinum-based chemotherapy) are currently available, such as lurbinectedin and topotecan. Further, with respect to the applicant's statements that IMDELLTRA® is the only FDA-approved therapy that has been specifically studied and demonstrated improvements in the subset of ES–SCLC patients who have become R/R to two or more therapies or that have stable brain metastases, we believe that these assertions may be relevant to substantial clinical improvement rather than newness and these patients may still be treated with lurbinectedin or topotecan. Therefore, we question the applicant's assertion that IMDELLTRA™ treats a unique patient population compared to existing technology.

We are inviting public comments on whether IMDELLTRA™ is substantially similar to existing technologies and whether IMDELLTRA™ meets the newness criterion.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that IMDELLTRA™ meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

IMDELLTRA™ COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for IMDELLTRA™.
Claims identified	Scenario 1: 788 claims mapping to 16 MS–DRGs, with 43.02% of claims mapping to MS–DRG 180 (Respiratory Neoplasms with MCC). Scenario 2: 459 claims mapping to 5 MS–DRGs, with 73.86% of claims mapping to MS–DRG 180 (Respiratory Neoplasms with MCC).
Charges removed for prior technology.	The applicant removed 100% of charges associated with drugs and cellular therapies to account for the chemotherapy agent IMDELLTRA™ will replace. The applicant noted there may be removed charges for non-chemotherapy agents, but was conservative by removing 100% of the drug and cellular therapy charges. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardization file posted with the FY 2025 IPPS/LTCH PPS final rule and the impact file posted with FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 12.9% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.

IMDELLTRA™ COST ANALYSIS—Continued

Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of a 10 mg dose of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. Per the applicant, it repeated this calculation for the 1 mg step up dose to confirm that, even if this dose is administered in the inpatient setting, the final inflated average case-weighted standardized charge per case exceeds the average case-weighted threshold for the cost criterion. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Scenario 1: —Average case-weighted threshold amount: $102,317. —Final inflated average case-weighted standardized charge per case: $230,190. Scenario 2: —Average case-weighted threshold amount: $73,433. —Final inflated average case-weighted standardized charge per case: $203,476.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that IMDELLTRA™ meets the cost criterion.

We are inviting public comments on whether IMDELLTRA™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that IMDELLTRA™ represents a substantial clinical improvement over existing technologies because IMDELLTRA™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments and the technology significantly improves clinical outcomes relative to services or technologies previously available. Specifically, per the applicant, IMDELLTRA™ is a novel treatment option that offers substantial clinical improvement through deep and durable response for patients with ES–SCLC relapsed on platinum-based chemotherapy. The applicant further stated that IMDELLTRA™ is the only approved DLL3-directed-CD3 T-cell engager for the treatment of ES–SCLC, for which there is a profound unmet need in this population who suffer from devastating outcomes and suboptimal care from limited and ineffective treatment options. The applicant provided four articles regarding outcomes from the phase I DeLLphi-300 and phase II DeLLphi-301 trials and the IMDELLTRA™ prescribing information to support these claims, as well as 16 background articles about SCLC and existing treatments for the disease.[88] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for IMDELLTRA™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
The majority of ES–SCLC patients who are relapsed or refractory to 1L treatment are, or become, unresponsive to previously approved 2L treatments.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.
There are limited treatment options for ES–SCLC patients who have relapsed, and IMDELLTRA™ is a new option for SCLC patients who have relapsed and are resistant to initial treatment options.	Ahn M, Cho B, et al. Tarlatamab for Patients with Previously Treated Small-Cell Lung Cancer. N Eng J Med. 2023;389:2063–75. IMDELLTRA™ (tarlatamab-dlle) injection, for intravenous use; Amgen, Inc., 2024. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IMDELLTRA™ is the first therapy that has shown meaningful improvements in outcomes in the subset of patients who have failed two or more prior therapies.	Ahn, 2023, *op. cit.* Sands J, Cho BC, et al. Tarlatamab Sustained Clinical Benefit and Safety in Previously Treated SCLC: DeLLphi-301 Phase 2 Extended Follow-up. Oral presentation (#OA10.03) at 2024 World Conference on Lung Cancer in San Diego, California. September 9, 2024. Dingemans A, Ahn M, et al. DeLLphi-301: Tarlatamab phase 2 trial in small cell lung cancer (SCLC)—Efficacy and safety analyzed by presence of brain metastasis. J Clin Oncology. 2024;42:8015. Amgen, Inc., 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Outcomes on existing therapies for ES–SCLC continue to be very poor, particularly as all previously approved therapies have high relapse rates.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.

[88] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
IMDELLTRA™ has shown substantial clinically meaningful improvement in outcomes relative to other available therapies for ES–SCLC patients.	Sands, 2024, *op. cit.* Ahn, 2023, *op. cit.* Amgen, Inc., 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
In ES–SCLC patients with stable brain metastases pre-treated with two or more prior therapies, IMDELLTRA™ showed similar clinical outcomes as patients without brain metastases in post-hoc analysis.	Ahn, 2023, *op. cit.* Dingemans, 2024, *op. cit.* Amgen, Inc., 2024, *op. cit.* Dowlati A, Hummel H–D, et al. Sustained Clinical Benefit and Intracranial Activity of Tarlatamab in Previously Treated Small Cell Lung Cancer: DeLLphi-300 Trial Update. J Clin Oncology. published online August 29, 2024. doi: 10.1200/JCO.24.00553. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IMDELLTRA™ has a generally manageable safety profile and a low incidence of treatment-related neutropenia.	Amgen, Inc., 2024, *op. cit.* Ahn, 2023, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for IMDELLTRA™, which we are summarizing in this section.

Comment: The applicant submitted a comment responding to questions raised at the Town Hall meeting. In response to a question regarding how the applicant controlled for differences in patient demographics when comparing to other studies, the applicant stated there is reliable information about patient demographics and outcomes in ES–SCLC patients on currently available treatment supporting that IMDELLTRA™ is a substantial clinical improvement. The applicant referred to a number of studies included in its application to support the statement. First, the applicant noted that topotecan was evaluated in a randomized, multicenter study of patients with SCLC who had relapsed at least 60 days after completion of 1L therapy; patients with documented brain metastases were included and represented 11.2 percent of the topotecan arm of the study.[89] The applicant also stated that lurbinectedin was evaluated in a phase II single-arm, open-label basket trial with SCLC patients who had previously failed on platinum-based chemotherapy; the patient population had a median age of 60 years and patients with brain metastases were excluded.[90] Per the applicant, while topotecan and lurbinectedin registrational trials did not study a third line (3L) patient population, these therapies have been studied in the real-world setting for U.S. patients since their FDA approvals in 1996 and 2020, respectively, including analyses of real-world overall survival (rwOS).[91] [92] [93] The applicant further stated that IMDELLTRA™ was evaluated in a phase 2 multi-cohort, open-label trial in patients R/R to one platinum-based treatment and at least one other line of therapy, and were Eastern Cooperative Oncology Group (ECOG) performance-status grade < 2. Per the applicant, in this pre-treated population, approximately 33 percent of patients had received 3 or more therapies; of the 99 patients treated with IMDELLTRA™, 48 percent were 65 years of age or older and 10 percent were 75 years of age or older.[94] In addition, per the applicant, there is a post-hoc analysis of the 23 percent of patients with stable, treated brain metastases receiving the FDA-approved dose.[95]

With respect to a question regarding how the applicant compared IMDELLTRA™'s overall response rate (ORR) to other therapies without data that shows the populations studied match, the applicant stated that as previously noted, there is a significant amount of clinical literature available regarding outcomes for ES–SCLC patients on currently available treatment to support the applicant's claims of substantial clinical improvement for IMDELLTRA™ without the need for head-to-head studies, which are not required as part of the new technology add-on payment criteria. Further, the applicant noted that tumor response (for example, ORR) is considered a direct measure of drug antitumor activity, which can be adequately evaluated in a single-arm study. Additionally, the applicant stated that overall survival (OS) and progression-free survival (PFS) endpoints must be interpreted with caution in single-arm trials and confirmatory phase III trials are needed to confirm OS and PFS results.

The applicant stated that it is clear from currently available literature that patients with ES–SCLC after failing on chemotherapy have extremely poor outcomes on existing therapies, where response and survival are measured in just a few months. The applicant again referred to a number of studies included in its application to support the statement. The applicant summarized the registrational trial results for the other currently FDA-approved treatments for adult 2L ES–SCLC patients and noted that topotecan demonstrated an ORR of 24.3 percent, a duration of response (DOR) of 3.3 months (14.4 weeks), a median PFS (mPFS) of 3.1 months (13.3 weeks), and a median OS (mOS) of 5.8 months (25 weeks) in its pivotal trial (n=107).[96] The applicant stated lurbinectedin demonstrated an ORR of 35 percent, a DOR of 5.3 months, a mPFS of 3.5 months, and mOS of 9.3 months in its pivotal trial (n=105). The applicant noted, however, that this clinical trial data lacks evidence on patients with brain metastases per the trial's exclusion criteria.[97] In addition, the applicant

[89] von Pawel J, Schiller J, et al. Topotecan Versus Cyclophosphamide, Doxorubicin, and Vincristine for the Treatment of Recurrent Small-Cell Lung Cancer. J Clin Oncology. 1999;17(2):658–667.

[90] Trigo J, Subbiah V, et al. Lurbinectedin as second-line treatment for patients with small-cell lung cancer: a single-arm, open-label, phase 2 basket trial. Lancet Oncol. 2020;21(5):645–654.

[91] Borghaei H, Pundole X, Sangaré L, et al. Natural history of SCLC patients treated in third-line and beyond: A retrospective real world study. *Lung Cancer.* 2024;193:10781. doi:10.1016/j.lungcan.2024.107819.

[92] Coutinho AD, Shah M, Lunacsek OE, Eaddy M, & Willey JP. Real-world treatment patterns and outcomes of patients with small cell lung cancer progressing after 2 lines of therapy. *Lung Cancer.* 2019;127:53–58.

[93] Desai A, Smith C, et al. Real-World Outcomes With Lurbinectedin in Second-Line Setting and Beyond for Extensive Stage Small Cell Lung Cancer. Clinical Lung Cancer. 2023;24(8):689–695.

[94] Anh, 2023, *op. cit.*

[95] Dingemans, 2024, *op. cit.*

[96] von Pawel, 1999, *op. cit.*

[97] Trigo, 2020, *op. cit.*

noted that lurbinectedin failed to reach its primary endpoint of OS in the confirmatory phase 3 ATLANTIS trial.[98] Further, the applicant referenced the real-world analysis of U.S. patients in the 3L setting by Borghaei et al. (2024), which found median rwOS was 5.3 months (n=326; 95 percent CI, 4.5–6.0) following initiation of 3L therapies (topotecan, lurbinectedin, immunotherapy, taxane monotherapy or platinum-based chemotherapy with immunotherapy). The applicant stated in addition that this analysis found the median time from SCLC diagnosis to 3L therapy initiation was 400 days.

Per the applicant, IMDELLTRA™ had an ORR of 40 percent and a mDOR of 9.7 months, with 43 percent of responses ongoing at data cutoff in an extended follow-up analysis. In addition, the applicant stated mOS was 15.2 months and was similar regardless of progression-free interval (<90 days or 90+ days) after 1L platinum-based chemotherapy (n=100).[99] The applicant further stated that based on a post-hoc analysis of the multi-cohort trial, efficacy outcomes were also similar for patients with stable, treated brain metastases and those without brain metastases.[100] The applicant noted that Dingemans et al. (2024) found stable, treated brain metastases patients in the trial had an ORR of 54.5 percent, mPFS of 7.1 months, and mOS of 14.3 months. The applicant noted that IMDELLTRA™ shows clinical improvement by allowing patients to possibly live for more than 4 to 6 months following initiation of 2L treatment. The applicant also noted that the American Society of Clinical Oncology (ASCO) recently came to a similar conclusion independently, as per the updated ASCO guideline on systemic therapy for SCLC submitted with respect to the substantial clinical improvement criteria.[101] The applicant stated ASCO had the same information available to it with respect to outcomes on lurbinectedin, topotecan, and IMDELLTRA™ as that provided by the applicant in its application, and updated ASCO guidelines stated that the cross-trial comparisons suggest that both lurbinectedin and IMDELLTRA™ are more effective than topotecan or other agents, although the DOR of >9 months reported with IMDELLTRA™ is substantially longer than that seen with other agents.

In addition to the studies submitted by the applicant in its application, the applicant noted that it has conducted an indirect treatment comparison (ITC) to evaluate the relative benefit in survival outcomes and response between IMDELLTRA™ versus real-world physicians' choice of therapy from a historical control cohort captured in the U.S. Flatiron electronic health records database.[102] The applicant provided the ITC's research protocol as additional background about how the ITC compared OS, PFS, and ORR,[103] and indicated that the study results are expected to be available in March 2025.

Response: We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether IMDELLTRA™ meets the substantial clinical improvement criterion. The applicant stated that IMDELLTRA™ offers a treatment option for patients with 2L+ ES–SCLC that are unresponsive to, or ineligible for, currently available treatments, however it is unclear that these patients are unresponsive or ineligible for existing 2L+ treatments for ES–SCLC, such as lurbinectedin and topotecan. The applicant claimed that the majority of ES–SCLC patients who are relapsed or refractory to 1L treatment are or become unresponsive to previously approved 2L treatments. For this claim, the applicant provided background articles regarding treatment of ES–SCLC, but did not indicate a patient population that IMDELLTRA™ treats that is ineligible or unresponsive to other 2L treatments. The applicant also claimed that there are limited treatment options for ES–SCLC patients who have relapsed and IMDELLTRA™ is a new option for these patients. However, we note that having limited treatment options does not demonstrate that these patients are unresponsive or ineligible for any available therapies. In addition, while the applicant provided results from the pivotal DeLLphi-301 study of IMDELLTRA™ stating that it is the first therapy that has shown meaningful outcome improvements in patients who have failed two or more prior therapies, the study did not list these therapies, and we also note that retreatment with platinum-based chemotherapy was considered an additional line of therapy per the study. Therefore, it is unclear that the study demonstrated that patients had failed existing 2L+ treatments, including lurbinectedin and topotecan. For these reasons, we question the assertion that IMDELLTRA™ offers a treatment for a patient population unresponsive to, or ineligible for, currently available treatments.

With respect to the applicant's statement that IMDELLTRA® improves clinical outcomes over existing technologies because outcomes on existing therapies for ES–SCLC continue to be very poor, particularly as all previously approved therapies have high relapse rates, and that, in the past 2 decades, relapsed ES–SCLC patients who have failed platinum-based chemotherapy have had few treatment options as only topotecan and lurbinectedin are FDA-approved and indicated for these patients, we note that the applicant provided outcome data for topotecan and lurbinectedin, in addition to highlighting that lurbinectedin, pembrolizumab, and nivolumab failed to show a benefit in OS in the confirmatory phase 3 clinical trials. However, the applicant did not provide relapse rates for current therapies, including IMDELLTRA™, and did not compare the provided outcome data to IMDELLTRA™, and therefore we question how this demonstrates that IMDELLTRA™ improves clinical outcomes relative to these therapies.

To support its other statements regarding improved outcomes for IMDELLTRA™, the applicant provided results from DeLLphi-301, a phase 2, single arm, open-label, international trial which evaluated antitumor activity and safety of IMDELLTRA™ in patients with advanced SCLC previously treated with two or more lines of therapy.[104] However, we note that, of the 134 patients treated with the target dose of IMDELLTRA™, only 14 were from North America (without further specification on the country), and we question whether differences in treatment guidelines between countries could affect generalizability to the

[98] Aix S, Ciuleanu T, et al. Combination lurbinectedin and doxorubicin versus physician's choice of chemotherapy in patients with relapsed small-cell lung cancer (ATLANTIS): a multicentre, randomised, open-label, phase 3 trial. *Lancet Respir Med.* 2023;11:74–86.

[99] Sands, 2024, *op. cit.*

[100] Dingemans, 2024, *op. cit.*

[101] Kalemkerian GP, Khurshid H, Ismaila N. Systemic Therapy for Small Cell Lung Cancer: ASCO Guideline Rapid Recommendation Update. JCO 0, JCO–24–02245.

[102] EMA, Real World Data Catalogues, Tarlatamab vs. Real-world Physicians' Choice Therapies in Patients with Relapsed or Refractory Small Cell Lung Cancer After Two or More Prior Lines of Treatment: Patient-level Indirect Treatment Comparison (ITC) of DeLLphi-301 vs. Flatiron Real-world Data; available at: *https://catalogues.ema.europa.eu/node/4199/administrative-details.* Accessed December 13, 2024.

[103] Per the applicant, the research protocol is available at *https://catalogues.ema.europa.eu/system/files/2024-10/20240049_tarlatamab_Protocol-Published%20Amendment.pdf.*

[104] Anh, 2023, *op. cit.*

Medicare population. We also note that 75 percent (101/134) of the patients who took the approved dose of 10 mg in DeLLphi-301 had a previous use of a programmed death ligand 1 (PD–L1) or programmed death 1 (PD–1) inhibitor,[105] which are recommended as part of the initial therapy for ES–SCLC, and we therefore question whether the results of the DeLLphi-301 study were different between the group of patients who previously received these therapies versus those who did not. We further note that the applicant also provided the Sands et al. (2024) presentation and the Dingemans et al. (2024) abstract which are unpublished overviews that do not provide full details on the study methods; therefore, we do not have sufficient information to evaluate these studies.

With respect to the claim that IMDELLTRA™ has shown substantial clinically meaningful improvement in outcomes relative to other available therapies for ES–SCLC patients, the applicant provided outcomes for IMDELLTRA™ from the DeLLphi-301 single arm, phase 2 trial and compared them to outcomes from trials for other approved treatments for patients who have relapsed on first-line chemotherapy. The applicant stated that IMDELLTRA™, lurbinectedin, and topotecan are FDA-approved and no treatments are specifically FDA-approved for 3L treatment. The applicant stated chemotherapy is a 3L treatment and has a mOS of 4.4 months, ORR of 21 percent, mDOR of 2.6 months, and mPFS of 2.3 months.[106] The applicant also noted that lurbinectedin can be used as a 3L agent, but mOS was 5.6 months according to real world data.[107] The applicant also stated IMDELLTRA™ had an ORR of 40 percent, mDOR of 9.7 months, mPFS of 4.9 months, and mOS of 14.3 months,[108] with an mOS of 15.2 months after extended follow-up.[109] The applicant further noted that in a subgroup analysis of 22 patients with stable, treated brain metastases, IMDELLTRA™ showed similar outcomes with an ORR of 54.5 percent, mPFS of 7.1 months, and mOS of 14.3 months.[110] The applicant stated the registrational study for topotecan included patients with brain metastases and reported a mOS of only 5.8 months,[111] while the pivotal phase II trial for lurbinectedin excluded patients with brain metastases and in a real-world analysis among 14 patients who received 3L therapy with lurbinectedin (11 of which with CNS metastases), the mOS was 5.6 months.[112] However, we note that the applicant also stated in its Town Hall comment that tumor response (for example, ORR) can be adequately evaluated in a single-arm study, while OS and PFS endpoints must be interpreted with caution in single-arm trials and confirmatory phase 3 trials are needed to confirm OS and PFS results. Therefore, we question the applicant's use of OS and PFS to support improved clinical outcomes with IMDELLTRA™ compared to previously available therapy. Additionally, the applicant stated that the trial demonstrated mOS of 14.3 months for IMDELLTRA™,[113] and compared it to lurbinectedin's mOS of 5.6 months according to real world data,[114] but we question whether it is appropriate to compare clinical trial and real world data. We note, for example, that the phase 2 single arm trial for lurbinectedin noted an OS of 9.3 months (Trigo et al. (2020)), and we therefore question how the applicant chose the historical control it used in these comparisons of outcomes. In addition, the applicant noted that ORR can be evaluated in a single-arm study and provides the ORR for IMDELLTRA™ (40 percent in 3L therapy [115] and 54.5 percent in patients with stable brain metastases [116]), but did not provide the ORR for topotecan or lurbinectedin in patients with stable brain metastases, nor in patients that are taking 3L therapy. Therefore, we question the applicant's assertion of improved clinical outcomes for IMDELLTRA™ compared to previously available therapy.

We agree with the applicant that head-to-head trials, while preferred, are not required for comparing currently available therapy. However, we note that among the clinical trial and real-world data provided for alternative therapies to IMDELLTRA™, there was no control for confounding variables to ensure similar patients were being compared to those who took IMDELLTRA™. Additionally, we note that the real-world data provided for lurbinectedin as third line therapy and the data for the subset of patients from DeLLphi-301 with brain metastases were small sample sizes of 14 and 22, respectively, which may limit generalizability of these results to the Medicare population as confounding variables could affect the results. We note that exclusion of patients with brain metastases from the pivotal phase 2 trial for lurbinectedin does not exclude use of this drug in this patient population.

We further question the use of von Pawel et al. (1999) study of topotecan as a comparator to IMDELLTRA™ since it was conducted approximately 25 years before the IMDELLTRA™ phase 2 trial (Ahn et al., 2023) and included some highly varied patient outcomes (such as topotecan duration of responses ranging from 9.4–50.1 weeks). We note that guidelines and treatment protocols for SCLC have evolved over this extended period and the resulting changes in care standards may have impacted the outcomes observed from the older study versus the more recent one.

In addition, the applicant stated that clinical trials of topotecan and lurbinectedin reported higher rates of ≥ Grade 3 neutropenia than reported in the DeLLphi-301 study with IMDELLTRA™ monotherapy, but did not consider other serious adverse events such as cytokine release syndrome (CRS) or immune effector cell-associated neurotoxicity syndrome (ICANS), which are possible side effects for IMDELLTRA™ but not for topotecan or lurbinectedin. We further note that there was no control for potential confounding variables in the patient populations in the comparisons of neutropenia rates, and it is therefore difficult to draw conclusions regarding relative side effect profiles among these different trials.

We are inviting public comments on whether IMDELLTRA™ meets the substantial clinical improvement criterion.

i. IntelliSep Test

Cytovale, Inc. submitted an application for new technology add-on payments for the IntelliSep® Test for FY 2026. According to the applicant, the IntelliSep® Test is a semi-quantitative test that assesses cellular host response via a microfluidic deformability cytometry of leukocyte biophysical properties and is intended for use in conjunction with clinical assessments and laboratory findings to aid in the early detection of sepsis with organ dysfunction for adults presenting to the Emergency Department (ED). The IntelliSep® Test generates an index value that falls within 1 of 3 discrete interpretation bands based on the probability of sepsis with organ dysfunction manifesting within the first 3 days after testing.

[105] Anh, 2023, *op. cit.*
[106] Coutinho, 2019, *op. cit.*
[107] Desai, 2023, *op. cit.*
[108] Ahn, 2023, *op. cit.*
[109] Sands, 2024, *op. cit.*
[110] Dingemans, 2024, *op. cit.*
[111] von Pawel, 1999, *op. cit.*
[112] Desai, 2023, *op. cit.*
[113] Ahn, 2023, *op. cit.*
[114] Desai, 2023, *op. cit.*
[115] Ahn, 2023, *op. cit.*
[116] Dingemans, 2024, *op. cit.*

Please refer to the online application posting for the IntelliSep® Test, available at *https://mearis.cms.gov/public/publications/ntap/NTP24100553685*, for additional detail describing the technology and the disease diagnosed in part by the technology.

With respect to the newness criterion, according to the applicant, the IntelliSep® Test was granted 510(k) clearance from FDA on December 20, 2022, for use in adult patients with signs and symptoms of infection who present to the ED. According to the applicant, the IntelliSep® Test was commercially available immediately after FDA marketing authorization. The applicant stated that one IntelliSep® Test is used per patient per inpatient stay.

The applicant stated that, effective April 1, 2025, the following ICD–10–PCS procedure code may be used to uniquely describe procedures involving the use of the IntelliSep® Test: XXE5X5A (Measurement of immune response, whole blood cellular assessment via microfluidic deformability, new technology group 10). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the IntelliSep® Test using the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that the IntelliSep® Test is not substantially similar to other currently available technologies because the IntelliSep® Test is the only FDA-cleared test that uses a microfluidic deformability cytometry technique for early detection of sepsis in the ED regardless of whether the patient is admitted to the hospital or not and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for the IntelliSep® Test for the applicant's complete statements in support of its assertion that the IntelliSep® Test is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	The IntelliSep® Test is the only test that uses a microfluidic deformability cytometry technique to measure the biophysical properties of thousands of individual leukocytes in rapid succession. These properties have been shown to differ in quiescent white blood cell populations when compared to those in septic patients, enabling for rapid assessment of the host response and the likelihood of having or developing sepsis. Other tests for sepsis exist, but these tests measure biomarker levels or gene expression to generate their signal.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The use of any test to detect the presence of sepsis does not impact the MS–DRG assignment of the discharge.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	While other tests can be used to detect the presence of sepsis, the IntelliSep® Test is the first and only FDA-cleared test for early detection of sepsis with organ dysfunction in adult patients with signs and symptoms of infection who present to the ED, regardless of whether the patient is admitted to the hospital or not. Other tests indicated for early detection of sepsis can only be administered after the patient has been admitted to the hospital.

With respect to the substantial similarity criteria, we note the following concerns. We note that the applicant did not compare the IntelliSep® Test's mechanism of action to those of other sepsis tests or detection tools, such as the Early Sepsis Indicator for monocyte distribution width (MDW), SeptiCyte® RAPID, and Sepsis ImmunoScore™. We further note that MDW measurement involves the assessment of white blood cells to detect pathogen-induced infections. Specifically, MDW measures the variability in peripheral monocyte morphologic characteristics that increase during early phases of infection after pathogen-induced monocyte activation.[117] Notably, monocytes (measured for MDW) are one type of leukocyte, and the IntelliSep® Test also evaluates leukocytes in its mechanism of action.[118] While the techniques of leukocyte measurement may differ, the subject of measurement appears to be the same or similar. Therefore, we question whether the IntelliSep® Test's measurement of leukocytes and their deformities is a unique mechanism of action, particularly in comparison to the Early Sepsis Indicator. Further, we question whether the measurement of different biomarkers or gene expression to determine the risk of sepsis is different than the measurement of leukocyte properties to determine the risk of sepsis. We are interested in information regarding how the IntelliSep® Test's mechanism of action differs from other such sepsis tests and detection tools.

In addition, while the applicant stated that the use of the IntelliSep® Test does not involve treatment of the same or similar population and disease as existing technologies, we note that the IntelliSep® Test is a diagnostic tool to evaluate patients with suspected infection, as are other FDA-cleared sepsis diagnostic tools, such as those that calculate Quick Sequential Organ Failure Assessment (qSOFA) scores (for example, SpassageQ[119] or NAVOY CDS®[120]). Furthermore, there are also other means of assessment, including body temperature, respiratory rate, heart rate, blood counts, and blood cultures, that are used to diagnosis sepsis. We also question whether a patient's location, whether in the ED, admitted to the hospital, or in the intensive care

[117] Malinovska, A., Hernried, B., Lin, A., Badaki-Makun, O., Fenstermacher, K., Ervin, A.M., Ehrhardt, S., Levin, S., & Hinson, J.S. (2023). Monocyte Distribution Width as a Diagnostic Marker for Infection: A Systematic Review and Meta-analysis. *Chest, 164*(1), 101–113. *https://doi.org/10.1016/j.chest.2022.12.049.*

[118] U.S. Food and Drug Administration. (2022). *510(k) approval letter for IntelliSep Test, 21 CFR 866.3215, device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis. https://www.accessdata.fda.gov/cdrh_docs/pdf22/K220991.pdf.*

[119] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230386.pdf.*

[120] *https://www.accessdata.fda.gov/cdrh_docs/pdf24/K240558.pdf.*

unit (ICU) constitutes a different population. Further, we note that there are existing sepsis diagnostic technologies that are also approved for use in the ED such as the Early Sepsis Indicator and Sepsis ImmunoScore™, which were FDA market-authorized on March 18, 2019 and April 2, 2024, respectively.[121] [122] Therefore, it is unclear that there are no existing technologies other than the IntelliSep® Test that are involved with the diagnosis of sepsis in adult patients who have signs and symptoms of infection.

We are inviting public comments on whether the IntelliSep® Test is substantially similar to existing technologies and whether the IntelliSep® Test meets the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that the IntelliSep® Test meets the cost criterion. The analysis followed the order of operations summarized in the following table.

INTELLISEP® TEST COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for the IntelliSep® Test.
Claims identified	2,708,804 claims mapping to 717 MS–DRGs, with 18.86% of claims mapping to MS–DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC).
Charges removed for prior technology.	Per the applicant, the IntelliSep® Test is not replacing a prior technology as it provides additional information to the clinician to determine if the patient has sepsis. As such, the applicant did not remove any estimated charges for a prior technology. The applicant stated that 25% of charges associated with Room and Board (revenue centers 011X–015X) and ICU/CCU (021X, 022X) were removed as the use of this technology can reduce average length of stay.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.102 for Laboratory from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $75,886. Final inflated average case-weighted standardized charge per case: $86,075.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the IntelliSep® Test meets the cost criterion.

We are inviting public comments on whether the IntelliSep® Test meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the IntelliSep® Test represents a substantial clinical improvement over existing technologies because the IntelliSep® Test is the only technology that is FDA-cleared for use in the ED to rapidly assess immune activation and identify sepsis risk in approximately 10 minutes, providing actionable results that significantly impact clinical decision-making and patient outcomes. The applicant provided 9 studies to support these claims,[123] as well as 19 background articles about international sepsis guidelines, antimicrobial therapy initiation, timing of antibiotic administration, and other topics related to sepsis detection. We note that two other articles were submitted as supporting evidence (Kraus et al., 2023; Rhee et al., 2017), which we believe should be characterized as background articles because they do not directly assess the use of the IntelliSep® Test.[124] Instead, Kraus et al. (2023) focused on evaluating key attributes of rapid host response sepsis tests via an expert review panel, and Rhee et al. (2017) estimated the U.S. incidence of sepsis and sepsis trends using electronic health records. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for the IntelliSep® Test for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.	
IntelliSep® Test assists physicians in identifying patients where sepsis is unlikely, allowing for the more rapid pursuit of alternate diagnoses.	Sheybani, Roya, Matt Sorrells, Daniel Henning, et al. ''Evaluation of a cellular host response test in sepsis diagnosis and risk-stratification in emergency patients with hemodynamic or cardiopulmonary instability'' CHEST 166, no. 4 (October 1, 2024): A2163–64. *https://doi.org/10.1016/j.chest.2024.06.1335* O'Neal HR Jr., et al. Cellular host response sepsis test for risk stratification of patients in the emergency department: a pooled analysis. Acad Emerg Med. 2024a. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

[121] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K181599.*

[122] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/DEN230036.pdf.*

[123] One of these studies (Sheybani et al., 2024) is a published abstract that was retracted.

[124] Kraus, C.K., Nguyen, H.B., Jacobsen, R.C., Ledeboer, N.A., May, L.S., O'Neal, H.R., Jr., Puskarich, M.A., Rice, T.W., Self, W.H., & Rothman, R.E. (2023). Rapid identification of sepsis in the emergency department. *Journal of the American College of Emergency Physicians Open, 4,* e12984. *https://doi.org/10.1002/emp2.12984.*

Applicant statements in support	Supporting evidence provided by the applicant
IntelliSep® Test allows clinicians to make early, appropriate antibiotic decisions in patients with suspected sepsis while pursuing antimicrobial stewardship targets.	O'Neal, 2024a, *op. cit.* Thomas CB, Hollis AK, Sorrells MG, et al. Evaluation of early-stage implementation results of a cellular host-response test in an emergency department setting. Presented at ECCMID 2024a. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test provides clinicians with actionable results sooner than pathogen-based detection systems.	Jagneaux T, Grantham A, Richard K, et al. Novel Diagnostic for Patients Presenting to the ED with Possible Infection. Association for Diagnostics & Laboratory Medicine Conference. July 31, 2024. O'Neal, 2024a, *op. cit.* O'Neal HR Jr, Sheybani R, Janz DR, et al. Validation of a Novel, Rapid Sepsis Diagnostic for Emergency Department Use. Crit Care Explor. 2024b;6(2):e1026. Published 2024b Feb 7. doi:10.1097/CCE.0000000000001026. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test outperforms current sepsis diagnostic tools available for use in the Emergency Department.	O'Neal, 2024a, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test effectively differentiates sepsis from non-specific biomarker elevations in various clinical conditions.	O'Neal, 2024a, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Sepsis is a dysregulated response to infection. IntelliSep® Test is the only FDA-cleared test to assess immune response in patients presenting to the ED.	Guillou L, Sheybani R, Jensen AE, et al. Development and validation of a cellular host response test as an early diagnostic for sepsis. PLoS One. 2021;16(4):e0246980. Published 2021 Apr 15. doi:10.1371/journal.pone.0246980. O'Neal, 2024a, *op. cit.* Sorrells MG, Seo Y, Magnen M, et al. Biophysical Changes of Leukocyte Activation (and NETosis) in the Cellular Host Response to Sepsis. Diagnostics. 2023;13:1435. doi:10.3390/diagnostics13081435. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
IntelliSep® Test reduces door to bedtime for patients presenting with Occult sepsis who appear clinically stable by triage staff. IntelliSep® Test identifies high-risk patients earlier, even when they appear clinically stable.	Jagneaux, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test results enable ED providers to decrease use of diagnostic images and testing, resulting in decreased exposure and associated risks.	O'Neal, 2024a, *op. cit.* Thomas, 2024a, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test's rapid turnaround time allows for prompt attention to infection source identification and control.	Jagneaux, 2024, *op. cit.* Thomas C, Richard K, Grantham A, et al. Evaluation of early stage implementation results of a cellular host-response test in decreasing sepsis mortality for patients presenting to the ED. Presented at: Society of Critical Care Medicine (SCCM) Annual Congress; February 23–25, 2025; Orlando, Florida, USA. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test aids in reducing risk of mortality amongst tested patients.	O'Neal, 2024a, *op. cit.* Jagneaux, 2024, *op. cit.* Thomas, 2025, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test aids in reducing average length of stay (LOS) amongst tested patients.	O'Neal, 2024a, *op. cit.* Jagneaux, 2024, *op. cit.* Thomas CB, Hollis A, Teague L, et al. The fiscal impact of a rapid sepsis diagnostic in the Emergency Department (ED). Presented at: 44th International Symposium on Intensive Care and Emergency Medicine (ISICEM); 2024b; Brussels, Belgium. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test aids improved compliance with the CMS SEP–1 and Surviving Sepsis Campaign 3-hour bundle compliance.	O'Neal, 2024a, *op. cit.* Jagneaux, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
IntelliSep® Test aids sepsis antibiotic initiation consistent with current consensus guidelines.	O'Neal, 2024a, *op. cit.* Jagneaux, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We also received a public comment in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the IntelliSep® Test, which we summarize in this section.

Comment: The applicant submitted a public comment in response to questions asked at the Town Hall regarding the comparison of the IntelliSep® Test to other sepsis tests, namely to technology that assesses MDW and SeptiCyte® RAPID. The applicant submitted an additional study (Sarani et al., 2024), which concluded that the IntelliSep® Test, along with von Willebrand factor (vWF)/ADAMTS13 ratios, may be useful and appear to be superior to the traditional marker, MDW, for the early diagnosis of sepsis in patients visiting the ED.[125] This 2024 study investigated the use of the IntelliSep® Test, MDW, and other biomarkers to diagnose sepsis in 44 patients (25 patients with a low probability of sepsis and 19 patients with a high probability of sepsis) who visited the ED at The University of Kansas Medical Center. The applicant noted that MDW is not widely used as a screening tool in the ED, which is where the IntelliSep® Test is indicated for use. Regarding comparison of the IntelliSep® Test to SeptiCyte® RAPID, the applicant stated that it believes a comparison between the two sepsis diagnostic tests is inappropriate given the differences in indicated uses for the tests, primarily the indicated location; IntelliSep® Test is indicated for use in the ED prior to the provider's decision to admit the patient, whereas SeptiCyte® RAPID is used first day post-admission to the ICU. The applicant cited a recent study that found only 16.1 percent of patients tested with the IntelliSep® Test are admitted to the ICU.[126]

Response: We thank the applicant for its comments. After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether the IntelliSep® Test meets the substantial clinical improvement criterion. Regarding the new study provided by the applicant in the Town Hall comment, we note that Sarani et al. (2024) does not compare the IntelliSep® Test and MDW with respect to the ability to diagnose sepsis earlier or resulting clinical outcomes (for example, length of stay or mortality).

The applicant made six claims in regard to the substantial clinical improvement assertion that the IntelliSep® Test offers the ability to diagnose sepsis in a patient population where the condition is currently undetectable or offers the ability to diagnose sepsis earlier in a patient population than allowed by currently available methods; however, we note that a number of these claims did not address this criterion. Specifically, the applicant stated that the IntelliSep® Test (1) allows clinicians to make early, appropriate antibiotic decisions in patients with suspected sepsis while pursuing antimicrobial stewardship targets; (2) outperforms current sepsis diagnostic tools available for use in the ED; (3) effectively differentiates sepsis from non-specific biomarker elevations in various clinical conditions; (4) is the only FDA-cleared test to assess dysregulated immune response to infection (sepsis) in patients presenting to the ED; and (5) has demonstrated a high NPV for sepsis and therefore allows for it to be ruled out where sepsis is unlikely. These claims discuss the reliability of the IntelliSep® Test outcomes or the potential benefits of sepsis risk stratification, or relate to not diagnosing sepsis, and do not address the ability of the IntelliSep® Test to diagnose a patient population where sepsis is currently undetectable or offer the ability to diagnose sepsis earlier than other technologies.

We further note that none of the claims made by the applicant under this assertion provided a comparison of time to diagnosis to currently available sepsis diagnostics in order to demonstrate that the IntelliSep® Test can diagnose sepsis earlier than currently available methods. While the applicant provided O'Neal et al. (2024b), which established the 7.2 minute testing turnaround time for the IntelliSep® Test to support the claim that it provides clinicians with actionable results sooner than pathogen-based detection systems, the only other testing time provided as a comparison was from a study comparing time to positivity between the BacT/Alert and BACTEC blood culture systems (Butler-Laporte et al., 2020). We would appreciate evidence comparing time to diagnosis for the IntelliSep® Test and other existing sepsis detection tools also developed to address the length of time to definite sepsis diagnosis with blood cultures, such as Early Sepsis Indicator or Sepsis ImmunoScore, in order to demonstrate the applicant's assertion that the IntelliSep® Test allows for faster detection of sepsis compared to existing technologies.

We further note that we did not receive any information demonstrating that clinicians changed the management of patients due to the use of the IntelliSep® Test. The Jagneaux et al. (2024) study measured time-to-bed assignment (TTB) when nurses at one medical center triaged patients in the ED waiting room, tested patients using the IntelliSep® Test, and placed patients with IntelliSep® Band 3 results in ED beds. The study showed that TTB for Band 3 was shorter than TTB for Band 1, but we question whether TTB between risk-stratified bands should be considered a change in management. The study did not include a control group or comparison to other sepsis tests or diagnostic tools to demonstrate differences in patient management between the use of the IntelliSep® Test and other standards of care. We further note that Jagneaux et al. (2024), which is an unpublished abstract, lacked details regarding the patient population, study protocol, and statistical analyses, and is only representative of a single medical center. We are therefore unclear whether the results may be influenced by potential confounding factors, and we question whether they are generalizable to other EDs or geographic regions as well as to the Medicare population.

The applicant also made seven claims in regard to the substantial clinical improvement assertion that the IntelliSep® Test significantly improves clinical outcomes relative to services or technologies previously available. However, we note that a number of these claims do not address this criterion. In particular, the applicant stated that the IntelliSep® Test (1) reduces door-to-bed time for patients presenting with occult sepsis who appear clinically stable by triage staff; (2) allows for prompt attention to infection source identification and control through its rapid turnaround time; (3) aids improved compliance with the CMS SEP–1 and Surviving Sepsis Campaign 3-hour bundle compliance; and (4) aids sepsis antibiotic initiation consistent with current consensus guidelines. First, we question whether the claim that the IntelliSep® Test reduces door-to-bed time is an appropriate proxy for timely

[125] Sarani, N., Dasgupta, A., Enders, M., Rowan, L., Elsarraj, H., Gralnek, S., Shay, M., Lemar, L.R., Simpson, S.Q., Cunningham, M.T., & Zheng, X.L. (2024). Clinical Utility of Recently Food and Drug Administration-Approved IntelliSep® Test (Sepsis Biomarker) for Early Diagnosis of Sepsis: Comparison with Other Biomarkers. *Journal of Clinical Medicine, 13*(16), 4852. *https://doi.org/10.3390/jcm13164852.*

[126] O'Neal, H.R., Jr, Sheybani, R., Kraus, C.K., Self, W.H., Shah, A.M., Thomas, C.B., Tse, H.T.K., & Scoggins, R. (2024b). Cellular host response sepsis test for risk stratification of patients in the emergency department: A pooled analysis. Academic Emergency Medicine, 31(9), 883–893. *https://doi.org/10.1111/acem.14923.*

antibiotic administration and the potential for subsequent clinical outcomes (such as mortality). The strength of the direct association between time from door-to-bed and clinical outcome improvement or whether any outcomes are inferred from surrogate endpoints is unclear. We also note that the provided evidence does not demonstrate whether the IntelliSep® Test is the driving factor, among all other tests and clinical practices, that allows timely infection source identification and control and, therefore, decreases mortality. Additionally, we are unclear about the direct association between the IntelliSep® Test and antibiotic initiation for sepsis consistent with current guidelines as this is also only inferred, and the IntelliSep® Test is one tool among others used to diagnose sepsis. We also question whether compliance with the CMS SEP–1 and Surviving Sepsis Campaign 3-hour bundles is intended as a proxy for decreased mortality that may occur from reducing the time to antibiotic administration. We note that a decrease in mortality is only inferred, and the provided evidence does not demonstrate that the IntelliSep® Test decreases mortality. We are unclear how these claims relate to a demonstration of substantial clinical improvement over existing technologies because these claims do not pertain to clinical outcomes described at § 412.87(b)(1)(ii)(C), such as a reduction in mortality or a decreased rate of at least one subsequent diagnostic or therapeutic intervention.

We also note that the claims and the provided evidence regarding the IntelliSep® Test's ability to significantly improve clinical outcomes relative to services or technologies previously available lack a comparison of the IntelliSep® Test to existing technologies used to diagnose sepsis, such as the previously discussed Early Sepsis Indicator, SeptiCyte® RAPID, and Sepsis ImmunoScore™. While the applicant stated in its Town Hall comment that a comparison between the IntelliSep® Test and SeptiCyte® RAPID is inappropriate due to the differences in indicated location, we question whether the impact of testing different patients in different environments within a hospital would be relevant to clinical outcomes such as timely antibiotic administration and mortality. In addition, we note that both Early Sepsis Indicator and Sepsis ImmunoScore™ are indicated for use in the ED. We are interested in comparative evidence for other sepsis diagnostic technologies in order to evaluate the IntelliSep® Test's clinical outcomes relative to other technologies. We also note that since much of the evidence provided across claims (Thomas et al. (2025); Thomas et al. (2024a); Thomas et al. (2024b)) is unpublished, the details provided do not include study protocols or statistical methods and measures. As such, we are unable to account for differences in the outcome measures or determine if the results are statistically significant. Further, because these study results are from one academic medical center, we question whether the results are generalizable to other hospitals and more broadly to the Medicare population. Where the Jagneaux et al. (2024) study was used to support claims regarding the IntelliSep® Test's ability to significantly improve clinical outcomes relative to services or technologies previously available, we also have the same concerns as previously discussed, including lack of details regarding the patient population, study protocol, and statistical analyses.

In addition, with respect to the claim that IntelliSep® Test results enable ED providers to decrease the use of diagnostic images and testing, resulting in decreased exposure and associated risks, while Thomas et al. (2024a) evaluated the impact of the IntelliSep® Test on blood culture orders, antibiotic usage, and patients' LOS for 1,275 patients who presented to an ED with signs or symptoms of infection, we note that the study did not determine whether a decrease in these measures resulted in patients experiencing decreased exposure and associated risks or a significant improvement in clinical outcomes relative to technologies previously available.

While the Jagneaux et al. (2024) study provided by the applicant did not measure mortality, the applicant provided the O'Neal, et al. (2024a) study, which did measure all-cause cumulative hospital mortality stratified by IntelliSep® bands; however, the study only compared the IntelliSep® Test to common traditional sepsis tests or detection tools, such as white blood cell count, procalcitonin, lactate, blood cultures, and the Sequential Organ Failure Assessment (SOFA). O'Neal et al. (2024a) did not provide hospital mortality data to demonstrate the IntelliSep® Test improved clinical outcomes relative to other technologies that are available, such as Early Sepsis Indicator, SeptiCyte® RAPID, and Sepsis ImmunoScore™.

Regarding the claim that the IntelliSep® Test aids in reducing average LOS among tested patients, the Thomas et al. (2024b) study submitted by the applicant found that incorporating the IntelliSep® Test and releasing its results to clinicians for 413 patients of a large U.S. academic medical center led to a reduction of 1.28 days for inpatients and 2.42 days for ICU patients, when compared to 196 patients in the control group for which the IntelliSep® Test was performed but not released to clinicians. We note that the study used control and intervention cohorts that were not concurrent, and we question the impact from varying confounders, such as changes in clinical policy. We note that the applicant also included background studies to demonstrate a positive association between longer hospital LOS and the probability of acquiring an infection, readmission, negative emotions, and increased hospital costs.[127] However, these studies did not assess the IntelliSep® Test's ability to affect LOS, rates of infection, readmission, or other clinical outcomes.

Lastly, we question how much capability should be attributed to the IntelliSep® Test when making clinical judgments and improving clinical outcomes, and we welcome additional information.

We are inviting public comments on whether the IntelliSep® Test meets the substantial clinical improvement criterion.

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

Contego Medical, Inc. submitted an application for new technology add-on payments for the Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection (Neuroguard IEP® System) for FY 2026. According to the applicant, the Neuroguard IEP® System combines a carotid stent with an integrated 40 µm embolic protection filter and post-dilation balloon. Per the applicant, the Neuroguard IEP® System restores and maintains vessel patency while stabilizing plaque, and by capturing small emboli during critical phases, it reduces the risk of stroke during the procedure and helps prevent future stroke.

Please refer to the online application posting for the Neuroguard IEP® System, available at *https://mearis.cms.gov/public/publications/ntap/NTP241004CNKB9*, for additional detail describing the technology and carotid artery disease.

[127] Hassan, M., Tuckman, H.P., Patrick, R.H., Kountz, D.S., & Kohn, J.L. (2010). Hospital length of stay and probability of acquiring infection. *International Journal of Pharmaceutical and Healthcare Marketing, 4*(4), 324–338. *https://doi.org/10.1108/17506121011095182.*

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

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Neuroguard IEP® System. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Neuroguard IEP® System beginning in FY 2026. The applicant stated that codes I65.21 (Occlusion and stenosis of right carotid artery), I65.22 (Occlusion and stenosis of left carotid artery), I65.23 (Occlusion and stenosis of bilateral carotid arteries), or I65.29 (Occlusion and stenosis of unspecified carotid artery) may be used to currently identify the indication for the Neuroguard IEP® System under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that the Neuroguard IEP® System is not substantially similar to other currently available technologies because it is a first-in-class, novel device that uses a different mechanism of action compared to existing technologies by integrating a stent with a 40 μm (3 to 4 times smaller than pores of traditional filters) embolic protection filter and a post-dilation balloon, aiming to streamline the procedure and increase the effectiveness of embolic protection during carotid stenting, and that no other similar device is currently available in the U.S., and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for the Neuroguard IEP® System for the applicant's complete statements in support of its assertion that the Neuroguard IEP® System is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Multiple clinical studies have reported that the majority of debris released during carotid stenting is less than 100 microns (μm). The Neuroguard IEP® System features an innovative 40 μm embolic protection filter, with pores 3–4 times smaller than traditional filters used in carotid artery stenting (CAS), providing a substantial clinical improvement in capturing those microembolic particles. Traditional embolic protection devices (EPDs) have pore sizes of 100 to 150 μm, allowing smaller microemboli to pass through, which can result in strokes and cognitive impairment for patients. Unlike other technologies, the Neuroguard IEP® System offers continuous protection during the most critical phases of carotid stenting—stent deployment and balloon dilation—when the risk of plaque dislodgement is highest. Conventional EPDs cannot use smaller pores because they are open throughout the entire procedure and must permit sufficient flow to reduce the risk of thrombosis and complications. In contrast, the Neuroguard IEP® System integrated filter is open only during the critical phases allowing it to use smaller pores (40 μm) without increasing thrombosis risk, delivering enhanced protection while maintaining safety. Unlike conventional CAS systems that rely solely on separate EPDs, the Neuroguard IEP® System's filter is integrated into the device and dynamically adjusted to create a complete seal against the artery wall, ensuring even the smallest micro-emboli are captured. This greatly reduces the risk of embolic particles traveling to the brain, demonstrating a substantial clinical improvement over existing technologies in stroke prevention. The Neuroguard IEP® System stent incorporates a hybrid design that balances flexibility and radial strength, enabling precise deployment and secure vessel scaffolding. This helps to minimize risks such as restenosis or stent migration, challenges often seen with traditional stents that compromise either flexibility or strength. The Neuroguard IEP® System's flexible segments facilitate deployment in challenging anatomy while maintaining long-term vessel support. The stent is designed to enhance precision, reduce trauma or migration risks, and allow for predictable deployment, helping to reduce procedural complications. By integrating embolic protection, stenting, and dilation into one device, the Neuroguard IEP® System eliminates the need or multiple devices, reducing catheter exchanges and procedural complexity. While traditional distal embolic protection devices have larger pores that allow micro-emoli to reach the brain, potentionally causing stroke or cognitive impairment, the Neuroguard IEP® System addresses this risk by capturing micro emboli, reducing the likelihood of such adverse events. This new mechanism of action offers a safer and more effective approach to treating carotid artery stenosis, representing a substantial clinical improvement over existing technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The Neuroguard IEP® System falls under the MS–DRGs related to procedures performed on the carotid arteries, which include stenting procedures. However, despite being assigned to the same MS–DRG, the Neuroguard IEP® System represents a distinct technological advancement that warrant separate consideration under the new technology add-on payment criteria. Its innovative approach to embolic protection and the demonstrated substantial clinical improvement over existing technologies justify the need for additional payment beyond the standard MS–DRG rates to ensure appropriate reimbursement and broader adoption of this superior technology.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	The Neuroguard IEP® System is used to treat the same disease, carotid artery stenosis, in the same patient population as existing carotid stent technologies. However, it offers substantial clinical improvements, particularly in reducing the risk of stroke during the procedure. Traditional CAS methods rely on separate EPDs, which have limitations in capturing small embolic particles, especially during the riskiest parts of the procedure—stent deployment and balloon dilation.

We have the following concerns with regard to the newness criterion. While the applicant asserted that the Neuroguard IEP® System is novel in that it uses a new mechanism of action because its 40 µm embolic protection filter has pores 3–4 times smaller than traditional filters used in CAS, we question whether this represents a new mechanism of action as both Neuroguard's filter and existing filters use a porous membrane to capture and remove embolic material while performing angioplasty and stenting procedures in carotid arteries. We note that the applicant asserted that this change in filter size may impact clinical outcomes, however, this is not relevant to mechanism of action. Furthermore, the Neuroguard IEP® System should always be used in conjunction with an available primary distal embolic protection device as described in the IFU,[128] which suggests that its filter would not impact the mechanism of action of the device. We also note that there are other existing embolic protection filters used during CAS procedures that have the same 40-micron pore size, such as the Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection (Paladin System with IEP) from the same manufacturer, which received FDA 510(k) clearance on September 6, 2018.[129]

In addition, while the applicant asserted that the Neuroguard IEP® System has a new mechanism of action because it integrates a stent with an embolic protection filter that opens during stent deployment and balloon dilation to streamline the procedure and increase the effectiveness of embolic protection during CAS, we question how integrating existing procedural devices into one device to eliminate the need for multiple devices results in a different mechanism of action, as this appears to describe an ease-of-use feature rather than having an impact on the technology's therapeutic outcome of improving carotid luminal diameter for patients with stenosis of the carotid artery.[130] It is unclear how the way in which the Neuroguard IEP® System treats carotid artery stenosis is different from the way in which the many existing carotid artery stents, filters, and post-dilation balloons available on the market, used together or as part of a system, treat carotid artery stenosis. Therefore, it appears these technologies may have the same or a similar mechanism of action as the Neuroguard IEP® System. We further note that the applicant stated that the Neuroguard IEP® System treats the same disease, carotid artery stenosis, in the same patient population as existing carotid stent technologies, and that it maps to the same MS–DRGs for carotid artery stenting procedures.

Accordingly, as it appears that the Neuroguard IEP® System and existing carotid stents or stent systems, such as the GORE Carotid Stent, RX Acculink™ Carotid Stent System, or Carotid WALLSTENT® Monorail® Endoprosthesis, or the Paladin System with IEP used with any available carotid artery stent, may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and would treat the same or similar patient population and disease, we question whether these technologies may be substantially similar to one another. We note that, per our policy, if technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for the technologies. Accordingly, if we determine that the Neuroguard IEP® System is substantially similar to existing carotid stents or systems as described previously, because the 3-year anniversary of the FDA clearance of all these current technologies occurred prior to FY 2026,[131] [132] [133] the Neuroguard IEP® System would not be considered new.

We are inviting public comment on whether the Neuroguard IEP® System is substantially similar to existing technologies and whether the Neuroguard IEP® System meets the newness criterion.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that the Neuroguard IEP® System meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

[128] Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection (*https://www.accessdata.fda.gov/cdrh_docs/pdf24/P240009A.pdf*).

[129] FDA. Section 510(k) premarket notification. Paladin Carotid Post-Dilation Balloon System with Integrated Embolic Protection. K181128. September 6, 2018 (*https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K181128*, accessed 2/5/2025).

[130] FDA. Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection. Pre-market approval. October 11, 2024.

[131] The 3-year anniversary of FDA PMA approval for the RX Acculink ™ Carotid Stent System was August 30, 2007. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P040012.*

[132] The 3-year anniversary of FDA PMA approval for Carotid WALLSTENT® Monorail® Endoprosthesis was October 23, 2011. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P050019.*

[133] The 3-year anniversary of FDA PMA approval for GORE Carotid Stent was November 1, 2021. *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?ID=P180010.*

NEUROGUARD IEP® SYSTEM COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for the Neuroguard IEP® System.
Claims identified	Scenario 1: 13,115 claims mapping to 69 MS–DRGs, with 49.68% claims mapping to MS–DRG 036 (Carotid Artery Stent Procedure Without CC/MCC). Scenario 2: 11,876 claims mapping to 3 MS–DRGs, with 54.86% of claims mapping to MS–DRG 036 (Carotid Artery Stent Procedure Without CC/MCC).
Charges removed for prior technology.	Per the applicant, use of the technology would replace current existing stent and dilating balloon technologies used in traditional carotid artery stenting. The applicant removed charges for the existing stent and dilating balloon by dividing the estimated costs by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Scenario 1: —Average case-weighted threshold amount: $101,119. —Final inflated average case-weighted standardized charge per case: $133,183. Scenario 2: —Average case-weighted threshold amount: $95,139. —Final inflated average case-weighted standardized charge per case: $116,240.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the Neuroguard IEP® System meets the cost criterion.

We are inviting public comments on whether the Neuroguard IEP® System meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that the Neuroguard IEP® System represents a substantial clinical improvement over existing technologies because the Neuroguard IEP® System significantly improves clinical outcomes relative to technologies previously available by using a 40 μm embolic protection filter that captures microemboli, unlike traditional filters (100–150 μm) that miss smaller emboli, leading to higher stroke rates. Further, the applicant asserted that the Neuroguard IEP® System demonstrated a zero percent stroke rate in the PERFORMANCE I study, 1.3 percent at 30 days, and 1.8 percent at 12 months in the PERFORMANCE II study, demonstrating substantial clinical improvement compared to other CAS technologies. The applicant provided 2 studies to support its claims, as well as a supplemental document that presents the 30-day and 12-month stroke rates of carotid artery stents from clinical studies, and 8 background articles about other FDA-approved CAS or EPD technologies.[134] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for the Neuroguard IEP® System for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology significantly improves clinical outcomes relative to services or technologies previously available

The Neuroguard IEP® System demonstrates a substantial clinical improvement over existing CAS technologies by integrating an embolic protection filter that minimizes the risk of stroke and cognitive impairment.	Langhoff R, Petrov I, Kedev S, et al., PERFORMACE 1 Study: Novel carotid stent system with integrated post-dilation balloon and embolic protection device. Catheter Cardiovasc Interv. 2022 Nov;100(6):1090–1099. Gray WA, Metzger DC, Zidar J, et al. The PERFORMANCE II Trial: A Prospective Multicenter Investigation of a Novel Carotid Stent System. JACC Cardiovasc Interv. Published online December 20, 2024. doi:10.1016/j.jcin.2024.10.031. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for the Neuroguard IEP® System.

After review of the information provided by the applicant, we have the following concerns regarding whether the Neuroguard IEP® System meets the substantial clinical improvement criterion. With respect to the claim that the Neuroguard IEP® System demonstrates a substantial clinical improvement over existing CAS technologies by integrating an embolic protection filter that minimizes the risk of stroke and cognitive impairment, we note that the applicant has provided evidence comparing the effects of the Neuroguard IEP® System to historical controls based on several clinical trials, including the Xact® Carotid Stent System of the SECURITY trial,[135] the ACCULINK carotid stent of the ARCHER

[134] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[135] FDA. SECURITY: Xact® Carotid Stent System—P040038/S043. Summary of Safety and Effectiveness Data. Published August 5, 2004. (*https://www.fda.gov/medical-devices/recently-approved-devices/xact-carotid-stent-system-p040038s043*, accessed 1/24/2025).

trial,[136] the Carotid WALLSTENT and FilterWire EX/EZ of the BEACH trial,[137] the GORE Carotid Stent of the SCAFFOLD trial,[138] the S.M.A.R.T. or Precise stent with Angioguard or Angioguard XP, Cordis EPD of the SAPPHIRE trial,[139] and Accunet and Acculink Systems of the CREST trial.[140] However, we did not receive information comparing the Neuroguard IEP® System with other currently available treatments developed more recently, such as GORE Carotid Stent, Sterling SL Balloon Dilatation Catheters, or Paladin System, and we would appreciate additional information comparing these technologies in order to inform our assessment of substantial clinical improvement.

In addition, we note that the applicant compared the Neuroguard IEP® System with historical controls based on externally controlled trials from at least a decade ago. While the results of the SCAFFOLD trial were published more recently, in 2020, other externally controlled trials were published or completed at least a decade earlier (SAPPHIRE: 2004; SECURITY: 2005; ARCHER: 2006; BEACH: 2008; CREST: 2010; ROADSTER: 2015). In particular, SAPPHIRE was conducted when CAS was new.[141] We also note that the pre- and post-treatment protocols for the PERFORMANCE II trial were more comprehensive compared to those of the SAPPHIRE trial [142] and that this may reflect changes in standards of care over the past two decades. For example, we note that the patients in the PERFORMANCE II had been given clopidogrel 75 mg (or equivalent) and aspirin 75 mg daily for one week before surgery, and dual antiplatelet therapy was required for at least 30 days after the procedure (and thereafter, at the physician's discretion and standard of care), whereas the patients in the SAPPHIRE trial were given an aspirin at a dose of 81 or 325 mg per day for at least 72 hours before the procedure and indefinitely after the procedure, and with clopidogrel 75 mg per day starting 24 hours before the procedure and continuing for two to four weeks after the procedure. We are also concerned that observed differences between the Neuroguard IEP® System and the historical controls may also reflect improvements in stent devices, access approaches, and embolic protection methods over the past decade that aimed at reducing the risk of stroke associated with CAS.[143] Therefore, we question whether the observed lower stroke rate was at least partly the result of a more advanced and comprehensive treatment protocol. We also question whether growth in CAS volume, a multitude of commercially available FDA-approved carotid stents, changes in standard of care, and trends in the prevalence of diabetes and hypertension in the U.S. population during the last two decades were considered in the interpretation of the findings of the two PERFORMANCE trials.

We are also concerned about the use of historical controls, given the differences among the trials, and question how these differences were taken into account in the development of the performance goal and in the comparison with the Neuroguard IEP® System on improving clinical outcomes. First, those trials differed in study design (SECURITY: non-randomized; BEACH, SCAFFOLD: single-arm; SAPPHIRE: RCT; CREST: RCT permuted block design) and length of follow-up (SECURITY, BEACH, ARCHER: 365 days; other: 3 years). Because these trials were not uniform in study design, we question whether results from these trials are comparable to each other. We further question whether the applicable technologies can be compared based on the outcomes achieved across these trials without considering differences between the clinical trials with respect to whether randomization and/or blinding were used in the study protocols, how patients were recruited and enrolled, patients' baseline clinical attributes, or length of follow up.[144] We also note that these trials defined some of their endpoints differently. For example, the SECURITY and SCAFFOLD trials measured 12-month outcomes, while the SAPPHIRE and ARCHER trials examined 31- to 365-day outcomes. While most of these trials assessed non-fatal myocardial infection (MI) and all-cause deaths, the BEACH trial reported Q-wave MI and neurologic deaths. Furthermore, we note that different inclusion criteria for asymptomatic patients were used, with the SAPPHIRE, SECURITY, BEACH, and SCAFFOLD trials including asymptomatic patients with ≥80 percent stenosis, and the CREST trial ≥70 percent stenosis. Regarding heterogeneity in the baseline clinical attributes of the patient samples, we note that the SECURITY, ARCHER, and BEACH trials included patients at least 80 years of age, while other trials did not. We further note that differences in the study population comorbidities and lesion characteristics may impact outcomes. In particular, the PERFORMANCE II trial had a higher proportion of diabetic patients (43 percent) than the SAPPHIRE (25 percent), CREST (31 percent), SECURITY (31 percent), and SCAFFOLD (40 percent) trials. Its proportion of patients with hypertension (93 percent) was higher than that of other trials (ARCHER: 84 percent; CREST: 86 percent; SAPPHIRE: 86 percent: BEACH: 89 percent). Its proportion of symptomatic patients (20 percent) was higher than that of the SCAFFOLD trial (13 percent), and lower than that of the ARCHER trial (24 percent). We are concerned that without adjusting for these differences across the trials, their results may not be comparable. We also question whether the lack of adjustment could have impacted accuracy of the performance goal which was based on the results of these trials. We welcome information about how these differences were accounted for in the development of the performance goal. We also welcome comments on how to consider the use of historical controls to compare the Neuroguard IEP® System's effects on clinical outcome improvement. Moreover, we are interested in information about the weighted objective performance criteria approach. Per the applicant, this approach adjusted for comorbid and anatomic

[136] Gray, W.A., Hopkins, L.N., Yadav, S., et al. (2006). Protected carotid stenting in high-surgical-risk patients: The ARCHeR results *Journal of Vascular Surgery* 44(2): 258–269.

[137] Cohen, D.J., Amarenco, P., Cramer, M.J., et al. Carotid Artery Revascularization in High-Surgical-Risk Patients Using the Carotid WALLSTENT and FilterWire EX/EZ: 1-Year Outcomes in the BEACH Pivotal Group. *J Am Coll Cardiol.* 2008;51(4):427–434. doi:10.1016/j.jacc.2007.10.022.

[138] Gray, W.A., Levy, E., Bacharach, J.M., et al. (2020). Evaluation of a novel mesh-covered stent for treatment of carotid stenosis in patients at high risk for endarterectomy: 1-year results of the SCAFFOLD trial. *Catheter Cardiovasc Interv.* 96:121–127.

[139] Yadav, J.S., Wholey, M.H., Kuntz, R.E., Fayad, P., Katzen, B.T., Mishkel, G.J., Bajwa, T.K., Whitlow, P., Strickman, N.E., Jaff, M.R., Popma, J.J., Snead, D.B., Cutlip, D.E., Firth, B.G., Ouriel, K., & Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy Investigators (2004). Protected carotid-artery stenting versus endarterectomy in high-risk patients. *The New England Journal of Medicine, 351*(15), 1493–1501. *https://doi.org/10.1056/NEJMoa040127.*

[140] Brott, T.G., Hobson, R.W. 2nd, Howard, G., et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis [published correction appears in N Engl J Med. 2010 Jul 29;363(5):498] [published correction appears in N Engl J Med. 2010 Jul 8;363(2):198]. *N Engl J Med.* 2010;363(1): 11–23. doi:10.1056/NEJMoa0912321.

[141] Yadav (2004), *op. cit.*

[142] Yadav (2004), *op. cit.*

[143] UpToDate. (2024). Overview of carotid artery stenting. UpToDate. Retrieved from *https://www.uptodate.com/contents/overview-of-carotid-artery-stenting/print?search=carotid%20artery%20stenting&source=search_result&selectedTitle=1~3.*

[144] Collignon O, Schritz A, Spezia R, et al. Implementing historical controls in oncology trials. *The Oncologist* 2021 (26):e858–e862.

high-risk factors and was calculated based on data from the ARCHER, SECURITY, BEACH, and SCAFFOLD trials. We also welcome information about how the comparative studies were selected.

We also question whether the observed differences in clinical outcomes between the Neuroguard IEP® System and the performance goal based on the historical comparator trials are statistically significant and clinically meaningful. For example, the applicant stated that the Neuroguard IEP® System demonstrated the result of zero percent for both 30-day and 12-month stroke rates in the PERFORMANCE I study, and 1.3 percent for the 30-day and 1.8 percent 12-month stroke rates in the PERFORMANCE II study. The applicant further stated that these rates were significantly lower than published clinical trials with similar symptomatic and asymptomatic patient populations, ARCHER (6.9 percent), BEACH (4.5 percent), SCAFFOLD (1.0 percent) SAPPHIRE (4.8 percent), and CREST (4.1 percent). We note that the SCAFFOLD trial reported a 30-day stroke rate of 1.1 percent for the primary analysis population, compared to the 1.3 percent rate in the PERFORMANCE II study. We welcome information about whether these differences were statistically significant and clinically meaningful, and how statistical significance was determined. We also welcome information about the weighted Z-test for the primary endpoint and how it may fully account for variability in patient comorbidities or procedural differences and enhance generalizability.

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

k. RYSTIGGO® (Rozanolixizumab-Noli)

UCB, Inc. submitted an application for new technology add-on payments for RYSTIGGO® for FY 2026. According to the applicant, RYSTIGGO® is a neonatal Fc receptor (FcRn) blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive (ab+). The applicant stated that gMG is a rare chronic autoimmune disorder in which antibodies destroy the communication between nerves and muscle, resulting in weakness of the skeletal muscles, particularly the eyes, mouth, throat, and limbs. Per the applicant, some gMG patients have MuSK ab+, a subtype of gMG that may lead to more severe symptoms and limited treatment options.

Please refer to the online application posting for RYSTIGGO®, available at *https://mearis.cms.gov/public/publications/ntap/NTP2410073H0PQ*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, RYSTIGGO® was granted BLA approval from FDA on June 26, 2023, for the treatment of gMG in adult patients who are AChR ab+ or MuSK ab+. According to the applicant, RYSTIGGO® was not available for sale until July 20, 2023, the date on which the product was released from U.S. Customs after being shipped from an overseas manufacturing facility. Per the applicant, RYSTIGGO® is administered as a subcutaneous infusion once each week for 6 weeks. Per the applicant, RYSTIGGO® is available in single-dose vials that contain 280 mg, 420 mg, 560 mg, or 840 mg of RYSTIGGO® at a concentration of 140 mg/mL. The applicant noted it used the following equation to calculate the weighted average cost per inpatient stay: [(percent of patients whose weight aligns to the 3mL vial × cost of the 3mL vial) + (percent of patients whose weight aligns to the 4mL vial × cost of the 4mL vial) + (percent of patients whose weight aligns to the 6mL vial × cost of the 6mL vial/100%] × 2 doses. The applicant stated that the typical inpatient stay for patients with gMG is 11 to 13 days, and thus, 2 doses would usually be administered during a typical inpatient stay.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify RYSTIGGO®. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for RYSTIGGO® beginning in FY 2026. The applicant stated that G70.00 (Myasthenia gravis without (acute) exacerbation) and G70.01 (Myasthenia gravis with (acute) exacerbation) may be used to currently identify the indication for RYSTIGGO® under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that RYSTIGGO® is not substantially similar to other currently available technologies because, while other treatments are available for gMG, about 40 percent of patients continue to experience exacerbations, and that RYSTIGGO® is the only treatment for patients with gMG who are AChR or MuSK ab+, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for RYSTIGGO® for the applicant's complete statements in support of its assertion that RYSTIGGO® is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	RYSTIGGO® is a subcutaneously infused monoclonal antibody (mAb) that specifically targets FcRn with high affinity, permitting the accelerated removal of all subclasses of immunoglobulin G (IgG). There are specific differences in FcRn affinities between RYSTIGGO® and other FcRn inhibitors. RYSTIGGO® is the only FcRn inhibitor that is FDA-approved for MuSK ab+ gMG in adults.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The administration of RYSTIGGO® to treat gMG is not expected to change the MS–DRG assignment of the discharge.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	While other treatments are available for gMG, about 40% of patients continue to experience gMG exacerbation, suggesting an inadequate response to existing treatment. RYSTIGGO® is the only FDA-approved treatment for patients with gMG that are MuSK ab+.

With respect to the substantial similarity criteria, while the applicant stated that RYSTIGGO® does not use the same or a similar mechanism of action as compared to existing technologies because there are specific differences in FcRn affinities between RYSTIGGO® and other FcRn inhibitors, we are unclear as to what the specific differences are and whether they rise to the level of a new mechanism of action. We note that VYVGART® is also an FcRn inhibitor approved for use in patients with gMG, and per FDA prescribing information, both technologies bind to the FcRn resulting in the reduction of circulating IgG.[145] [146] We welcome additional information about how the mechanism of action for RYSTIGGO® differs from other existing FDA-approved therapies, including FcRn inhibitors such as VYVGART®. We note that the applicant also stated that RYSTIGGO® does not involve the treatment of the same or similar type of disease and the same or similar patient population when compared to an existing technology because while there are other treatments for gMG, about 40 percent of patients continue to experience gMG exacerbation, suggesting an inadequate response to existing treatment and RYSTIGGO® is the only FDA-approved treatment for patients with gMG that are MuSK ab+. However, we note there are other standard of care treatment options for patients with AChR ab+ and MuSK ab+ gMG, such as pyridostigmine, glucocorticoid therapy, and plasmapheresis. In addition, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS® are also treatment options for patients with AChR ab+ gMG. Therefore, we question the assertion that RYSTIGGO® does not involve the treatment of the same or similar type of disease and the same or similar patient population when compared to existing technology.

We are inviting public comments on whether RYSTIGGO® is substantially similar to existing technologies and whether RYSTIGGO® meets the newness criterion.

With respect to the cost criterion, the applicant provided an analysis to demonstrate that RYSTIGGO® meets the cost criterion. The analysis followed the order of operations summarized in the following table.

RYSTIGGO® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for RYSTIGGO®.
Claims identified	22,213 claims mapping to 641 MS–DRGs, with none exceeding more than 8.28% of the total identified cases.
Charges removed for prior technology.	Per the applicant, use of the technology may replace current drug charges for therapies. The applicant removed 100% of drug charges from the identified cases, which, as the applicant stated, is likely an overestimation of charges that would be replaced by RYSTIGGO® since patients may receive some ancillary drug treatments with RYSTIGGO®. The applicant did not remove indirect charges related to the new technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $80,760. Final inflated average case-weighted standardized charge per case: $236,731.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that RYSTIGGO® meets the cost criterion.

We are inviting public comments on whether RYSTIGGO® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that RYSTIGGO® represents a substantial clinical improvement over existing technologies because RYSTIGGO® is the only FDA-approved product for anti-MuSK ab+ gMG in adult patients, and is an option for patients unresponsive to, and not treated by, conventional therapies. The applicant also asserted that RYSTIGGO® significantly improves clinical outcomes relative to services or technologies previously available. The applicant provided seven articles regarding the MycarinG study and its open-label extension studies, as well as a meta-analysis regarding efficacy of newer therapies for MG, to support these claims. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for RYSTIGGO® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[145] argenx U.S., Inc. *VYVGART® (efgartigimod alfa-fcab) injection* [Package Insert]. (Revised 8/2024). Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761195s004,761304s003lbl.pdf.*

[146] UCB, Inc. *RYSTIGGO® (rozanolixizumab-noli) injection, for subcutaneous use* [Package Insert]. (Revised 6/2024). Available at: *https://www.accessdata.fda.gov/spl/data/c6e71126-50c1-4ae2-9d82-b053d605b9cb/c6e71126-50c1-4ae2-9d82-b053d605b9cb.xml.*

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
RYSTIGGO® is the only FDA-approved therapy for gMG in adult patients who are MuSK ab+.	Habib AA, Sacconi S, Antonini G, et al. Efficacy and safety of rozanolixizumab in patients with muscle-specific tyrosine kinase antibody-positive generalised myasthenia gravis: a subgroup analysis of the randomised, double-blind, placebo-controlled, adaptive phase III MycarinG study. Ther Adv Neurol Disord. 2024a;17:1–16. Bril V, Drużdż A, Grosskreutz J, et al. Safety and efficacy of rozanolixizumab in patients with generalised myasthenia gravis (MycarinG): a randomised, double-blind, placebo-controlled, adaptive phase 3 study. Lancet Neurol. 2023a;22(5):383–394. Habib AA, Sacconi S, Pascuzzi RM, et al. Repeated cycles of rozanolixizumab treatment in patients with muscle-specific kinase antibody-positive generalized myasthenia gravis [Poster 203]. AANEM 2023.
RYSTIGGO® provides a treatment option for adult patients with generalized myasthenia gravis (gMG) whose disease is not responsive to, and not treated by, conventional therapies.	Bril, 2023a, *op. cit.* Vu T, Drużdż A, Habib AA, et al. Efficacy of rozanolixizumab in generalized myasthenia gravis: subgroup analyses from the randomized phase 3 MycarinG study [Abstract 002951], AAN 2023.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
RYSTIGGO® offers further clinical improvement in addition to standard of care (SOC) therapies for adult patients with gMG.	Bril V, Drużdż A, Grosskreutz J, et al. Long-term efficacy and safety of symptom-driven cyclical rozanolixizumab treatment in patients with generalized myasthenia gravis: A pooled analysis of a Phase 3 study and two open-label extension studies [P1–5.012]. Neurology. 2023b;100(17_supplement_2):3747. Sacconi S, Habib AA, Antonini G, et al. Rozanolixizumab in muscle-specific kinase autoantibody-positive myasthenia gravis: Further analyses from MycarinG study [Poster EPO–391]. EAN 2023. Saccà F, Pane C, Espinosa PE, Sormani MP, Signori A. Efficacy of innovative therapies in myasthenia gravis: A systematic review, meta-analysis and network meta-analysis. Eur J Neurol. 2023;30:3854–3867. Habib AA, Kaminski HJ, Grosskreutz J, et al. Clinically meaningful improvement in physical fatigue and muscle weakness fatigability with rozanolixizumab: Post hoc analysis of MG Symptoms PRO responder rates in the MycarinG study [Poster P4–11–001]. AAN 2024b.

We also received written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for RYSTIGGO®.

Comment: The applicant submitted a comment in response to questions raised at the Town Hall. Regarding a question on the differences in the sample sizes reported within the Bril et al. (2023a) study versus the FDA [147] integrated review, the applicant restated the patient population included in the MycarinG study, as described in Bril et al. (2023a) and Habib et al. (2024a). Per the applicant, the information from the MycarinG study aligns with the product label.[148] The applicant further noted that the number of study participants may vary based on the analysis conducted (intent to treat, data availability, study completion, etc.). The applicant emphasized that gMG is a rare disease, with the MuSK ab+ patient population being even rarer. According to the applicant, the number of patients in the MycarinG study is consistent with other rare disease treatment clinical trials and was acceptable to FDA.

Regarding a question asking about why the applicant used a post hoc 97.5 percent CI instead of a 95 percent CI for statistical significance in the MycarinG study, how such significance was found in the MuSK ab+ subgroup analysis when there were only 16 MuSK ab+ patients in the MycarinG study (discussed further later in this section), and how significance was only found in those treated in the 7mg/kg dose but not the 10mg/kg dose in the MG–ADL and not for either dose in the quantitative myasthenia gravis score (QMG) assessment, the applicant stated that the parallel gatekeeping approach was used for the primary and secondary endpoints. The applicant stated that this was a means of adjusting for multiple testing across the 2 dose arms and across the different endpoints, while maintaining an overall type 1 error rate of 5 percent. According to the applicant, in the primary endpoint, each dose arm was tested against placebo at two and a half percent. The applicant commented that the MuSK ab+ subgroup analysis was part of the planned efficacy analysis and that the results were clinically significant in having over a two-point reduction in MG–ADL, but noted that these results were not subject to planned statistical testing.

The applicant also responded to a question on the validity of the MG–ADL and QMG used in the MycarinG study, including why the MG–ADL was used as the primary endpoint. The applicant stated that objective assessments were the primary endpoint for clinical trials related to gMG prior to 2017. The applicant stated that the REGAIN trial (Howard et al., 2017),[149] evaluating eculizumab, was published in 2017 and was the first trial to introduce MG–ADL as a primary endpoint. According to the applicant, the current FDA standard evolved following the REGAIN trial, and, consistent with FDA direction to manufacturers, most ongoing phase 3 trials now rely on the MG–ADL as a primary endpoint, emphasizing patient-reported outcome measures which may be more sensitive to clinical change than QMG. The applicant further noted that currently available MG-specific outcome measures include objective,

[147] U.S. Food and Drug Administration, Center for Drug Evaluation and Research (2023). Integrated Review of BLA 761286 (RYSTIGGO®). U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/drugsatfda_docs/nda/2023/761286Orig1s000IntegratedR.pdf.*

[148] UCB, Inc., 2024, *op. cit.*

[149] Howard, J.F., Jr, Freimer, M., O'Brien, F., Wang, J.J., Collins, S.R., Kissel, J.T. and (2017), QMG and MG–ADL correlations: Study of eculizumab treatment of myasthenia gravis. Muscle Nerve, 56: 328–330. *https://doi.org/10.1002/mus.25529.*

patient-reported, and composite measures. Per the applicant, in the MycarinG study, patient-reported and objective measures were used as either primary or secondary endpoints. The applicant stated that several studies have been conducted to assess validity and correlation of different MG endpoints, and that expert consensus has recommended the use of standardized assessments such as MG–ADL or QMG scores in assessment of patients with gMG. The applicant included several articles on validation, correlation, and consensus on addressing variability in MG clinical trials.[150] [151] [152] [153] The applicant stated that it appreciates that CMS is not bound by FDA determinations, but asserted that it is practically impossible, particularly in rare disease trials, to use different assessment measures when government agencies suggest conflicting measurements.

Finally, in response to a question asking how RYSTIGGO® compares with existing standard of care therapies and specifically newer agents, the applicant stated that RYSTIGGO® was not compared against a treatment-naïve placebo group for ethical reasons. Per the applicant, in the MycarinG trial, patients in the placebo and treatment groups were allowed to remain on their standard of care therapies, such as non-steroidal immunosuppressive therapy (methothrexate, cyclosporine, azathioprine, tacrolimus), steroids, and pyridostigmine, such that they were randomized to either the RZL+standard-of-care group or the placebo+standard-of-care group. The applicant stated that the MycarinG study therefore looked at the benefits of RYSTIGGO® beyond standard of care therapies. According to the applicant, for the reasons previously explained, there is no head-to-head comparison against other biologics or newer therapies available in treatment-naïve patients. The applicant noted that currently available therapies also do not have an FDA indication for MuSK ab+ gMG.

We also received a few comments expressing general support for new technology add-on payments for RYSTIGGO® stating that RYSTIGGO® offers a new and significant clinical improvement in care for gMG patients who are MuSK ab+.

Response: We thank the applicant and commenters for their comments.

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether RYSTIGGO® meets the substantial clinical improvement criterion. While the applicant stated that RYSTIGGO® is the only FDA-approved therapy for gMG in adult patients who are MuSK ab+, and that this subtype is challenging to treat, as patients are usually unresponsive and often intolerant of pyridostigmine (a standard first-line MG therapy), we note that the applicant also stated that 3,4-diaminopyridine treatments may have mild to moderate effect. We further note that, as mentioned previously, other therapies such as pyridostigmine, glucocorticoid therapy, and plasmapheresis are also available options for these patients, and we therefore question that RYSTIGGO® offers a treatment option for patients with MuSK ab+ gMG who have no other treatment options. The applicant also stated that RYSTIGGO® provides a treatment option for the approximately 10 to 20 percent of patients with gMG whose disease is not responsive to, and not treated by, conventional therapies due to inadequate response or intolerable side effects, however, we question whether the evidence provided demonstrates that there is a population of patients with gMG with no other treatment options. To support this claim, the applicant provided the double-blind, placebo-controlled, phase 3 MycarinG study, which randomized 200 patients (1:1:1) to receive RYSTIGGO® 7 mg/kg, RYSTIGGO® 10 mg/kg, or placebo in addition to their current gMG treatment (where permitted by the study inclusion criteria) for 6 weeks, as well as an abstract of a post hoc subgroup analysis of this study (Vu et al., 2023) which stratified trial results based on the number of prior therapies.[154] The applicant stated that the MycarinG study demonstrated RYSTIGGO®, in addition to standard of care, significantly improved clinical outcomes by reducing MG–ADL, QMG, and MG Composite (MGC) scores in adult patients with gMG, including those with prior standard of care treatments such as corticosteroids, parasympathomimetics, and non-steroidal immunosuppressants. We note that permitted concomitant medications were cholinesterase inhibitors, oral corticosteroids, azathioprine, ciclosporin, methotrexate, mycophenolate mofetil, and tacrolimus. All of these medications, except for cholinesterase inhibitors, required a stable dose. We question if the cholinesterase inhibitor dose may have affected the results of the study since the dose may not have been stable throughout the trial. In addition, other standard of care treatment options for patients were excluded, including rituximab products, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®, and we therefore question if RYSTIGGO® is the only treatment option for patients with gMG who have failed conventional therapy.

The applicant also provided an abstract of a subgroup analysis (Vu et al., 2023) of the MycarinG study and stated the subgroup analysis demonstrated that RYSTIGGO® significantly improved outcomes based on a reduction in MG–ADL in patients who had previously undergone myasthenia gravis standard treatments based on stratification on number of prior therapies, excluding acetylcholinesterase inhibitors, but including corticosteroids, non-steroidal immunosuppressants, IVIg, and plasma exchange. However, it is unclear how a subgroup analysis on the number of prior therapies provides evidence that RYSTIGGO® is the only treatment option for patients unresponsive to conventional therapies. We also note that acetylcholinesterase inhibitors were excluded from this subgroup analysis, but these are part of the standard of care for MG.

With respect to the applicant's assertion that RYSTIGGO® improves clinical outcomes over existing therapies, the applicant submitted three presentation posters (Bril et al., 2023b; Sacconi et al., 2023; Habib et al., 2024b) that provided efficacy and safety results from the MycarinG study and 2 open-label extension studies (MG0004 and MG007) which we note are not published or peer-reviewed. We note that two of the poster presentations (Bril et al., 2023b and Habib et al., 2024b) do not report the statistical significance of results and, therefore, we are uncertain as to how significant the results are. With regards to the MycarinG study, per the applicant's Town Hall comment, patients were allowed to remain on standard of care therapies such as non-

[150] Howard, 2017, *op. cit.*

[151] McPherson, T., Aban, I., Duda, P.W., Farzaneh-Far, R., Wolfe, G.I., Kaminski, H.J., Cutter, G., Lee, I., & of the MGTX Study Group (2020). Correlation of Quantitative Myasthenia Gravis and Myasthenia Gravis Activities of Daily Living scales in the MGTX study. *Muscle & Nerve, 62*(2), 261–266. *https://doi.org/10.1002/mus.26910.*

[152] Meisel, A., Saccà, F., Spillane, J., Vissing, J., & MG Collegium Sub-committee. (2024). Expert consensus recommendations for improving and standardising the assessment of patients with generalised myasthenia gravis. *European Journal of Neurology, 31*(7), e16280. *https://doi.org/10.1111/ene.16280.*

[153] Thomsen j.L.S, Andersen H. (2020). Outcome measures in clinical trials of patients with myasthenia gravis. *Front Neurol.* 11, 596382. *https://doi.org/10.3389/fneur.2020.596382.*

[154] Bril, 2023a, *op. cit.*

steroidal immunosuppressive therapy, steroids, and pyridostigmine. However, we note that various other standard of care therapies were excluded such as rituximab products, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®. Without a comparison to these therapies, we question whether RYSTIGGO® improves clinical outcomes relative to all previously available therapies. Given the 6-week duration of the trial, we also question how natural changes in symptoms were accounted for since symptoms can wax and wane in patients with gMG. We further note that the MycarinG and the open-label extension studies involved only 8 weeks (MycarinG and MG0004) or 16 weeks (MG0007) of observation, which makes it more difficult to assess the frequency of prolonged remission rates and how the adverse event rates, such as for cancer and infection, compare with existing therapies. We are also interested in more information on the lack of a dose-response effect with RYSTIGGO®. For instance, there was a least squares mean (LSM) in MG–ADL of −7.28 in the rozanolixizumab (RLZ) 7 mg/kg group and −4.16 in the RLZ 10 mg/kg group within the MuSK ab+ population and an LSM of −3.03 in the RLZ 7 mg/kg group and a similar LSM of −3.36 in the RLZ 10 mg/kg group within the AChR ab+ population. We also note there is only about a 2 to 2.5-point difference between RYSTIGGO® and placebo for MG–ADL in the AChR ab+ subpopulation and the overall population. Specifically, for the AChR ab+ population, the LSM difference versus placebo in the RLZ 7 mg/kg group was −1.94 and in the RLZ 10 mg/kg group was −2.26 and for the overall population, the LSM difference versus placebo was −2.59 in the RLZ 7 mg/kg group and −2.62 in the RLZ 10 mg/kg group. The applicant stated that these findings were statistically significant. We note that the study considered a 2-point difference in MG–ADL as a clinically meaningful improvement. We would appreciate clarification on how the study defined clinically meaningful improvement.

In addition, with respect to the MuSK ab+ population in the MycarinG trial, we note there were 21 MuSK ab+ patients in the studies submitted by the applicant. We further note that the FDA Integrated Review for RYSTIGGO® indicated that 16 patients tested positive for the MuSK ab+ and we would appreciate clarification regarding this discrepancy in numbers. We note in its Town Hall comment that the applicant emphasized that gMG, particularly MuSK positive gMG, is a rare disease and the number of patients in the study is consistent with other rare disease treatment clinical trials and was acceptable to the FDA. However, we question if the results are generalizable to the Medicare population since only 2 patients treated with RYSTIGGO were from the U.S. and only 1 patient treated was 65 years or older.[155] We also note that not all efficacy outcomes were statistically significant within the MuSK ab+ population. Specifically, the LSM difference in QMG between RYSTIGGO® and placebo was not statistically significant for either the RLZ 7 mg/kg group (97.5 percent confidence interval −14.24, 0.41) nor the RLZ 10 mg/kg group (97.5 percent confidence interval −9.73, 3.45). Further, we note there appears to be a difference in the disease severity between the MuSK ab+ patients in the placebo and treatment arms. For example, results from Habib et al. (2024a) indicated that among the MuSK ab+ population of the MycarinG study, all patients with severe (Class IV) disease at baseline per the Myasthenia Gravis Foundation of America (MGFA) classification system were in the placebo arm (3⁄8), while individuals in the treatment groups all had mild or moderate (Class II or Class III) disease at baseline. We question how this difference may have impacted the placebo group's outcomes relative to the those of the treatment groups. Additionally, a higher percentage of patients were taking corticosteroids in the RYSTIGGO® groups (80 percent in 7 mg/kg group and 87.5 percent in 10 mg/kg group) compared to placebo (62.5 percent) and we question if this difference in background therapy could have affected the outcomes since oral corticosteroids were a permitted concomitant medication in the trial. We also note that the trial excluded individuals with severe oropharyngeal or respiratory weakness, and we question whether this exclusion would affect the generalizability of the results for this MuSK ab+ subpopulation, as the applicant indicated that patients with MuSK ab+ gMG tend to have more severe disease with a potential unmet need for treatment options.

The applicant also provided a meta-analysis comparing innovative therapies in MG, stating that it demonstrated that anti-FcRn treatments such as RYSTIGGO® showed greater effects on QMG, MGC, and MG–QoL15 compared to complement inhibitors, with VYVGART® and RYSTIGGO® having the highest probabilities of being the most effective treatment for MG–ADL and QMG. However, we note that the same article indicated no significant difference in MG–ADL between complement inhibitors and anti-FcRn treatments. Additionally, we note that the analysis found that VYVGART® had the highest probability of being the best treatment, followed by RYSTIGGO®.[156] We note that we did not receive any other evidence comparing complement inhibitors or anti-FcRn treatments with RYSTIGGO® to demonstrate improved outcomes. Therefore, we would appreciate additional information comparing RYSTIGGO® to these other therapies in order to inform our assessment of whether RYSTIGGO® demonstrates a substantial clinical improvement over existing technologies. In addition, we note that the meta-analysis included seven clinical trials, only two of which included patients positive for MuSK ab+, MycarinG and ADAPT, a trial studying VYVGART®. The meta-analysis did not include trials studying other standard of care therapies in patients with MuSK ab+ gMG. Since the meta-analysis did not include a comparison of current therapies in patients with MuSK ab+ gMG, we question how this analysis demonstrates RYSTIGGO® improves clinical outcomes relative to previously available therapy for patients with MuSK ab+ gMG.

We also note that, while the applicant stated that RYSTIGGO® meets patient preferences for convenience by its ability to be administered via a subcutaneous infusion by a healthcare provider, either at an infusion clinic or at home with nurse assistance, the applicant does not provide a comparison of administration to other available therapies. We would further appreciate additional information on how the administration method for RYSTIGGO® demonstrates that the technology significantly improves one or more of the clinical outcomes described under the regulations at § 412.87(b)(1)(ii)(C).

We are inviting public comments on whether RYSTIGGO® meets the substantial clinical improvement criterion.

l. SYMVESS™ (Acellular Tissue Engineered Vessel-Tyod)

Humacyte, Inc. submitted an application for new technology add-on payments for SYMVESS™ for FY 2026. According to the applicant, SYMVESS™ is a bioengineered, implantable blood vessel indicated for use in adults as a vascular conduit for extremity arterial injury when urgent

[155] U.S. FDA CDER, 2023, *op. cit.*

[156] Saccà, 2023, *op. cit.*

revascularization is needed to avoid imminent limb loss and when autologous vein grafting is not feasible. The applicant stated that SYMVESS™ is composed of organized extracellular matrix proteins in the tubular form of a blood vessel and is used to repair, bypass, or replace arteries that have sustained traumatic injuries.

Please refer to the online application posting for SYMVESS™, available at *https://mearis.cms.gov/public/publications/ntap/NTP24100639G2M*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, SYMVESS™ was granted BLA approval from FDA on December 19, 2024, for use in adults as a vascular conduit for extremity arterial repair when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein grafting is not feasible. The applicant stated that FDA required a lot release that shows results of all applicable tests prior to distribution of SYMVESS™ and that it submitted the required paperwork to FDA on December 26, 2024. The applicant stated that on February 26, 2025, FDA notified the applicant that the required review of commercial batch information was completed and authorized the applicant to commence commercial shipment; therefore, per the applicant, SYMVESS™ became commercially available as of February 26, 2025. Per the applicant, the average number of units of SYMVESS™ anticipated to be used per inpatient stay is 1 unit.

The applicant stated that, effective October 1, 2024, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of SYMVESS™: X2R50WA (Replacement of right upper extremity artery using bioengineered human acellular vessel, open approach, new technology group 10), X2R60WA (Replacement of left upper extremity artery using bioengineered human acellular vessel, open approach, new technology group 10), X2R70WA (Replacement of right lower extremity artery using bioengineered human acellular vessel, open approach, new technology group 10), or X2R80WA (Replacement of left lower extremity artery using bioengineered human acellular vessel, open approach, new technology group 10).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that SYMVESS™ is not substantially similar to other currently available technologies because it does not use the same or a similar mechanism of action compared to existing technologies, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for SYMVESS™ for the applicant's complete statements in support of its assertion that SYMVESS™ is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	SYMVESS™ uses a unique mechanism of action compared to existing guideline-recommended treatments for the anticipated indication. SYMVESS™ is a bioengineered implantable vessel that is grown from human cells and then decellularized. The resulting SYMVESS™ consists of extracellular matrix proteins, in the form of a tubular blood vessel, that stimulate patient cell recruitment after implantation. Cellular repopulation and remodeling of the SYMVESS™ result in a living, functional part of the vasculature. The autologous vein grafts' mechanism of action involves biological integration, promoting natural endothelial function, reducing thrombosis risk, and adapting to the arterial environment through arterialization. SYMVESS™'s mechanism of action offers several advantages: (1) reduces time to revascularization with an off-the-shelf option; (2) avoids vein harvesting complications; (3) provides a consistent conduit size; and (4) regenerates into a living blood vessel. The synthetic grafts' mechanism of action provides immediate revascularization but does not integrate into the host and is not remodeled by patient cells. Synthetic grafts are made of non-biodegradable polymers that often stimulate foreign body responses, fibrosis, and thrombosis when implanted into patients. Lacking native extracellular matrix proteins architecture, synthetic grafts also interact poorly with the patient's immune system, which raises the risk of graft infection in contaminated wound beds. SYMVESS™, which is comprised of human extracellular matrix proteins, repopulates with cells, has a low infection rate, and does not stimulate fibrosis nor a foreign body reaction. The mechanism of action of ligation is to stop blood flow through the injured artery but without revascularization, while amputation functions by removing part or all the injured limb to prevent further complications and save a patient's life. SYMVESS™ offers an alternative by providing a vessel capable of restoring blood flow, preserving limb functionality.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	The use of SYMVESS™ will likely be assigned to the same MS–DRGs where existing technologies to treat significantly damaged arteries due to traumatic injuries, are assigned.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	SYMVESS™ is used to treat the same type of disease in a similar patient population as existing technologies. Traumatic vascular injury can be caused by motor vehicle accidents, industrial accidents, falls, gunshot wounds, knife wounds, etc. For all these types of injuries to the extremities, if an autologous vein is available for arterial repair, then such injuries are typically repaired using a harvested vein from the patient. However, regardless of the mechanism of injury, in some cases, an autologous vein is not available, or its use is not feasible in a given trauma situation. In some situations, there may not be enough time to harvest the vein, or the trauma surgeon may not have the necessary training to harvest a vein. Regardless of the situation, the patient or the injury mechanism, SYMVESS™ is anticipated to provide a new treatment option to patients where revascularization using a harvested autologous vein is not feasible. By addressing the needs of these specific patients, SYMVESS™ expands the treatment options available for saving life and limb following vascular trauma, ensuring better outcomes for a broader patient population.

We have the following concerns with regard to the newness criterion. The applicant stated that SYMVESS™ has a novel mechanism of action based on its manufacturing, composition, and post-operative regenerative properties. However, we are interested in more information about how the composition of SYMVESS™ is associated with its post-operative regenerative properties, and specifically how these regenerative properties are associated with its mechanism of action to achieve a therapeutic outcome, as well as how the association between SYMVESS™'s regenerative properties and mechanism of therapeutic action differs from that of autologous vein grafts. In addition, we question whether physiological changes, such as arterialization, cellular repopulation, and fibrosis, that occur after a conduit is implanted, should be considered part of the mechanism of action. We also note that the applicant stated that the mechanism of action of synthetic grafts is immediate revascularization, and we question whether that is not also the mechanism of action of SYMVESS™ and/or autologous vein grafts.

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

With respect to the cost criterion, the applicant provided an analysis to demonstrate that SYMVESS™ meets the cost criterion. The analysis followed the order of operations summarized in the following table.

SYMVESS™ COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for SYMVESS™.
Claims identified	1,540 claims mapping to 90 MS–DRGs, with 18.83% of claims mapping to MS–DRG 252 (Other Vascular Procedures with MCC).
Charges removed for prior technology.	Per the applicant, use of the technology would replace other implantable devices. The applicant removed 100% of charges for implantable devices from the identified cases, as to take a conservative approach in its cost analysis. The applicant did not remove any indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of SYMVESS™ by the national average-cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule.
Cost analysis results	Average case-weighted threshold amount: $143,227. Final inflated average case-weighted standardized charge per case: $423,141.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that SYMVESS™ meets the cost criterion.

We are inviting public comments on whether SYMVESS™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SYMVESS™ represents a substantial clinical improvement over existing technologies because SYMVESS™ is a new treatment option for patients with extremity vascular trauma where autologous vein grafts are infeasible, has improved secondary patency compared to synthetic grafts, and has lower amputation and infection rates. The applicant also stated that SYMVESS™ enables quicker perfusion of injured extremities compared to autologous grafts, reducing ischemia time and complication risks. The applicant provided 6 documents, including 2 studies and 2 FDA-related documents, to support these claims, as well as 10 background articles about extremity arterial trauma outcomes, trauma surgery clinical guidelines, and the impact of repair duration on extremity arterial injuries.[157] The following table summarizes the applicant's assertions regarding the

[157] Background articles are not included in the following table but can be accessed via the online posting for the technology.

substantial clinical improvement criterion. Please see the online posting for SYMVESS™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
SYMVESS™ is the first and only bioengineered blood vessel approved for extremity vascular trauma.	Food and Drug Administration. U.S. Department of Health and Human Services. Grant of Regenerative Medicine Advanced Therapy Designation for Human Acellular Vessel (HAV). U.S. Department of Health and Human Services, Food and Drug Administration. Granted May 2, 2023. Humacyte Global, Inc. Section 2.5 Clinical Overview: Biologics License Application 125812 for Human Acellular Vessel (HAV) (Excerpt Clinical Data). Submitted December 2023. Moore EE, Curi M, Namias N, et al. Bioengineered Human Arteries for the Repair of Vascular Injuries. JAMA Surg. Published online November 20, 2024. doi:10.1001/jamasurg.2024.4893. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
SYMVESS™ is a new treatment option for patients with extremity vascular trauma, where autologous vein grafts are not feasible.	Humacyte Global, Inc, 2023, *op. cit.* Humacyte Global, Inc. ATEV Clinical Overview—Vascular Trauma Background and Cross-Population Generalizability. 2024a. Moore, 2024, *op. cit.*
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
Conduit infection rates are lower with SYMVESS™ compared to synthetic grafts in extremity vascular trauma.	Moore, 2024, *op. cit.* Humacyte Global, Inc, 2023, *op. cit.* Humacyte Global, Inc, 2024a, *op. cit.* Humacyte. Data on File—Propensity Score Matched Analysis Results. 2024b. Wang, J., Blalock, S.K.F., Levitan, G.S., Prichard, H.L., Niklason, L.E., & Kirkton, R.D. (2023). "Biological mechanisms of infection resistance in tissue-engineered blood vessels compared to synthetic expanded polytetrafluoroethylene grafts." Journal of Vascular Surgery: Vascular Science, 4, 100120. DOI: 10.1016/j.jvssci.2023.100120. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
SYMVESS™ results in lower amputation rates as compared to synthetic grafts.	Humacyte Global, Inc, 2023, *op. cit.* Humacyte Global, Inc, 2024a, *op. cit.* Humacyte. 2024b, *op. cit.* Moore, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
SYMVESS™ significantly improves secondary patency rates as compared to synthetic grafts.	Humacyte Global, Inc, 2023, *op. cit.* Humacyte Global, Inc, 2024a, *op. cit.* Humacyte. 2024b, *op. cit.* Moore, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
SYMVESS™ enables quicker reperfusion of injured extremities compared to autologous vein grafts, reducing risk of complications and amputation.	Humacyte Global, Inc, 2023, *op. cit.* Moore, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We also received written public comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SYMVESS™, which we are summarizing in this section.

Comment: Two commenters submitted comments on SYMVESS™. A commenter stated that SYMVESS™ has not demonstrated non-inferiority to synthetic grafts or provided evidence for when SYMVESS™ should be used instead of a synthetic graft in any of what the commenter described as underpowered, non-comparative trauma clinical trials (V005 and the V017). The commenter stated that instead of conducting a head-to-head trial, synthetic graft benchmarks that compared unfavorably to SYMVESS™ were used in the V005 and V017 trials. The commenter stated that the total number of evaluable patients was only 51 (V005) and 16 in the observational study (V017), which was not enough to show significance. In terms of primary patency rate, which was the primary endpoint of the V005 and V017 trials, the commenter noted that primary patency is defined as intervention free functionality, and that graft literature reports primary patency rates in months to years. The commenter also noted that the applicant reported primary patency and adverse events data at 30-day endpoints, while most of these vascular grafts are in patients for months to years. The commenter also expressed concern that the applicant defines secondary patency as functionality after a thrombolytic intervention. The commenter stated that secondary patency data can be open to interpretation because multiple interventions may have been used to keep SYMVESS™ open, even if the technology is not functional. In terms of the Wang et al. (2023) study, which compared SYMVESS™ to ePTFE grafts

in patients requiring a conduit for hemodialysis, the commenter stated that 10 times more thrombotic events occurred in the SYMVESS™ group (N=126) versus the control (arteriovenous fistula, AVF) (N=12) group, and that there was twice as much stenosis in the SYMVESS™ group (N=228) versus the control group (N=115). The commenter was not supportive of approving new technology add-on payments for SYMVESS™.

The other commenter stated that SYMVESS™ does not represent a meaningful improvement of the standard of care. According to the commenter, the actual study cohort for the V005 trial was modified. Specifically, the study enrolled 72 patients and treated 69 with SYMVESS™ on an intention-to-treat basis (ITT), and only 51 were included in the analysis, representing an analysis on modified intention to treat basis (mITT). According to the commenter, the reasons given were that, of the 18 SYMVESS™ recipients who were not included in the analysis, 16 had iatrogenic injuries and 2 had thoracic injuries. Per the commenter, the 51-patient cohort was referred to as ITT, even though 69 actually received the product. The commenter also stated that to its knowledge, the data of the 18 patients have never been shared. The commenter also stated that the inclusion and exclusion criteria of the V017 trial were very different from those of the V005 trial. Per the commenter, the V017 trial may include patients who can be treated with either autologous veins or SYMVESS™, and that any limb threatening injury could be included in the patient cohort. The commenter also noted that although the average Injury Severity Score (ISS) between V005 and V017 were similar (about 20.0), V017 has a much higher variance (standard deviation [SD]=18.9) than V005 (SD=10.5). The commenter also noted that the range of SD was not disclosed. Per the commenter, even one extremely high ISS could skew the average up if it was otherwise low, and that there were no exclusion criteria in V017 for ISS higher than 60. The commenter also stated that while SYMVESS™ may have superior initial uptake in the human body than PTFE grafts, its performance drops off significantly over time in both trauma and dialysis. The commenter stated that in terms of long-term patency, long-term graft studies show that after a year or two, the patency levels off, so even 12-months or 24-months is enough to make some highly educated guesses about the long-term patency of the product.

In terms of secondary patency, the commenter noted that the 12-month rate for the combined samples of V005 and V017 was about 73 percent, and that, based on information from Humacyte's press release from August 2024,[158] the 12-month secondary patency for V017 was 87 percent. According to the commenter, since V017 had a sample size of 16, and the combined sample size was 67, this would imply that the results from V005 were in fact much lower than those of V017. According to the commenter, solving (((X * 51) + (0.87 * 16))/67) = 0.73 yielded a 12-month secondary patency rate of 68.6 percent (X ≈ 0.686078) for V005 which was much lower than 78.9 percent, the applicant's 30-day synthetic grafts benchmark for secondary patency, and 18.4 percent lower than the secondary patency of V017 (87 percent). According to the commenter, the outcomes of the two trials were different, which it described as two obviously different data set results. The commenter speculated that the difference in the long-term outcomes of V005 and V017 can be explained by the baseline health of the patients in each trial. The commenter also stated that the difference in patency between the two trials was obvious if safety signals are considered. Per the commenter, according to the adverse event data of Moore study (2024), the patients in the V017 trial were implicitly much healthier than those in the V005 trial either at presentation in clinic or afterwards. The commenter stated that it would be unlikely for the two trials to have similar outcomes. The commenter questioned whether removing one of the inclusion criteria in V005, that patients who received SYMVESS™ would have to be unable to receive arteriovenous grafts (AVG), would increase the average health of the patients.

The commenter also stated that the Moore study (2024) provided the confidence intervals for the amputation, infection, and death rates, but not for the ISS. Per the commenter, the mean ($\bar{x}$) and standard deviation (SD) for the ISS were similar for the two trials (V005: $\bar{x}$=20.8, SD=10.5; V017: $\bar{x}$=20.1, SD=18.9). Per the commenter, three of the 16 patients in V017 had no ISS reported, and that the synthetic graft variance was much smaller (SD=2.4). According to the commenter, per the Moore team (2024), no deaths were attributed to SYMVESS™.[159] The commenter stated that overall survival is generally not differentiated this way in the literature, and that deaths resulting from injuries were counted as such regardless of whether the SYMVESS™ graft was patent or not. The commenter stated that the death rate for the two trials was 5.9 percent and zero percent, and that the death rate for the 2 trials combined was 3.5 percent, which was higher than the 3.4 percent synthetic graft benchmark for all-cause death. The commenter stated it believed this was probably due to thrombotic events caused by SYMVESS™. The commenter also stated that the absence of p-value in the applicant's report of trial results made it hard to tell whether those results were due to chance.

In terms of the synthetic graft benchmarks, the commenter stated that historical comparisons are always a last resort way to compare two products in a clinical trial, and that it is hard to compare two trials that were run in different sites, on different people, under different conditions, at different periods in time. According to the commenter, previous clinical trials for the indication of vascular trauma had tested different technologies (autologous vein grafts, different synthetic grafts) on different types of patients (for example, civilian versus military) on different parts of the body for short- versus long-term. The commenter stated that trial results may be skewed by a historical control that performed much better or much worse than its comparator in a previous trial. In addition, the commenter stated that the way we treat thrombosis with post-graft drug regimens has evolved over time, and some studies found that the use of post-surgery prescription drugs can drastically impact outcomes. Per the commenter, those are the reasons that it becomes challenging to evaluate graft performance in 2024 using historical controls from 2004. The commenter asserted that head-to-head comparison is a feasible study design in trauma.

The commenter noted that in Fox (2005), one of the papers in the meta-analysis of the Moore study (2024), the infection and amputation rates for the PTFE grafts were very high, and that all of the grafts had become infected and failed, resulting in amputation. Per the commenter, Fox mentioned that he had only examined one-third of all the patients, that the median ISS was 40 (range: 16–75), which, the commenter noted, was double the average for V005 ($\bar{x}$=20.8) and V017 ($\bar{x}$=20.1). According

[158] Humacyte presents positive long-term results in ATEV™ in treatment of vascular trauma in military setting of Ukraine Humanitarian Program (*https://investors.humacyte.com/news-releases/news-release-details/humacyte-presents-positive-long-term-results-atevtm-treatment*, accessed 1/30/2025).

[159] Moore (2024), *op. cit.* p. E5.

to the commenter, Perkins (2016), another paper in the meta-analysis, analyzed 579 extremity injuries and showed that amputations happened more often among those with higher ISS. Moreover, the commenter stated that while the studies in the synthetic graft meta-analysis reported percent of patients who received a synthetic graft, infection rate, and amputation rate, only some reported whether the patients who received a synthetic graft developed infection or underwent amputation as a result of the synthetic graft. In addition, while the Moore study (2024) reported that the meta-analysis included 281 synthetic grafts, the commenter noted that it was unable to replicate that number. Moreover, the commenter stated that the Rudstrom paper (2008), another study in the meta-analysis, specifically looked at iatrogenic injuries. The commenter questioned why patients with iatrogenic injuries were excluded from the evaluable cohorts in the V005 and V017 trials, but the synthetic graft benchmarks included the results of patients with iatrogenic injuries. The commenter expressed doubt as to whether iatrogenic injuries were excluded from the meta-analysis.

Furthermore, the commenter stated that SYMVESS™ should be compared with Artegraft®, a biological off-the-shelf solution approved for trauma, hemodialysis, and lower extremity bypass surgeries and owned by LeMaitre. The commenter noted that according to the Statistical Analysis Plan for SYMVESS™, besides the synthetic graft benchmarks, the applicant also created a non-autologous vein and non-synthetic graft benchmark.[160] Per the commenter, this benchmark has not been shared publicly, and as a result, the results of what that benchmarking activity yielded or what the comparative to the Artegraft® or other xenografts look like remain unclear.

Regarding the Wang study (2023), the commenter stated that the applicant did not demonstrate non-inferiority in months 18 and 24 and therefore failed the study. According to the commenter, although SYMVESS™ demonstrated initially superior secondary patency and uptake in the human body, there was significant degradation over time, which brings into question the robustness of the technology. Per the commenter, the finding that SYMVESS™ performed worse than ePTFE in terms of secondary patency after one year is important because if the technology needs to be replaced more often, this potentially introduces significant risk to the patient by needing to undergo an additional surgery.

The commenter also added that the results from the SYMVESS™ studies conducted in America have generally lower secondary patency rates. Per the commenter, when interpreting the SYMVESS™ clinical data, only the U.S. data should be considered, especially given the large variance in the injury data and the fact that the applicant did not exclude patients who could have received an autologous vein graft. The commenter stated that those were the major variables that greatly influenced the outcome of the Moore study (2024). The commenter concluded that SYMVESS™ is inferior to standard of care alternatives that are already approved in trauma.

Response: We thank the commenters for their comments. After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we have the following concerns regarding whether SYMVESS™ meets the substantial clinical improvement criterion. We note that being the first and only bioengineered blood vessel for vascular trauma may relate to newness but does not explain how the technology treats patients unresponsive to or ineligible for existing treatment options. Additionally, while the applicant stated that SYMVESS™ is a treatment option for patients ineligible for autologous vein grafts, we note that these patients could still receive other available treatment options, which may include, but are not limited to: primary repair, shunting, use of synthetic or other graft for bypass or interposition grafting, and amputation. Therefore, it is unclear that SYMVESS™ offers a treatment option for patients ineligible for or unresponsive to currently available treatments.

With respect to the assertion that SYMVESS™ significantly improves clinical outcomes relative to services or technologies previously available, the applicant stated that SYMVESS™ is associated with lower conduit infection and amputation rates, and significantly improves secondary patency rates compared to synthetic grafts. To support these claims, the applicant provided the Moore et al. (2024) study, which compared pooled results from two single-arm clinical trials using SYMVESS™ (V005 and V017) to synthetic graft benchmarks derived from a systematic review and meta-analysis of literature. However, we question the reliability and validity of the synthetic graft benchmarks against which Moore et al. (2024) compared SYMVESS™ effects on clinical outcomes. V005 was a prospective phase II/III trial of 69 civilian patients with vascular injuries at U.S. and Israeli level 1 trauma centers from September 2018 through June 2023. V017 was a retrospective trial of 19 wounded war fighters and other patients from a humanitarian program in Ukraine from June 2022 through June 2023. Moore et al. (2024) developed the three synthetic graft benchmarks based on a meta-analysis of 12 studies published between 2005 and 2022.[161] [162] [163] [164] [165] [166] [167] [168] [169] [170] [171] [172] Of these 12 studies, 7 used samples of

[160] Moore et al (2024), op. cit., Supplement 6: Statistical Analysis Plan for Systematic Literature Review and Meta-analysis. Version 2.0 Final, 25 May 2023, p. 6.

[161] Fox, C.J., Gillespie, D.L., O'Donnell, S.D., Rasmussen, T.E., Goff, J.M., Johnson, C.A., Galgon, R.E., Sarac, T.P., & Rich, N.M. (2005). Contemporary management of wartime vascular trauma. *Journal of Vascular Surgery, 41*(4), 638–644. *https://doi.org/10.1016/j.jvs.2005.01.010.*

[162] Laverty, R.B., Brock, S.G., Walters, T.J., & Kauvar, D.S. (2021). Outcomes of Arterial Grafts for the Reconstruction of Military Lower Extremity Arterial Injuries. *Annals of Vascular Surgery, 76,* 59–65. *https://doi.org/10.1016/j.avsg.2021.03.006.*

[163] Lin CH, Consuegra MDL, Lin TS, Revisiting Management Strategies for Popliteal Artery Injuries. *Ann Plast Surg.* 2022 Mar 1;88(1s Suppl 1):S44–S49.

[164] Perkins ZB, Yet B, Glasgow S, Marsh DWR, Tai NRM, Rasmussen TE, Long-term, patient-centered outcomes of lower-extremity vascular trauma. *J Trauma Acute Care Surg.* 2018 Jul;85(1S Suppl 2):S104–S111.

[165] Ramdass, M.J., & Harnarayan, P. (2017). A decade of major vascular trauma: Lessons learned from gang and civilian warfare. *Annals of the Royal College of Surgeons of England, 99*(1), 70–75. *https://doi.org/10.1308/rcsann.2016.0296.*

[166] Rayamajhi S, Murugan N, Nicol A, et al. Penetrating femoral artery injuries: an urban trauma centre experience. *Eur J Trauma Emerg Surg* 2019 Oct;45(5):909–917.

[167] Rudström H, Bergqvist D, Ogren M, Björck M, Iatrogenic vascular injuries in Sweden. A nationwide study 1987–2005. *Eur J Vasc Endovasc Surg.* 2008 Feb;35(2):131–8.

[168] Sharrock AE, Tai N, Perkins Z, et al. Management and outcome of 597 wartime penetrating lower extremity arterial injuries from an international military cohort. *J Vasc Surg.* 2019 Jul;70(1):224–232.

[169] Stonko DP, Betzold RD, Abdou H, et al. AAST PROOVIT Study Group. In-hospital outcomes in autogenous vein versus synthetic graft interposition for traumatic arterial injury: A propensity-matched cohort from PROOVIT. *J Trauma Acute Care Surg.* 2022 Feb 1;92(2):407–412.

[170] Urrechaga E, Jabori S, Kang N, et al. Traumatic Lower Extremity Vascular Injuries and Limb Salvage in a Civilian Urban Trauma Center. *Ann Vasc Surg.* 2022 May;82:30–40.

[171] Vertrees A, Fox CJ, Quan RW, Cox MW, Adams ED, Gillespie DL, The use of prosthetic grafts in complex military vascular trauma: a limb salvage strategy for patients with severely limited autologous conduit. *J Trauma.* 2009 Apr;66(4):980–3.

[172] Watson JD, Houston R 4th, Morrison JJ, Gifford SM, Rasmussen TE, A retrospective cohort comparison of expanded polytetrafluorethylene to autologous vein for vascular reconstruction in modern combat casualty care. *Ann Vasc Surg.* 2015;29(4):822–9.

soldiers from the wars in Iraq and Afghanistan and 5 used samples of civilians in the U.S., Trinidad and Tobago, and Sweden. We note that these 12 studies were conducted using different trial designs, patient samples with different baseline demographic and clinical attributes, and during a long period of time when innovations and guidelines for management of extreme arterial injury continued to emerge and evolve. In addition, these studies used different inclusion and exclusion criteria for injury types and followed different documentation protocols for details about injuries. Furthermore, they implemented different treatments based on different surgical decisions, including Dacron or PTFE synthetic grafts, primary repair, shunting, oversew, reversed vein, or amputation. Half of these studies conducted follow-up periods on clinical outcomes, ranging from 36 days to 10 years. We are concerned that not accounting for these differences in the meta-analysis may confound the results on clinical outcomes and limit the reliability of the comparison between SYMVESS™ and synthetic grafts. In addition, more than half (N=7) of the 12 studies were published before 2019 and we question whether the meta-analysis sufficiently accounts for more recent advances in post-graft drug therapy and other recent advances in treatments for extremity vascular trauma. Moreover, we are concerned about whether there is any empirical evidence that the three synthetic graft benchmarks reflect the clinical outcomes that patients would attain if they have received guideline-based care for extremity vascular trauma. We note that none of the 12 studies made claims regarding the association between guideline-based implementation of synthetic graft treatments and extremity vascular trauma outcomes. Also, in 9 of the 12 studies, the number of synthetic graft recipients ranged from 3 to 16. We question if these samples were sufficiently powered to detect statistically significant and clinically meaningful differences between synthetic grafts and comparators on clinical outcomes. As previously discussed, only half of the 12 studies conducted follow up on clinical outcomes; however, none indicated whether the patients who received synthetic grafts remained in the trial throughout the follow-up periods. Consequently, we are interested in additional information on the reliability and validity of Moore et al. (2024) study's synthetic graft benchmarks, which were developed based on 12 studies with heterogeneous study designs, injury types, interventions, and follow-up protocols. Additionally, we note that the patient samples in the V005 and V017 trials may not be comparable to those in the 12 studies. We are interested in whether and how the differences, such as the availability of treatments and standard of care, between the V005 trial's SYMVESS™ recipients and the 12 studies' patient populations were accounted for in the meta-analysis and interpretation of the clinical outcomes of the Moore et al. (2024) study.

We further note that the Moore et al. (2024) study also combined the results of the V005 and V017 trials for comparison to the synthetic grafts benchmarks, and we question whether the combined results can be generalized to the Medicare population. In the combined sample (N=67), the 51 civilian patients of the V005 trial accounted for 76 percent of the combined total, while the 16 military patients of the V017 trial accounted for 24 percent of the combined total. We question whether the combined results can be extrapolated to a civilian or military population. In addition, we note that while the average age of both of the trials' patient populations were comparable (V005: 33.5 years; V017: 34.2 years); they differed in the distribution of a number of variables, including the types of injuries and trauma. As a result, we question whether it is appropriate to combine the results from these trials, and whether any outcomes from the trials are generalizable to the Medicare population, which may have a different distribution of various types of injuries and trauma. We also note that the applicant acknowledged the lack of Medicare-aged study participants in the Moore et al. (2024) study, and stated that the proportion (3 percent) of Medicare-aged patients in the V005 and V017 clinical trials was comparable to that in clinical databases (4.6 percent in the National Trauma Data Bank® (NTDB®) and 4.5 percent in the PROspective Observational Vascular Injury Trial (PROOVIT) registry). According to the applicant, the V005 and V017 trials included two patients at least 65 years of age who experienced vascular or extremity trauma (Humacyte Global, Inc., 2023). The applicant compared the percent of SYMVESS™ recipients 65 years of age or older with that of trauma patients in the PROOVIT registry, which includes data of vascular injuries from 14 level 1 or 2 trauma centers in the U.S. since February 2013 (DuBose et al., 2015).[173] According to the applicant, the PROOVIT registry included 47 patients who were 65 years of age or older and had vascular or extremity trauma. Both of the SYMVESS™ patients over the age of 65 in the V005 and V017 trials had lower extremity trauma but no upper extremity trauma. In comparison, 43 percent of the patients in the PROOVIT registry had lower extremity trauma, and 57 percent had upper extremity trauma. Therefore, we continue to question whether the findings of the V005 and V017 trials are generalizable to the Medicare population.

We are also concerned that the sample sizes of the 2 trials in the Moore et al. (2024) study were too small to ensure that the estimates for clinical outcomes were reliable, as the V017 trial included only 16 cases and the V005 trial included 51. We note that the sample size for the V005 trial was calculated for analyzing 30-day patency rate, which was the primary endpoint of the trial.[174] The Moore team estimated that at least 40 cases would be needed to yield sufficient power for the testing of patency rate at 30 days after implant. However, whether a sample size yields sufficient power depends partly on the effect size, that is, the difference in outcomes between subjects receiving treatments versus control that is statistically significant and clinically meaningful. We question whether, due to the sample size for the V005 trial, the study findings with respect to patency, infections, amputations, and death are sufficient to support that the technology provides a substantial clinical improvement over existing technologies with respect to these outcomes.

Moreover, we note that there are differences in the outcome data for the V005 trial in the Moore (2024) study and the SYMVESS™ United States Prescribing Information (USPI).[175] We note that the USPI reports clinical outcomes for the two trials separately and does not present the combined outcomes. We also note that the clinical outcomes data for V017 are identical between the Moore study (2024) and Section 14, Clinical Studies, of the

[173] DuBose JJ, Savage SA, and Fabian TC, et al. (2015). The American Association for the Surgery of Trauma PROspective Observation Vascular Injury Treatment (PROOVIT) registry: Multicenter data on modern vascular injury diagnosis, management, and outcomes. *Journal of Trauma and Acute Care Surgery* 78(2).

[174] Moore (2024), op.cit. Supplement #2, Statistical Analysis Plan for CLO–PRO–V005, Version 8. p. 10.

[175] Humacyte Global, Inc. SYMVESS USPI [Package Insert]. (Revised 12/2024). Available at: *https://www.fda.gov/media/184625/download?attachment.*

USPI. For the V005 trial, the Moore study (2024) reported the primary patency rate as 84.3 percent (43/51),[176] and the USPI 66.7 percent (36/54).[177] Thus for primary patency, SYMVESS™ exceeded the synthetic graft benchmark (78.9 percent) according to the Moore study, but not according to the USPI. In terms of secondary patency, the Moore study (2024) reported the rate as 90.2 percent (46/51), the USPI 72.2 percent (39/54). Therefore, for secondary patency, SYMVESS™ exceeded the synthetic grafts benchmarks according to the Moore study (2024), but not according to the USPI. In terms of amputation, the Moore study (2024) reported the 30-day rate as 9.8 percent (5/51), the USPI reported 30-day limb salvage rate as 75.9 percent (41/54), or 24.1 percent (13/54) in terms of 30-day amputation rate. In terms of limb salvage, therefore, SYMVESS™'s performance exceeded the synthetic graft benchmark (24.3 percent) according to the Moore study (2024), and was comparable according to the USPI. Also, while the Moore study (2024) reported a 30-day all-cause mortality rate (5.9 percent), which was higher than the corresponding synthetic grafts benchmark (3.4 percent), the USPI does not provide any mortality rates. Given the variation by data source as to whether SYMVESS™ performed better than the synthetic grafts benchmarks for primary and secondary patency and amputation rates, we question the applicant's assertion of clinical improvement compared to synthetic grafts.

Regarding Wang et al. (2023), a prospective, multicenter, phase III randomized clinical trial comparing the effects of SYMVESS™ to that of synthetic ePTFE grafts as an arteriovenous conduit for hemodialysis access in patients with ESRD, we note that the study sample did not assess patients with vascular trauma, and both arms were made up of dialysis patients, who are in general immunocompromised and have comorbidities, unlike trauma patients.[178] The differences in clinical profiles between ESRD and trauma patients may confound the difference between the two groups in conduit-related infection rate, limb salvage rate, and other graft-related clinical outcomes. While the applicant provided this study to demonstrate that SYMVESS™ provides improved infection rate compared to synthetic grafts, we question the extent to which the infection rates of SYMVESS™ in ESRD patients can be extrapolated to patients with extreme arterial injury, for which the technology is indicated.

We also note that while the applicant provided studies comparing SYMVESS™ to synthetic grafts to demonstrate improved outcomes, we remain unclear about how the clinical outcomes of SYMVESS™ recipients compare to those who receive other currently available treatments for extremity vascular trauma, like cryopreserved human grafts or xenografts. We would be interested in additional evidence comparing SYMVESS™ and these grafts in order to inform our assessment of substantial clinical improvement over existing technologies.

Lastly, we question the applicant's claim that SYMVESS™ enables quicker reperfusion of injured extremities compared to autologous vein grafts which reduces the risk of complications. According to the indication, SYMVESS™ is used when autologous vein graft is not feasible. Thus, SYMVESS™ would not be an alternative for nor comparable to autologous vein grafts. We welcome clarification or further information about this claim.

We are inviting public comments on whether SYMVESS™ meets the substantial clinical improvement criterion.

m. TECELRA® (Afamitresgene Autoleucel)

Adaptimmune, LLC submitted an application for new technology add-on payments for TECELRA® for FY 2026. According to the applicant, TECELRA® is a melanoma-associated antigen A4 (MAGE–A4)-directed genetically modified autologous T-cell immunotherapy (also referred to as an autologous T-cell receptor (TCR) therapy) indicated for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA–A*02 subtype positive, and whose tumor expresses the MAGE–A4 antigen. Per the applicant, TECELRA® is composed of T cells genetically modified to express affinity-enhanced TCRs specific to the MAGE–A4 protein, which is expressed by synovial sarcoma tumor cells at varying frequencies.

Please refer to the online application posting for TECELRA®, available at *https://mearis.cms.gov/public/publications/ntap/NTP241004LTDY2*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, TECELRA® was granted BLA accelerated approval from FDA on August 1, 2024 for treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy; are HLA–A*02:01P, HLA–A*02:02P, HLA–A*02:03P, or HLA–A*02:06P positive; and whose tumor expresses the MAGE–A4 antigen as determined by FDA-approved or cleared companion diagnostic devices. Per the applicant, TECELRA® was commercially available immediately after receiving FDA marketing authorization. The applicant stated that TECELRA® is a single, one-time, patient-specific treatment delivered as an intravenous infusion containing 2.68×10^9 to 10×10^9 MAGE–A4 TCR positive T-cells, in one or more infusion bag(s).

The applicant stated that, effective October 1, 2022, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of TECELRA®: XW03368 (Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8) or XW04368 (Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

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

[176] Moore (2024), *op. cit.,* Table 2.

[177] SYMVESS USPI, *op. cit.* Table 2.

[178] U.S. Centers for Disease Control and Prevention. (2023, May 11). People Who Are Immunocompromised: Know how to protect yourself and what to do if you get sick. U.S. Department of Health and Human Services, Centers for Disease Control and Prevention. *https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html.*

regarding the substantial similarity criteria. Please see the online application posting for TECELRA® for the applicant's complete statements in support of its assertion that TECELRA® is not substantially similar to other currently available technologies.

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	TECELRA®'s mechanism of action is distinct from that of other marketed therapeutic products. TECELRA® is a type of adoptive cell therapy, which are innovative cancer immunotherapies that involve collecting lymphocytes (white blood cells, or peripheral blood mononuclear cells) from the patient for the purpose of genetically modifying and expanding the lymphocytes to improve their tumor-fighting capabilities before returning the re-engineered cells to the patient. Although CAR T-cell therapies are also adoptive cell therapies, their mechanism of action is different compared to TCR T-cell therapies such as TECELRA®. Specifically, CAR T-cell therapies use an antibody-derived single-chain antibody-variable fragment (scFv) that recognizes cell surface antigens. By contrast, TCR T-cell therapies recognize a specific peptide presented at the cancer cell surface as peptide-HLA complexes. TECELRA® is comprised of T cells that have hypervariable CDRs modified to express affinity to the MAGE–A4 protein, which is expressed in certain solid tumors at varying frequencies. TECELRA® is the first and only FDA-approved MAGE–A4 targeted therapy of any kind. Although other therapies are utilized for the treatment of patients with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, pazopanib (VOTRIENT), a small molecule antiangiogenic tyrosine kinase inhibitor, is the only agent indicated for second-line (2L) treatment of soft tissue sarcoma (STS).
Is the technology assigned to the same MS–DRG as existing technologies?	No	As reflected in the FY 2025 Medicare IPPS Final Rule, CMS assigned TECELRA®'s unique ICD–10–PCS codes (XW03368 (Introduction of afamitresgene autoleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 8) and XW04368 (Introduction of afamitresgene autoleucel immunotherapy into central vein, percutaneous approach, new technology group 8)) to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies). TECELRA® is the only therapy approved for synovial sarcoma assigned to MS–DRG 018 and the only TCR T-cell therapy assigned to MS–DRG 018. Other technologies assigned to MS–DRG 018 do not treat synovial sarcoma and have different mechanisms of action.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	TECELRA® is the first FDA-approved engineered TCR T-cell therapy and the only therapy specifically studied in and approved for synovial sarcoma patients. Synovial sarcoma is a specific form of STS and is a rare disease that tends to occur in younger individuals, with a median age of initial clinical presentation being in the third decade of life. Prior to TECELRA®, there were no FDA-approved therapies specifically for the treatment of synovial sarcoma. Pazopanib was studied in broader STS populations that included a subgroup of patients with synovial sarcoma (less than 10% of patients) but was not approved by FDA specifically for the treatment of synovial sarcoma. No other technology is specifically indicated for the treatment of adult patients with synovial sarcoma. To the extent other therapies are used for the treatment of synovial sarcoma off-label consistent with National Comprehensive Cancer Network (NCCN) clinical guidelines, synovial sarcoma patients were mere subpopulations of a larger STS subject pool across multiple histologies and without formal a priori subgroup efficacy analyses. Thus, we know of no studies in which synovial sarcoma patients were the focus population to determine safety and efficacy of the treatments.

We note that the applicant stated that TECELRA® is the only FDA-approved therapy specifically studied and approved for patients with synovial sarcoma, therefore, it does not involve the treatment of a similar type of disease or patient population as existing technologies. While the applicant stated that other therapies in the National Comprehensive Cancer Network Clinical Practice Guidelines (NCCN Guidelines®), such as pazopanib, are indicated for use in the broader STS population rather than specifically for synovial sarcoma, we note that synovial sarcoma is a type of STS. Consequently, we question whether existing treatments indicated for STS, which can be used for the treatment of specific subtypes of STS such as synovial sarcoma, would treat the same or similar patient population as TECELRA®.

We are inviting public comments on whether TECELRA® is substantially similar to existing technologies and whether TECELRA® meets the newness criterion.

With respect to the cost criterion, the applicant provided four analyses to demonstrate that TECELRA® meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

TECELRA® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for TECELRA®.

TECELRA® COST ANALYSIS—Continued

Claims identified	Scenario 1: 1,123 claims mapping to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies). Scenario 2: 374 claims mapping to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies). Scenario 3: 374 claims mapping to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies). Scenario 4: 2,174 claims mapping to 37 MS–DRGs, with 10.81% of claims mapping to MS–DRG 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal System and Connective Tissue Disorders with CC).
Charges removed for prior technology.	Scenarios 1–3: Per the applicant, claim charges for cell and gene therapy products were removed when they were reported on the claims. For all other claims, the applicant removed the total drug charges from the claims. The applicant stated that removing all drugs charges is an overestimate of charges needing to be removed. Scenario 4: Per the applicant, no prior technology charges were removed since these cases likely do not include any high-cost therapies like MS–DRG 018 does. The applicant did not remove indirect charges related to the prior technology in all four scenarios.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application.
Inflation factor	The applicant applied an inflation factor of 8.406% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the wholesale acquisition cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Average case-weighted threshold amount: $1,554,026. Final inflated average case-weighted standardized charge per case: —Scenario 1: $4,286,667. —Scenario 2: $4,383,746. —Scenario 3: $4,207,244. —Scenario 4: $4,186,358.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all four scenarios, the applicant asserted that TECELRA® meets the cost criterion.

We are inviting public comments on whether TECELRA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that TECELRA® represents a substantial clinical improvement over existing technologies because TECELRA® is the first and only FDA-approved therapy for eligible patients with unresectable or metastatic synovial sarcoma; is a new treatment option for eligible patients with unresectable or metastatic synovial sarcoma, who are unresponsive to existing systemic therapies after first-line (1L) progression; offers significant clinical improvement in overall response rate (ORR) and overall survival (OS) compared to existing therapies; and is well-tolerated with a manageable safety profile. The applicant provided 1 published study, TECELRA®'s prescribing information, and an FDA press release to support these claims, as well as 15 background articles about TCR T-cell therapies, expression of MAGE–A4 in tumors, the prevalence of HLA–A subtypes, other 2L synovial sarcoma treatments, and the burden of illness for patients with synovial sarcoma and myxoid/round cell liposarcoma (MRCLS).[179] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for TECELRA® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
TECELRA® is the first and only FDA-approved engineered TCR T-cell therapy.	FDA Press Release. FDA Approves First Gene Therapy to Treat Adults with Metastatic Synovial Sarcoma. August 2, 2024. Available from: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treat-adults-metastatic-synovial-sarcoma.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
TECELRA® is the first and only FDA-approved therapy for patients with unresectable or metastatic synovial sarcoma.	U.S. Food and Drug Administration, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

[179] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
TECELRA® is a new treatment option for patients with unresectable/metastatic synovial sarcoma, unresponsive to existing systemic therapies after first-line progression due to limited effectiveness, ORRs and OS.	D'Angelo SP, Araujo DM, Abdul Razak AR, et al. Afamitresgene autoleucel for advanced synovial sarcoma and myxoid round cell liposarcoma (SPEARHEAD–1): an international, open-label, phase 2 trial (2024): Lancet 403;10435:1460–1471. TECELRA [package insert]. Philadelphia, PA: Adaptimmune, LLC; 2024. The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
TECELERA® offers a significant clinical improvement in ORR and OS as compared to existing therapies.	D'Angelo, 2024, *op. cit.* Adaptimmune, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.
TECELERA® is well tolerated and has a manageable safety profile.	D'Angelo, 2024, *op. cit.* Adaptimmune, 2024, *op. cit.* The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TECELRA®.

After review of the supporting evidence provided by the applicant, we have the following concerns regarding whether TECELRA® meets the substantial clinical improvement criterion. With respect to the assertion that TECELRA® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, we note that TECELRA® being the first approved TCR therapy may relate to mechanism of action under the newness criterion, but is not relevant to the demonstration of substantial clinical improvement. Further, while the applicant stated that TECELRA® is the first and only therapy approved specifically for patients with unresectable or metastatic synovial sarcoma, we note that synovial sarcoma is a subtype of the broader STS group. According to the applicant, there were no therapies approved by the FDA specifically for synovial sarcoma, and pazopanib and trabectedin are two therapies that may be used to manage synovial sarcoma in subsequent-line settings. However, according to the NCCN Clinical Guidelines® for STS, there are other available treatments that treat advanced and metastatic STS, including synovial sarcoma, which include pazopanib and trabectedin. Therefore, we question whether the applicant's claim supports that TECELRA® offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments given there are other available treatments for patients with STS that would also treat patients with unresectable or metastatic synovial sarcoma. In addition, while the applicant stated that TECELRA® is a new treatment option for patients with unresectable or metastatic synovial sarcoma unresponsive to existing systemic therapies after previous 1L treatments such as anthracycline-based or ifosfamide-based therapy due to limited effectiveness, ORR, and OS, it is unclear whether this patient population is unresponsive to or ineligible for other existing treatments such as trabectedin, in which higher response rates of 27–51% have been reported.[180] We note that while patients in the SPEARHEAD–1 study received multiple previous lines of systemic therapy, the study did not list these therapies while noting that bridging therapy, including pazopanib, trabectedin, ifosfamide, or doxorubicin, was permissible between leukapheresis and lymphodepletion at the investigators' discretion. Therefore, we question whether TECELRA® offers a treatment for a patient population unresponsive to, or ineligible for, currently available treatments.

With regard to the claim that TECELRA® offers a significant clinical improvement in ORR and OS compared to existing therapies, the applicant provided the SPEARHEAD–1 phase II clinical trial (D'Angelo et al., 2024), which assessed TECELRA®'s efficacy in 44 patients (aged 16 to 75 years) with metastatic or unresectable synovial sarcoma who previously received at least 1 prior line of anthracycline-containing or ifosfamide-containing chemotherapy. The SPEARHEAD–1 study found that synovial sarcoma patients treated with TECELRA® had an ORR of 39 percent and a median OS (mOS) of 16.9 months. According to the applicant, the study demonstrated a higher ORR and longer mOS than those from historical studies with pazopanib (18.9 percent, 10.3 months), trabectedin (12.3 percent, 10.4 months), gemcitabine/docetaxel (4.5–5.0 percent, 8.4–14 months), and regorafenib (8 percent, 13.4 months).[181] [182] [183] [184] The applicant also stated that, although listed in the NCCN Clinical Guidelines® for STS, eribulin, dacarbazine, temozolomide, and vinorelbine have not been adequately studied in previously treated unresectable or metastatic synovial sarcoma patients, and therefore, their effectiveness for this patient population cannot be determined (NCCN, 2024). However, we note that patients with unresectable or metastatic synovial sarcoma treated with TECELRA® demonstrated a mOS of

[180] Takahashi M, Takahashi S, Araki N, et al. Efficacy of trabectedin in patients with advanced translocation-related sarcomas: pooled analysis of two phase II studies. Oncologist 2017; 22: 979–88.

[181] Carroll, C., Patel, N., Gunsoy, N.B., Stirnadel-Farrant, H.A., & Pokras, S. (2022). Meta-analysis of pazopanib and trabectedin effectiveness in previously treated metastatic synovial sarcoma (second-line setting and beyond). *Future Oncology, 18*(32), 3651–3665. *https://doi.org/10.2217/fon-2022-0348.*

[182] Pender, A., Davis, E.J., Chauhan, D., Messiou, C., Al-Muderis, O., Thway, K., . . . & Jones, R.L. (2018). Poor treatment outcomes with palliative gemcitabine and docetaxel chemotherapy in advanced and metastatic synovial sarcoma. *Medical Oncology, 35,* 1–5. *https://doi.org/10.1007/s12032-018-1193-5.*

[183] Tansir, G., Rastogi, S., Kumar, A., Barwad, A., Mridha, A.R., Dhamija, E., . . . & Bhoriwal, S. (2023). A phase II study of gemcitabine and docetaxel combination in relapsed metastatic or unresectable locally advanced synovial sarcoma. *BMC Cancer, 23*(1), 639. *https://doi.org/10.1186/s12885-023-11099-4.*

[184] Mir, O., Brodowicz, T., Italiano, A., Wallet, J., Blay, J.Y., Bertucci, F., . . . & Penel, N. (2016). Safety and efficacy of regorafenib in patients with advanced soft tissue sarcoma (REGOSARC): a randomised, double-blind, placebo-controlled, phase 2 trial. *The Lancet Oncology, 17*(12), 1732–1742. *https://doi.org/10.1016/S1470-2045(16)30507-1.*

16.9 months, which is similar to the historical benchmark results from patients treated with gemcitabine/docetaxel (8.4 to 14 months) and regorafenib (13.4 months). In addition, we note that the mOS for SPEARHEAD–1 non-responders was comparable to existing therapies, and we question whether the baseline characteristics of the study population, such as biomarkers of resistance to TECELRA® rather than the treatment itself, may account for the observed survival outcomes. Furthermore, we note that TECELRA® is indicated for patients with tumors expressing the MAGE–A4 tumor antigen, and we question whether the provided historical benchmark results for other treatments in which study participants were not tested for biomarkers, such as MAGE–A4, may represent different target populations from that of TECELRA®. Finally, we note that the applicant compared the clinical outcomes from the SPEARHEAD–1 study to historical controls without appropriate statistical adjustments to account for differences in study designs. We question whether these differences may introduce confounders which could reduce the validity of the results of the comparison.

With respect to the claim that TECELRA® is well-tolerated and has a manageable safety profile, the applicant stated that the SPEARHEAD–1 clinical trial found that 75 percent of patients experienced cytokine release syndrome (CRS), with only one patient experiencing grade ≥3 CRS, and one patient experienced symptoms consistent with grade 1 immune effector cell-associated neurotoxicity syndrome (ICANS). The applicant stated that, compared to CAR T-cell therapies, the CRS associated with TECELRA® is modest (Tsimberidou et al., 2021). However, we are unclear why the applicant compared the safety profile of TECELRA® to CAR T-cell therapies (which are not approved for use in STS) rather than other available therapies that treat unresectable or metastatic synovial sarcoma. Therefore, we are interested in evidence comparing TECELRA®'s safety profile to other, non-CAR T-cell treatments for unresectable or metastatic synovial sarcoma. The applicant also stated that because TECELRA® is a single administration, recipients are less likely to experience repeated adverse events from the infusion compared to treatments requiring multiple/regular continuous or cyclical administrations; however, we question the basis for this claim as the applicant did not provide any supporting evidence.

We are inviting public comments on whether TECELRA® meets the substantial clinical improvement criterion.

n. ZIIHERA® (Zanidatamab-hrii)

Jazz Pharmaceuticals, Inc. submitted an application for new technology add-on payments for ZIIHERA® for FY 2026. According to the applicant, ZIIHERA® is a bispecific human epidermal growth factor receptor 2 (HER2)-directed antibody for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) biliary tract cancer (BTC).

Please refer to the online application posting for ZIIHERA®, available at *https://mearis.cms.gov/public/publications/ntap/NTP240925MW5YD*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, ZIIHERA® was granted BLA approval from FDA on November 20, 2024, for the treatment of adults with previously treated, unresectable or metastatic HER2-positive (IHC 3+) BTC as detected by an FDA-approved test. According to the applicant, ZIIHERA®'s market availability was delayed to allow for final packaging with FDA approved labels and package inserts as well as to allow time for shipment to channel distribution points, therefore, ZIIHERA® became commercially available as of December 2, 2024. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, such as related to packaging and shipment to channel distribution points.

According to the applicant, ZIIHERA® is administered intravenously in doses of 20 mg/kg once every 2 weeks until disease progression or unacceptable toxicity; therefore, the dose per inpatient stay is 1,400 mg.

The applicant stated that effective October 1, 2024, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of ZIIHERA®: XW033CA (Introduction of zanidatamab antineoplastic into peripheral vein, percutaneous approach, new technology group 10) or XW043CA (Introduction of zanidatamab antineoplastic into central vein, percutaneous approach, new technology group 10). The applicant stated that C22.1 (Intrahepatic bile duct carcinoma), C23 (Malignant neoplasm of gallbladder), C24.0 (Malignant neoplasm of extrahepatic bile duct), C24.8 (Malignant neoplasm of overlapping sites of biliary tract), C24.9 (Malignant neoplasm of biliary tract, unspecified); or Z51.11 (Encounter for antineoplastic chemotherapy) may be used to currently identify the indication for ZIIHERA® under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

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

Substantial similarity criteria	Applicant response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	ZIIHERA® is not the same or substantially similar to any therapies currently used to treat adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC. It is a bispecific HER2-directed, biparatopic antibody that simultaneously binds to 2 nonoverlapping, distinct sites on HER2: the ECD4 and ECD2 domains. Trans-binding of ZIIHERA® with HER2 results in receptor crosslinking, clustering, and internalization, which leads to a reduction of HER2 from the cell surface. It reduces phosphorylation of HER2 family members (including EGFR, HER2, and HER3), downstream signaling, and ligand-dependent and -independent proliferation. Distinctly, ZIIHERA® potently induces CDC, ADCC, and ADCP. ZIIHERA® is substantially differentiated mechanistically and clinically from currently available anti-HER2 agents: HERCEPTIN®, indicated for the treatment of HER2-overexpressing breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma; PERJETA®, indicated for use in combination with HERCEPTIN® and DOCETAXEL for HER2+ metastatic breast cancer; and ENHERTU®, indicated for HER2+ and HER2-low breast cancer, non-small cell lung cancer (NSCLC) activating HER2 mutations, HER2+ gastric or gastroesophageal junction adenocarcinoma, and HER2+ solid tumors (not specifically studied in BTC), when no other satisfactory treatment options for unresectable/metastatic HER2 (IHC 3+) BTC exist. ZIIHERA®'s distinct mechanisms of action were confirmed in preclinical models where ZIIHERA® exhibited improved antitumor activity compared with HERCEPTIN® alone and HERCEPTIN®PERJETA® in head-to-head comparisons across a range of tumors and HER2 expression levels: 1) ZIIHERA® binds adjacent HER2 reorganization not observed with HERCEPTIN® or PERJETA®; 2) ZIIHERA®, but not HERCEPTIN® or HERCEPTIN®+PERJETA®, elicit potent CDC against high HER2-expressing tumor cells in vitro (the only HER2 agent that can elicit CDC); and 4) ZIIHERA® mediates HER2 internalization and downregulation, inhibition of both cell signaling and tumor growth, ADCC and ADCP, and shows superior in vivo antitumor activity compared to HERCEPTIN®+PERJETA® in a HER2-expressing xenograft model. ZIIHERA® is also highly differentiated mechanistically and clinically from chemotherapeutic regimens or other therapies used in first line (1L) and second line (2L) treatment of BTC. It is not a chemotherapy. Its unique asymmetric design, its biparatopic bispecific binding, and ability to induce HER2 receptor crosslinking is believed to drive the multiple mechanisms of action of ZIIHERA® and its clinical activity as a single agent. ZIIHERA® is the first and only bispecific HER2-directed antibody indicated for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC.
Is the technology assigned to the same MS–DRG as existing technologies?	Yes	While ZIIHERA® will not map to MS–DRGs distinct from other treatments administered to patients diagnosed with BTC, patient cases receiving intravenous infusion of ZIIHERA® will be identified by unique ICD–10–PCS procedures codes for ZIIHERA® administration: XW033CA and XW043CA, effective October 1, 2024.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	ZIIHERA® is the first and only bispecific HER2-directed, biparatopic antibody approved by FDA for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC. Results from the pivotal, single-arm phase IIb HERIZON–BTC–01 study support ZIIHERA® having meaningful clinical benefit and potential as a new standard of care for patients with HER2+ (IHC 3+) BTC.

After review of the information provided by the applicant, we note that while the applicant stated that ZIIHERA® is the first and only bispecific HER2-directed, biparatopic antibody approved by FDA for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC, there are several existing treatment options for patients with unresectable/metastatic HER2+ (IHC 3+) BTC such as FOLFOX, FOLFIRI, STIVARGA®, or ENHERTU®.[185] Therefore, it is unclear how ZIIHERA® treats a new patient population or disease as compared to these existing treatments.

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

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that ZIIHERA® meets the cost criterion. Each analysis followed the order of operations summarized in the following table.

ZIIHERA® COST ANALYSIS

Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD–10–CM codes, ICD–10–PCS codes, and MS–DRGs used by the applicant, see the cost criterion codes and MS–DRGs attachment included in the online posting for ZIIHERA®.
Claims identified	Scenario 1: 152 claims mapping to 13 MS–DRGs, with 12.50% of claims mapping to MS–DRG 847 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis with CC). Scenario 2: 3,807 claims mapping to 30 MS–DRGs, with 44.44% of claims mapping to MS–DRG 435 (Malignancy of Hepatobiliary System or Pancreas with MCC).

[185] National Comprehensive Care Network (NCCN). (2024, November 27). NCCN Guidelines Version 5.2024 Biliary Tract Cancers. Retrieved on January 8, 2025, from *https://www.nccn.org.*

ZIIHERA® COST ANALYSIS—Continued

Charges removed for prior technology.	Per the applicant, the utilization of ZIIHERA® would replace chemotherapy charges. The applicant removed 15.9% of radiology charges from identified cases in which BTC was the primary diagnosis and removed 19.9% of radiology charges from identified cases in which BTC was a secondary diagnosis. Per the applicant, these percentages were derived based on an analysis of the revenue center file from the 100% Inpatient Standard Analytic File (SAF) in FY 2023. The applicant estimated the percentage of chemotherapy therapy-related radiology charges for each set of cases by dividing the sum of charges for chemotherapy-related revenue codes (0331, 0332, 0335) by the sum of charges for the revenue codes comprising total radiology charges. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
Inflation factor	The applicant applied an inflation factor of 8.406% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
Charges added for the new technology.	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
Cost analysis results	Scenario 1: —Average case-weighted threshold amount: $87,202. —Final inflated average case-weighted standardized charge per case: $197,284. Scenario 2: —Average case-weighted threshold amount: $93,683. —Final inflated average case-weighted standardized charge per case: $209,487.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that ZIIHERA® meets the cost criterion.

We are inviting public comments on whether ZIIHERA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that ZIIHERA® represents a substantial clinical improvement over existing technologies because it is a bispecific HER2-directed antibody with multiple, distinct mechanisms of action and a differentiated clinical profile, and it is the first and only FDA-approved treatment for HER2+ (IHC 3+) BTC. In addition, the applicant asserted that ZIIHERA® fulfills an unmet need for this patient population by providing an optimal chemotherapy-free treatment option, where patients also have the potential to achieve meaningfully improved clinical benefits. The applicant provided 1 study and 2 poster presentations of the same study to support these claims, as well as 3 background articles on other treatments for advanced BTC.[186] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for ZIIHERA® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Applicant statements in support	Supporting evidence provided by the applicant
Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
ZIIHERA® is the first and only bispecific HER2-directed antibody for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC.	Pant S, et al. Zanidatamab in previously treated HER2-positive biliary tract cancer: overall survival and longer follow-up from the phase 2b HERIZON–BTC–01 study. American Society of Clinical Oncology annual meeting. 2024. Abstract; Poster 4091. Harding JJ, et al. Zanidatamab for HER2-amplified, unresectable, locally advanced or metastatic biliary tract cancer (HERIZON–BTC–01): a multicentre, single-arm, phase 2b study. Lancet Oncol. 2023;24(7):772–82. The applicant also provided background information and supplemental material to support this claim, which can be accessed via the online posting for the technology.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	
In HERIZON–BTC–01, ZIIHERA® demonstrated clinical benefit of sustained/durable response rates and longer overall survival compared to previously reported outcomes of 2L therapies for advanced BTC.	Pant, 2024, *op. cit.* Harding, 2023, *op. cit.* The applicant also provided background information and supplemental material to support this claim, which can be accessed via the online posting for the technology.

[186] Background articles and supplemental material are not included in the following table but can be accessed via the online posting for the technology.

Applicant statements in support	Supporting evidence provided by the applicant
Treatment with ZIIHERA® provides a marked clinical benefit with a significantly higher response rate than previously reported for currently preferred 2L chemotherapy regimen.	Pant, 2024, *op. cit.* Harding, 2023, *op. cit.* The applicant also provided background information and supplemental material to support this claim, which can be accessed via the online posting for the technology.
The overall benefit:risk assessment of ZIIHERA® is favorable. ZIIHERA® fulfills an unmet medical need and provides an option for patients to receive clinical benefit with a low risk of harm.	Harding, 2023, *op. cit.* Wasan H, et al. Health-related quality of life outcomes in patients with zanidatamab-treated HER2-positive biliary tract cancer in the Phase 2b HERIZON–BTC–01 study. Presented at European Society for Medical Oncology (ESMO) 2023; Poster presentation, Poster 101P. Pant, 2024, *op. cit.* The applicant also provided background information and supplemental material to support this claim, which can be accessed via the online posting for the technology.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for ZIIHERA®.

After review of the information provided by the applicant, we have the following concerns regarding whether ZIIHERA® meets the substantial clinical improvement criterion. With respect to the assertion that ZIIHERA® offers a treatment option for a patient population unresponsive to or ineligible for existing therapies, the applicant stated that ZIIHERA® is the first and only FDA-approved bispecific HER2-directed antibody for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC. However, we note that while the target (HER2+) and type of therapy (bispecific antibody) for a particular indication may relate to mechanism of action under the newness criterion, it is not relevant to the demonstration of substantial clinical improvement. Further, we note that the applicant stated that FOLFOX is the preferred subsequent line therapy option for these patients, and we also note that NCCN guidelines list additional available therapies including: FOLFIRI, ENHERTU®, and HERCEPTIN® plus TUKYSA®. We further note that while the applicant provided studies describing outcomes from the HERIZON–BTC–01 trial of ZIIHERA® as well as background studies describing outcomes for other treatment options in 2L advanced BTC, the studies did not demonstrate that patients eligible for treatment with ZIIHERA® are unable to receive other existing therapies. Therefore, we question whether ZIIHERA® offers a treatment option for a patient population unresponsive to, or ineligible for other existing therapies.

With respect to the assertion that ZIIHERA® significantly improves clinical outcomes relative to services or technologies previously available, the applicant provided 1 published peer-reviewed study of HERIZON–BTC–01 (Harding et al., 2023) and 2 poster presentations that are analyses of HERIZON–BTC–01 (Pant et al., 2024; Wasan et al., 2023) in support of its claims. Harding et al. (2023) and Pant et al. (2024) provided results of the phase IIB HERIZON–BTC–01, a global, multicenter, single arm, cohort study assessing ZIIHERA® treatment in 87 patients with HER2+ BTC, which were grouped into cohorts based on immunohistochemistry (IHC): cohort 1, n=80 (HER2+ (IHC 2+ or IHC 3+)) and cohort 2, n=7 (IHC 0 or IHC 1+). We note that the HERIZON–BTC–01 study did not compare ZIIHERA® outcomes to outcomes for other existing treatments, and therefore we question the extent to which this can be relied upon for a finding of substantial clinical improvement. We note that 63 percent of the study's patients were enrolled at clinical trial sites in Asia, and we question whether the location of the clinical trial sites being outside of the US could affect the generalizability of the findings to the U.S. Medicare patient population. We also question whether the study's sample size may have impacted the ability to perform or interpret comparative analyses within and between the two different patient cohorts.

With respect to the applicant's claim that, in HERIZON–BTC–01 study (Harding et al., 2023), ZIIHERA® demonstrated a clinical benefit of sustained/durable response rates, longer OS, and a significantly higher response rate compared to previously reported outcomes of 2L advanced BTC therapies, we note that while the applicant provided background studies comparing FOLFOX and FOLFIRI to ZIIHERA®, the supporting evidence provided did not compare ZIIHERA® to other FDA-approved therapies used for unresectable/metastatic BTC such as ENHERTU®. The applicant stated that ZIIHERA®'s median confirmed objective response rate (cORR) of 51.6 percent represents a marked clinical benefit for the target population, which is approximately 10-fold higher than the previously reported median ORR for FOLFOX and significantly more than the historical response rate of 7.7 percent for 2L chemotherapy regimens, noting the highest historical rate reported of 14.8 percent was seen in the FOLFIRI regimen. However, we question whether the differences in the studies' reported responses are comparable given that the studies are different in design, protocol, and methodology, which may limit the ability to interpret the outcomes. While the applicant stated that FOLFOX chemotherapy regimen remains the preferred 2L treatment of advanced BTC, as there are other treatments used in the 2L+ treatment of advanced BTC, we would appreciate additional information on the comparison of outcomes with ZIIHERA® to those with other FDA-approved therapies used for advanced/metastatic BTC.

With respect to the claim that ZIIHERA® has a manageable safety profile with favorable tolerability in adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC, the applicant stated that, in contrast to chemotherapy regimens used as 2L or later therapies, ZIIHERA® as a single agent is well tolerated in the pretreated BTC patient population and the resulting adverse events are manageable. In support of this claim, the applicant provided results of the HERIZON–BTC–01 study (Harding et al., 2023, Wasan et al., 2023, and Pant et al., 2024), which measured safety and quality of life in 87 patients. We are concerned that the safety and quality of life data were combined in both the Harding et al. (2023) and Pant et al. (2024) studies for cohort 1 (n=80) (HER2+ (IHC 3+ or IHC 2+)) and cohort 2 (n=7) (IHC 1+ or IHC 0), and the Wasan paper reported from cohort 1 (HER2+ (IHC 3+ or IHC 2+)). Therefore,

these studies did not provide data on safety and treatment-related adverse events for IHC 3+ BTC patients separately. We note that since ZIIHERA® is indicated for use in patients with HER2+ (IHC 3+) BTC only, we question whether the inclusion of patients with HER2+ (IHC 2+) BTC and patients with IHC 1+ or IHC 0 BTC is appropriate to demonstrate outcomes for HER2+ (IHC 3+) BTC patients specifically. We question whether this analysis provides sufficient evidence as to ZIIHERA®'s overall benefit-risk profile and how it compares to other treatments given that Wasan et al. and Pant et al., which are unpublished and non-peer-reviewed conference posters, do not include full details of the study and methodology, which therefore may limit our ability to interpret the results. We further note that HERIZON–BTC–01 was a single arm study and that the clinical outcome and HRQoL data are not specific to IHC 3+ BTC patients, in accordance with ZIIHERA®'s FDA indication.

We are inviting public comments on whether ZIIHERA® meets the substantial clinical improvement criterion.

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

As discussed previously, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization for the indication covered by the Breakthrough Device designation, may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2-to-3-year newness period to be considered ''new,'' and must also still meet the cost criterion.

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our proposal to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we are continuing to summarize each application in this proposed rule. However, while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the alternative pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the applicable new technology add-on payment criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2026 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted), including tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2026 new technology add-on payment applications. In addition, for certain FY 2026 new technology add-on payment applications, we are making available separate tables listing the ICD–10–CM codes and/or ICD–10–PCS codes that we believe would be used to identify cases relevant to the Breakthrough Device-designated indications, or would be appropriate to exclude for cases related to FDA market authorized indications that are not covered by the Breakthrough Device designation indications, for purposes of the new technology add-on payment, if approved, in Table 10 associated with this proposed rule, available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*. Click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. Please see section VI of the Addendum for additional information regarding tables associated with this proposed rule.

We received 34 applications for new technology add-on payments for FY 2026 under the new technology add-on payment alternative pathway. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58948 through 58958) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69242 through 69245), we finalized that beginning with the new technology add-on payment applications for FY 2025, for technologies that are not already FDA market authorized for the indication that is the subject of the new technology add-on payment application, applicants must have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and must provide documentation of FDA acceptance or filing to CMS at the time of application submission, consistent with the type of FDA marketing authorization application the applicant has submitted to FDA. See § 412.87(e) and further discussion in the FY 2024 and the FY 2025 IPPS/LTCH PPS final rules (88 FR 58948 through 58958; 89 FR 69242 through 69245). Of the 34 applications received under the alternative pathway, 1 application was not eligible for consideration for new technology add-on payment because it did not meet these requirements; and 4 applicants withdrew their applications prior to the issuance of this proposed rule. Of the remaining 29 applications, 27 of the technologies received a Breakthrough Device designation from FDA. The remaining two applications were designated as a QIDP by FDA. We did not receive any applications for technologies approved through the LPAD pathway.

In accordance with the regulations under § 412.87(f)(2), applicants for new technology add-on payments for FY 2026 for Breakthrough Devices must have FDA marketing authorization by May 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under § 412.87(f)(3), applicants for new technology add-on payments for FY 2026 for QIDPs and technologies approved under the LPAD pathway must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. The policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742) provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments, provided that the technology receives FDA

marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2025 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in this proposed rule we are making a proposal to approve or disapprove each of these 29 applications for FY 2026 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide a table summarizing background information and the cost analysis for each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2026. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

1. 4WEB Medical Ankle Truss System

The following table summarizes the information provided in the new technology add-on payment application for the 4WEB Medical Ankle Truss System. We note that 4WEB Medical, Inc. submitted an application for new technology add-on payments for the 4WEB Medical Ankle Truss System for FY 2024, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26924 through 26926), which the applicant withdrew prior to the issuance of the FY 2024 IPPS/LTCH PPS final rule (88 FR 58919).

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	4WEB Medical Ankle Truss System	
Technology Info	**Applicant**	4WEB Medical, Inc.
	Description	Per the applicant, the 4WEB Medical Ankle Truss System (ATS) is for use with a premarket authorized tibiotalocalcaneal (TTC) nail as part of a TTC fusion system to manage ankle bone defects that occur after a failed ankle arthrodesis or arthroplasty.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241005L44VA
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the 4WEB Medical ATS is for use with a premarket authorized TCC nail as part of a TTC fusion system to manage ankle bone defects that may be associated with the following indications: - Failed ankle arthrodesis - Failed ankle arthroplasty The anatomical landmarks necessary for the design and creation of ATS PMDs must be present and identifiable on appropriate radiography scans. The ATS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.
	FDA marketing authorization indication	The 4WEB Medical ATS is for use as an accessory to the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a TCC fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk for loss of limb. The ATS is not intended for standalone use. The anatomical landmarks necessary for the design and creation of ATS devices that are patient matched must be present and identifiable on appropriate radiography scans. The ATS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft.
	FDA marketing authorization information	Per the applicant, the Breakthrough Device designation includes the use of the device after a failed ankle arthrodesis or failed ankle arthroplasty, which would be considered a salvage procedure as indicated in the FDA-cleared indication.
	FDA marketing authorization date	March 21, 2024
	Commercial availability	According to the applicant, the 4WEB Medical ATS was not immediately available for sale as the technology must be used with an FDA-cleared nail, and therefore a third-party distributor had to be engaged that could distribute the ATS System with an FDA-cleared nail. The applicant stated that the production of the ATS System could not be started until the distribution agreement was executed. Per the applicant, when scaling up to the production printing quantity, the manufacturer had to scrap the first batch of implants because part of the build did not print correctly. According to the applicant, this was not discovered until inspection, which by the time that occurred, was approximately one month later. Per the applicant, it did not receive the first batch that passed inspection until January 8th, 2025, which was the first date the device was available.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2023, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of the 4WEB Medical ATS: XRGJ0B9 (Fusion of right ankle joint using open-truss design internal fixation device, open approach, new technology group 9), XRGK0B9 (Fusion of left ankle joint using open-truss design internal fixation device, open approach, new technology group 9), XRGL0B9 (Fusion of right tarsal joint using open-truss design internal fixation device, open approach, new technology group 9), or XRGM0B9 (Fusion of right tarsal joint using open-truss design internal fixation device, open approach, new technology group 9).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the 4WEB Medical Ankle Truss System.
	Claims identified	Scenario 1: 67 claims mapping to 6 MS-DRGs, with 17.91% of claims mapping to MS-DRG 493 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC). Scenario 2: 255 claims mapping to 19 MS-DRGs, with 18.82% of claims mapping to MS-DRG 493 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC).
	Charges removed for prior technology	The applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). The applicant stated that the use of the technology is expected to replace a portion of devices included in these claims, although it will not replace all devices, nor any medical supplies required to perform the procedure. However, an estimate of the percentage of these total charges for devices that would be replaced could not be determined. The applicant explained that to be as conservative as possible, the analysis removed 100% of these charges. The applicant did not

		remove any indirect charges related to the prior technology as it believed that financial impact of utilizing the ATS on hospital resources compared to prior technologies is minimal.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the expected hospital acquisition cost of the technology by the national cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Scenario 1: - Average case-weighted threshold amount: $103,093 - Final inflated average case-weighted standardized charge per case: $188,608 Scenario 2: - Average case-weighted threshold amount: $106,780 - Final inflated average case-weighted standardized charge per case: $194,544 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that the 4WEB Medical ATS meets the cost criterion.

After review of the information provided by the applicant, since the indication for which the applicant received 510(k) clearance is included within the scope of the Breakthrough Device designation indication, it appears that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We agree with the applicant that the 4WEB Medical ATS meets the cost criterion and are therefore proposing to approve the 4WEB Medical ATS for new technology add-on payments for FY 2026 for use as an accessory to the Stryker T2 Ankle Arthrodesis Nail or the Stryker Valor Hindfoot Fusion Nail as part of a TCC fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk for loss of limb.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the 4WEB Medical ATS to the hospital to be $23,500 per patient. Per the applicant, one 4WEB Medical ATS is used per patient per hospital discharge. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the 4WEB Medical ATS would be $15,275 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

2. AeroPace® System

The following table summarizes the information provided in the new technology add-on payment application for the AeroPace® System.

		AeroPace® System
Technology Info	**Applicant**	Lungpacer(R) Medical Inc.
	Description	Per the applicant, the AeroPace® System is intended for temporary stimulation of the phrenic nerve(s) to increase diaphragmatic strength. Per the applicant, it is indicated to improve weaning success increase weaning, reduce ventilator days, and reduce reintubation – in patients ages 18 years or older on mechanical ventilation (MV) >96 hours and who have not weaned.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241004B25FM
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the proposed indication for use is to achieve earlier weaning from invasive MV in patients aged 18 years or older, who are not hypervolemic, and who have failed at least two spontaneous breathing trials.
	FDA marketing authorization indication	The AeroPace® System is indicated to improve weaning success - increase weaning, reduce ventilator days, and reduce reintubation - in patients ages 18 years or older on MV ≥96 hours and who have not weaned.
	FDA marketing authorization information	Per the applicant, the FDA-approved indication is consistent with its clinical trials and Breakthrough Device designation and MV treatment guidelines. The applicant stated that the Lungpacer Diaphragm Pacing Therapy System is the generic name, while the AeroPace® System is the commercial name for the device.
	FDA marketing authorization date	December 4, 2024
	Commercial availability	According to the applicant, the AeroPace® System is not commercially available immediately after FDA approval as it will take time following FDA approval to finalize the company's commercial operations and market materials to include the final labeling and regulatory information. The applicant stated that it anticipates the AeroPace® System to be commercially available on October 1, 2025.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the AeroPace® System.
	Claims identified	Broad Analysis: 83,011 claims mapping to 344 MS-DRGs, with 30% of claims mapping to MS-DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours). Narrow Analysis: 15,925 claims mapping to 264 MS-DRGs, with 31% of claims mapping to MS-DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours).
	Charges removed for prior technology	According to the applicant, the use of the AeroPace® System would be additive to the current practice. The applicant did not remove any direct charges for prior technologies being replaced, as there is no current technology for patients who may be treated with temporary transvenous diaphragm activation (TTDA) using the AeroPace® System. The applicant removed the indirect charges in the cost analysis. Per the applicant, the AeroPace® System may result in up to three fewer days on MV. The applicant estimated the charges per day associated with MV based on a presentation published by the Agency for Healthcare Research and Quality (AHRQ) in 2017. The applicant multiplied the charges per day by three days and inflated the charges using the annual IPPS rate-of-change for charges amount from FY 2018 through FY 2023. The applicant then applied the three-year inflation factor from the IPPS outlier fixed-loss threshold calculation to the respective amounts.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule and the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant did not add any direct nor indirect charges related to the new technology. Per the applicant, the clinical data indicates that ICU days and charges for other indirect services are unchanged and are determined or influenced based on other patient clinical factors.
	Cost analysis results	Broad Analysis: - Average case-weighted threshold amount: $226,579 - Final inflated average case-weighted standardized charge per case: $374,929 Narrow Analysis: - Average case-weighted threshold amount: $230,227 - Final inflated average case-weighted standardized charge per case: $365,719 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the AeroPace® System meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant received PMA approval from FDA is

included within the scope of the Breakthrough Device designation indication, it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We note that the applicant stated that the technology is not yet available for sale because it would take time following FDA approval to finalize its commercial operations and market materials to include the final labeling and regulatory information. We are interested in additional information regarding the cause for any delay in the technology's market availability, as it received FDA approval on December 4, 2024, and the applicant states that it is not expected to be commercially available until October 1, 2025.

We agree with the applicant that the AeroPace® System meets the cost criterion and are therefore proposing to approve the AeroPace® System for new technology add-on payments for FY 2026, for use to improve weaning success—increase weaning, reduce ventilator days, and reduce reintubation—in patients ages 18 years or older on MV ≥96 hours and who have not weaned.

The applicant has not provided an estimate for the cost of the AeroPace® System at the time of this proposed rule. The applicant stated that the operating components include the AeroPace® Catheter and the Airway Sensor. The applicant also noted the capital components of the AeroPace® Neurostimulation Console, Catheter Cable, Handheld Controller, and Airway Sensor Cable. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant stated that the cost of the AeroPace® Neurostimulation Console, Catheter Cable, Handheld Controller, and Airway Sensor Cable are capital costs. Therefore, it appears that these components are not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the AeroPace® System would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

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

3. AGENT™ Paclitaxel-Coated Balloon Catheter

The following table summarizes the information provided in the new technology add-on payment application for the AGENT™ Paclitaxel-Coated Balloon Catheter.

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	AGENT™ Paclitaxel-Coated Balloon Catheter	
Technology Info	Applicant	Boston Scientific Corporation
	Description	Per the applicant, the AGENT™ Paclitaxel-Coated Balloon Catheter is a semi-compliant percutaneous coronary intervention (PCI) catheter; the balloon portion of the device is coated with a TransPax coating. Per the applicant, the AGENT™ Drug Coated Balloon is designed to inhibit restenosis by delivering the drug, paclitaxel, to the diseased coronary arterial tissue.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007T6YMA
FDA Info	Breakthrough Device designation indication	Per the applicant, the AGENT Paclitaxel Drug Coated Balloon Catheter (Agent DCB) is indicated for Percutaneous Transluminal Coronary Angioplasty (PTCA) in coronary arteries 2.0 mm to 4.0 mm in diameter to treat in-stent restenosis (ISR), up to 26mm in length, for the purpose of improving myocardial perfusion.
	FDA marketing authorization indication	The AGENT™ Paclitaxel-Coated Balloon Catheter is intended to be used after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR.
	FDA marketing authorization information	Per the applicant, the FDA-approved indication is for the same patient population as the Breakthrough Device designation, but the language is slightly different because changes to the indication verbiage were made to provide additional clarity.
	FDA marketing authorization date	February 29, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA approval.
Coding	Unique ICD-10-PCS Code(s)	The applicant provided a list of procedure codes that, effective October 1, 2024, may be used to uniquely identify procedures involving the use of the AGENT™ Paclitaxel-Coated Balloon Catheter under the ICD-10-PCS coding system in the online application posting.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the AGENT™ Paclitaxel-Coated Balloon Catheter.
	Claims identified	15,435 claims mapping to 101 MS-DRGs, with 33.86% of claims mapping to MS-DRG 321 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices) and 23.79% of claims mapping to MS-DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC).
	Charges removed for prior technology	The applicant did not remove charges for PCI angioplasty procedures with a "Z" in the 6th position of the ICD-10-PCS code indicating no stent was utilized. The applicant removed estimated charges for PCI stent procedures with a "D","E","F","G" in the 6th position of the code indicating one or more bare metal stents (BMS) were utilized. Per the applicant, the median cost of C1876 (Stent, non-coated/non-covered, with delivery system) published by CMS in the documentation released with the CY25 OPPS proposed rule rate setting file was converted to charges using the national departmental cost-to-charge ratio for Implantable Devices published in the FY 2025 IPPS/LTCH PPS final rule. The applicant removed charges for PCI stent procedures with a "4","5","6","7" in the 6th position of the ICD-10-PCS code indicating one or more drug-eluding stents (DES) were utilized. Per the applicant, the median cost of C1874 (coated/covered, with delivery system) published by CMS in the documentation released with the CY25 OPPS proposed rule rate setting file was converted to charges using the national departmental cost-to-charge ratio for implantable devices published in the FY 2025 IPPS/LTCH PPS final rule. In both scenarios, the applicant removed charges for only one stent, regardless of the number of arteries and devices indicated by the procedure code because it was unclear how many stents would be replaced by the technology, as the ISR diagnosis code is not artery specific. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule and the impact file posted with the FY 2023 IPPS/LTCH final rule.
	Inflation factor	The applicant applied a 3-year inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges associated with one AGENT™ Drug-Coated Balloon by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $139,326 Final inflated average case-weighted standardized charge per case: $186,485 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant received PMA approval from FDA is

included within the scope of the Breakthrough Device designation indication, it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.[187]

We agree with the applicant that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion and are therefore proposing to approve the AGENT™ Paclitaxel-Coated Balloon Catheter for new technology add-on payments for FY 2026 for use after appropriate vessel preparation in adult patients undergoing PCI in coronary arteries 2.0 mm to 4.0 mm in diameter and lesions up to 26 mm in length for the purpose of improving myocardial perfusion when treating ISR.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the AGENT™ Paclitaxel-Coated Balloon Catheter to the hospital to be $6,175 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the AGENT™ Paclitaxel-Coated Balloon Catheter would be $4,013.75 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

4. alfapump® System

The following table summarizes the information provided in the new technology add-on payment application for the alfapump® system.

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[187] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

	alfapump® system	
Technology Info	Applicant	Sequana Medical NV
	Description	Per the applicant, the alfapump® system is an implanted subcutaneous device with rechargeable battery allowing fluid removal from the peritoneal cavity to the urinary bladder where it is then eliminated via urination. Per the applicant, the alfapump® system provides an alternative to standard treatments for refractory ascites, that is, large volume paracentesis (LVP) with albumin and transjugular intrahepatic shunts.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP240930MJNT7
FDA Info	Breakthrough Device designation indication	Per the applicant, the alfapump® System is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.
	FDA marketing authorization information	This device is intended for single patient use only in adult patients with refractory or recurrent ascites due to liver cirrhosis. It is indicated for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder, where it can be eliminated through normal urination.
	FDA marketing authorization date	December 20, 2024
	Commercial availability	According to the applicant, the alfapump® system is not expected to be commercially available immediately after FDA approval due to internal production capacity and the phased roll out plan into Liver Transplant centers to have the best possible care for patients suffering from recurrent and refractory ascites. The applicant stated that the alfapump® system would not be commercially available until July 2025.
Coding	Unique ICD-10-PCS Code(s)	Effective October 1, 2020, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of the alfapump® system: 0W1G3J6 (Bypass peritoneal cavity to bladder with synthetic substitute, percutaneous approach) and 0JH80YZ (Insertion of other device into abdomen subcutaneous tissue and fascia, open approach).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the alfapump® system.
	Claims identified	838 claims mapping to 3 MS-DRGs, with 75.3% of claims mapping to MS-DRG 423 (Other Hepatobiliary or Pancreas O.R. Procedures with MCC).
	Charges removed for prior technology	The applicant estimated the charges for the prior technology by calculating the average of the total revenue charges per claim from revenue centers 0274, 0278, and 0279 for each MS-DRG. The applicant stated that while revenue centers 0278 and 0279 would be used a proxy for device charges of prior technologies, a small number of cases (<11) also include line item charges in revenue center 0274, and therefore, the applicant added revenue center 0274 to accurately remove all prior device charges. The applicant removed indirect charges related to prior technology using a length of stay (LOS) reduction, along with the sum of the average specific identified drug charges, average ICU charges, average CCU charges, and average OR charges of analyzed claims for each MS-DRG. According to the applicant, the LOS reduction adjusts room and board charges to account for potentially shorter LOS for the use of technology than the analyzed hospital claims. The applicant determined the room and board charges by summing the total revenue line-item charges per claim for Room and Board (revenue centers 0110, 0111, 0117, 0119, 0120, 0121, 0127, 0129, 0131, 0151, and 0164) and calculated the average for each MS-DRG. The applicant estimated the LOS for implantation of the alfapump® system based on its clinical trial. The applicant calculated the LOS reduction by reducing the average room and board charges for hospital claims by the proportional difference between the average LOS for hospital claims and the implantation of the alfapump® system. The applicant determined the specific identified drug, ICU, CCU, and OR charges by summing the total revenue line-item charges per claim associated with ICU (revenue centers 0200, 0201, 0202, 0206, 0208, and 0209), CCU (revenue centers 0210, 0214, and 0219), OR (revenue centers 0360, 0361, and 0369), and Specific Drug (revenue centers 0634, 0635, and 0636). Per the applicant, radiology, CT scans, and other diagnostic imaging are assumed to be utilized regardless of prior or new technology used. The applicant stated that other medical and sterile surgical supplies as well as general anesthesia are expected to be utilized at a similar rate to prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule and correction amendment.

	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the alfapump® system by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. To calculate the average operating room costs for implantation of the alfapump® system, the applicant used an estimated surgical time based on its clinical trial and an estimated average operating room cost per minute based on the literature. The applicant added indirect charges related to the new technology by dividing the average operating room costs related to the new technology by the national average cost-to-charge ratio of 0.16 for Operating Room from the FY 2025 IPPS/LTCH PPS final rule.
	Cost analysis results	Average case-weighted threshold amount: $130,906 Final inflated average case-weighted standardized charge per case: $260,109 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the alfapump® system meets the cost criterion.

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As noted, the applicant stated that the technology is not expected to be commercially available until July 2025 due to its internal production capacity and the phased roll out plan into Liver Transplant centers. We are interested in additional information regarding any delay, such as whether the technology would be available for sale during its phased roll out plan.

We agree with the applicant that the alfapump® system meets the cost criterion and are therefore proposing to approve the alfapump® system for new technology add-on payments for FY 2026, in adult patients with refractory or recurrent ascites due to liver cirrhosis for the removal of excess peritoneal fluid from the peritoneal cavity into the bladder.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the alfapump® system to the hospital to be $30,000 per patient. Per the applicant, the alfapump® system is a single patient use implantable device, and one device is used per hospital stay. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the alfapump® system would be $19,500 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the alfapump® system meets the cost criterion and our proposal to approve new technology add-on payments for the alfapump® system.

5. aprevo®-C Cervical Interbody Fusion Device

The following table summarizes the information provided in the new technology add-on payment application for the aprevo®-C cervical interbody fusion device.

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	aprevo®-C cervical interbody fusion device	
Technology Info	**Applicant**	Carlsmed, Inc.
	Description	Per the applicant, the aprevo®-C cervical interbody fusion devices are intended to stabilize intervertebral spaces of the cervical spine (C2-T1) and facilitate fusion. Per the applicant, the devices are custom-made to achieve a patient-specific cervical alignment plan and have surfaces that match the irregular topography of each patient's cervical vertebral endplates.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007U130K
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the aprevo®-C cervical interbody fusion devices are intended for use in skeletally mature patients with degenerative cervical conditions including cervical disc degeneration, stenosis, deformity, and/or instability of the cervical spine (C2-T1) at one or more levels. Degenerative disc disease (DDD) is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had at least six weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. The aprevo®-C cervical interbody fusion devices can be used with supplemental fixation, such as an anterior plate or as a standalone construct to be used integrated bone screw fixation.
	FDA marketing authorization indication	The aprevo® Cervical ACDF Interbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. The aprevo® Cervical ACDF Interbody System must be used with supplemental fixation systems. For hyperlordotic corrections (≥ 20 lordosis), the system must be used with at least an anterior cervical plate as supplemental fixation. The aprevo® Cervical ACDF-X Interbody System are interbody fusion devices indicated at one or more levels of the cervical spine (C2-T1) in patients with the following degenerative cervical conditions: cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion. Cervical disc disease is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had at least six (6) weeks of non-operative treatment. These devices are to be filled with autograft bone and/or allogenic bone graft composed of cancellous, cortical, and/or cortico-cancellous bone. When used as a standalone system, the aprevo® Cervical ACDF-X Interbody implant with integrated screw fixation is intended for use at multiple contiguous levels, or up to two levels when used in trauma, deformity or failed previous fusions. Deformity procedures to correct coronal angulation or any use of hyperlordotic correction (>20 °) must include supplemental fixation such as posterior cervical screw fixation or anterior plating.
	FDA marketing authorization information	Per the applicant, the FDA 510(k) indication was modified from the Breakthrough Device designation indications to remove the unlimiting terminology "degenerative cervical conditions including…" and to describe the specific indications using language that matches that use in predicate cervical interbody devices. The applicant also stated that there are two separate Indications for Use statements to distinguish between supplemental fixation and the standalone indication in which integrated fixation is used, both of which were included in the Breakthrough Device designation.
	FDA marketing authorization date	November 15, 2024
	Commercial availability	According to the applicant, the aprevo®-C cervical interbody fusion device will not be immediately available for sale because the commercial release date will align with the start of the new technology add-on payment. The applicant stated that the technology is expected to be commercially available on October 1, 2025.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-PCS codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the aprevo®-C cervical interbody fusion device.
	Claims identified	Cost Analysis 1: 17,041 claims mapping to 69 MS-DRGs, with 42.57% of claims mapping to MS-DRG 472 (Cervical Spinal Fusion with CC).

		Cost Analysis 2: 15,140 claims mapping to 5 MS-DRGs, with 47.92% of claims mapping to MS-DRG 472 (Cervical Spinal Fusion with CC).
	Charges removed for prior technology	Per the applicant, the aprevo®-C cervical interbody fusion device will replace other implantable devices, but it is difficult to identify the exact differences in care that patients treated with the aprevo®-C cervical interbody fusion device would receive, both before and in conjunction with treatment with the aprevo®-C cervical interbody fusion device. Therefore, to be conservative, the applicant removed 100% of charges associated with implantable devices. The applicant stated that this removal could over-estimate charges for other devices that would be replaced by the aprevo®-C cervical interbody fusion device. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the aprevo®-C cervical interbody fusion device by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Cost Analysis 1: - Average case-weighted threshold amount: $140,223 - Final inflated average case-weighted standardized charge per case: $246,092 Cost Analysis 2: - Average case-weighted threshold amount: $135,395 - Final inflated average case-weighted standardized charge per case: $230,290 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the aprevo®-C cervical interbody fusion device meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant received 510(k) clearance from FDA is included within the scope of the Breakthrough Device designation, it appears that the FDA 510(k) clearance indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We note that the applicant stated that the technology is expected to be commercially available starting October 1, 2025, to align with the start of the new technology add-on payment. We are interested in additional information regarding the cause for any delay in the technology's market availability as the technology received FDA clearance on November 15, 2024.

We agree with the applicant that the aprevo®-C cervical interbody fusion device meets the cost criterion and are therefore proposing to approve the aprevo®-C cervical interbody fusion device for new technology add-on payments for FY 2026, as interbody fusion devices indicated at one or more levels of the cervical spine (C2–T1) in patients with the following degenerative cervical conditions: cervical disc disease, instability, trauma including fractures, deformity defined as kyphosis, lordosis, or scoliosis, cervical spondylotic myelopathy, spinal stenosis, and failed previous fusion.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the aprevo®-C cervical interbody fusion device to the hospital to be $32,500 per patient. The applicant stated that the average number of cervical interbody fusion (CIBF) devices per procedure is 4.42 if the patient has a deformity and 1.7 if the patient has a degenerative condition. Per the applicant, based on the projected mix between these diagnoses, the average number of aprevo®-C CIBF per procedure is expected to be 3.25. The applicant stated that the selling price will be $19,000 for the first level, and $6,000 for each additional level. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the aprevo®-C cervical interbody fusion device would be $21,125 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

6. CERAMENT® G

The following table summarizes the information provided in the new technology add-on payment application for CERAMENT® G.

BILLING CODE 4120–01–P

	CERAMENT® G	
Technology Info	Applicant	BONESUPPPORT, Inc.
	Description	Per the applicant, CERAMENT® G is an implantable bone void filler (device/drug combination product), consisting of calcium sulfate, hydroxyapatite, and gentamicin sulfate. Per the applicant, CERAMENT® G elutes 17.5 mg gentamicin/ mL paste.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410079G5KA
FDA Info	Breakthrough Device designation indication	Per the applicant, CERAMENT G is a resorbable, gentamicin-containing ceramic bone graft indicated for use as a bone void filler as part of the surgical procedure where there is a risk of bacterial contamination such as open, fresh fractures with osseous defects which are surgically created or a result of traumatic injury to the bone. CERAMENT G can augment provisional hardware to help support bone fragments during the surgical procedure. CERAMENT G resorbs and is replaced by bone during the healing process and is protected from bacterial colonization by gentamicin. CERAMENT™ G protects bone healing by reducing subsequent colonization of the bone void filler in orthopedic surgical procedures.
	FDA marketing authorization indication	CERAMENT G is a resorbable, gentamicin-eluting ceramic bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to bone infection and open fractures. By eluting gentamicin, CERAMENT G can reduce the occurrence and reoccurrence of bone infection from gentamicin sensitive microorganisms in order to protect bone healing. CERAMENT G can augment provisional hardware to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process. CERAMENT G resorbs and is replaced by bone during the healing process.
	FDA marketing authorization information	The applicant stated that open fracture is included in both the Breakthrough Device Designation and FDA 510(k) clearance indication.
	FDA marketing authorization date	March 13, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA clearance.
Coding	Unique ICD-10-PCS Code(s)	Effective October 1, 2021, the following ICD-10-PCS codes may be used to uniquely describe procedures involving the use of CERAMENT® G: XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and ICD-10-PCS codes used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for CERAMENT® G.
	Claims identified	6,521 claims mapping to 39 MS-DRGs, with 20.92% of claims mapping to MS-DRG 493 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC).
	Charges removed for prior technology	Per the applicant, no prior technology is expected to be replaced by CERAMENT® G based on discussions with surgeons and a review of published literature on open fracture management. The applicant stated that it did not remove any direct charges for prior technologies being replaced, as it believed that there are no standard treatments given to reduce the occurrence of infection in open fractures beyond standard systemic antibiotics, which will still be provided to patients treated with CERAMENT® G. The applicant did not remove any indirect charges as it believed that the choice of device is the sole difference between cases treated with CERAMENT® G and cases treated with prior technology. The applicant stated that besides the choice of device, the procedure is the same, and the services provided during the course of the hospitalization are the same.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the FY 2023 MedPAR preliminary rule file (fee for service claims only) and impact and standardizing files posted with the FY 2024 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for CERAMENT® G by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.297 for Supplies and Equipment from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology, as it believed that there are no differences from prior technology other than choice of device.
	Cost analysis results	Average case-weighted threshold amount: $116,339.66 Final inflated average case-weighted standardized charge per case: $203,490.37 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that CERAMENT® G meets the cost criterion.

BILLING CODE 4120–01–C

We note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of

the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment. Therefore, only the use of CERAMENT® G for open fractures, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2026. We note that CERAMENT® G is also indicated for use for bone infections and was approved for new technology add-on payment for that indication in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48961 through 48966). As discussed in section II.E.4. of the preamble of this proposed rule, we are proposing to discontinue making new technology add-on payments for FY 2026 for use of CERAMENT® G for bone infections. We believe cases involving the use of CERAMENT® G related to bone infections, which would no longer be eligible for new technology add-on payment in FY 2026, would be identified by the ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) in combination with the ICD–10–CM codes in category M86 (Osteomyelitis). We are inviting public comments on the use of these codes to exclude the indication for use of CERAMENT® G related to bone infections, which would not be eligible for the new technology add-on payment for FY 2026, if approved.

We agree with the applicant that CERAMENT® G meets the cost criterion and are therefore proposing to approve CERAMENT® G for new technology add-on payments for FY 2026 for use as a bone void filler intended for use in defects in the extremities of skeletally mature patients as an adjunct to systemic antibiotic therapy and surgical debridement as part of the standard treatment approach to open fractures.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost to the hospital to be $8,750 per patient. The applicant stated that the cost of 10 cc of CERAMENT® G would be $8,750, and expected that 10 cc of CERAMENT® G would be used per patient as indicated in a long-term study of 81 patients with open fractures.[188]

[188] Henry, J, Ali, A., and Elkhidir, I et al. (2023). Long-term follow-up of open Gustilo-Anderson IIIB fractures treated with an adjuvant local antibiotic hydroxyapatite bio-composite. *Cureus* 15(5): e39103. DOI 10.7759/cureus.39103.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of CERAMENT® G would be $5,687.50 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether CERAMENT® G meets the cost criterion and our proposal to approve new technology add-on payments for CERAMENT® G for FY 2026.

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

The following table summarizes the information provided in the new technology add-on payment application for the Dexcom G7 Hospital CGM System.

BILLING CODE 4120–01–P

	Dexcom G7 Hospital Continuous Glucose Monitoring (CGM) System	
Technology Info	**Applicant**	Dexcom
	Description	Per the applicant, the Dexcom G7 Hospital Continuous Glucose Monitoring System (Dexcom Hospital System) is a real-time CGM device indicated for use by healthcare professionals to monitor and manage glucose levels of patients ages 18 years and older in a hospital environment.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007GNM42
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Dexcom G6 Pro Hospital CGM System (Dexcom Hospital System) is a real-time CGM device indicated for use by healthcare professionals to monitor and manage glucose levels of insulin-treated diabetes patients ages 18 years and older in a hospital environment. The Dexcom Hospital System aids the healthcare professional in the detection of episodes of hyperglycemia and hypoglycemia, facilitating acute therapy adjustments. Interpretation of the real-time Dexcom Hospital System results should be made by the healthcare professional based on the glucose trends and several sequential readings over time. The Dexcom Hospital System is intended to interface with authorized hospital network partner systems to send glucose data to EMRs for retrospective review by a healthcare professional. The Dexcom Hospital System can be used alone or in conjunction with cleared or approved hospital network partner systems for managing a patient's glucose or assessing glycemic variability.
	FDA marketing authorization information	The applicant anticipates a De Novo classification decision from FDA before May 1, 2025. Per the applicant, the expected FDA indication includes any patients ages 18 or older that requires CGM in the hospital inpatient setting, while the Breakthrough Device Designation indication is for insulin-treated diabetic patients. The applicant stated that the name of the technology has been changed to the Dexcom G7 Hospital Continuous Glucose Monitoring System.
	Commercial availability	The applicant stated that it anticipates that the technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Dexcom G7 Hospital CGM System.
	Claims identified	Scenario 1: 744,284 claims mapping to 757 MS-DRGs, with none exceeding more than 8% of the total identified cases. Scenario 2: 736,840 claims mapping to 756 MS-DRGs, with none exceeding more than 8% of the total identified cases.
	Charges removed for prior technology	The applicant removed 100% of charges associated with revenue centers 0270, 0271, 0272 and 0279. The applicant stated that while the use of the Dexcom G7 Hospital CGM System is not expected to replace any other supplies, the charges associated with these revenue centers were removed to be as conservative as possible. The applicant did not remove any indirect charges as the applicant believed that the financial impact of utilizing the Dexcom G7 Hospital CGM System on hospital resources compared to prior technologies is minimal.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant did not add any direct nor indirect charges related to the new technology. Per the applicant, no other hospital charges were assumed to be required for implanting the technology.
	Cost analysis results	Scenario 1: - Average case-weighted threshold amount: $75,695 - Final inflated average case-weighted standardized charge per case: $79,339 Scenario 2: - Average case-weighted threshold amount: $75,533 - Final inflated average case-weighted standardized charge per case: $79,009 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that the Dexcom G7 Hospital CGM System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we note that under the eligibility criteria for approval under the alternative pathway for

certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2026. As noted by the applicant, the expected De Novo indication is not limited to insulin-treated diabetes patients, as noted in the Breakthrough Device designation. Therefore, it appears that only the use of the Dexcom G7 Hospital CGM System for insulin-treated diabetes, and the FDA Breakthrough Device designation it received for that use, would be relevant for purposes of the new technology add-on payment application for FY 2026.

We believe the relevant ICD–10–CM codes to identify the Breakthrough Device-designated indication for use of the technology in insulin-treated diabetes patients would be the ICD–10–CM code Z79.4 (Long term (current) use of insulin) in combination with: the ICD–10–CM codes in the categories E08 (Diabetes mellitus due to underlying condition), E09 (Drug or chemical induced diabetes mellitus), E11 (Type 2 diabetes mellitus), or E13 (Other specified diabetes mellitus), or the ICD–10–CM codes in the subcategories O24.1 (Pre-existing type 2 diabetes mellitus, in pregnancy, childbirth and the puerperium), O24.3 (Unspecified pre-existing diabetes mellitus in pregnancy, childbirth and the puerperium), O24.8 (Other pre-existing diabetes mellitus in pregnancy, childbirth, and the puerperium), or O24.9 (Unspecified diabetes mellitus in pregnancy, childbirth and the puerperium). Insulin-treated diabetes patients may also be identified by: the ICD–10–CM codes in category E10 (Type 1 diabetes mellitus), the ICD–10–CM codes in the subcategory O24.0 (Pre-existing type 1 diabetes mellitus, in pregnancy, childbirth and the puerperium), or the ICD–10–CM codes O24.414 (Gestational diabetes mellitus in pregnancy, insulin controlled), O24.424 (Gestational diabetes mellitus in childbirth, insulin controlled), or O24.434 (Gestational diabetes mellitus in the puerperium, insulin controlled). We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

We agree with the applicant that the Dexcom G7 Hospital CGM System meets the cost criterion and are therefore proposing to approve the Dexcom G7 Hospital CGM System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

The applicant has not provided an estimate for the cost of the Dexcom G7 Hospital CGM System at the time of this proposed rule. The applicant stated that the following components are included for the cost of the technology: the operating cost of the Dexcom G7 Hospital CGM Wearable Sensor and Applicator, and the capital cost of the Dexcom G7 Hospital CGM System Display App. Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant stated that the cost of the Dexcom G7 Hospital CGM System Display App 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, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the Dexcom G7 Hospital CGM System would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

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

8. DrugSorb-ATR Device

The following table summarizes the information provided in the new technology add-on payment application for the DrugSorb-ATR Device.

BILLING CODE 4120–01–P

	DrugSorb-ATR Device	
Technology Info	**Applicant**	CytoSorbents, Inc.
	Description	Per the applicant, the DrugSorb-ATR device is indicated for the removal of ticagrelor to reduce the severity of perioperative bleeding in patients undergoing coronary artery bypass grafting (CABG) within two days of ticagrelor discontinuation.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP24100700MP6
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the CytoSorb device is indicated for the removal of ticagrelor in a cardiopulmonary bypass circuit during emergent and urgent cardiothoracic surgery.
	FDA marketing authorization information	The applicant anticipates a De Novo classification decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation. Per the applicant, the expected FDA indication for this device includes a subset of procedures that are included in the Breakthrough Designation indication. The expected FDA indication is for the removal of ticagrelor in CABG procedures as opposed to the broader Breakthrough Designation indication in emergent and urgent cardiothoracic surgery. Per the applicant, the CytoSorb device named in the Breakthrough Device designation letter is the same device as the DrugSorb-ATR Device.
	Commercial availability	The applicant anticipates that this technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the DrugSorb-ATR Device.
	Claims identified	5,893 claims mapping to 28 MS-DRGs, with 21.72% of claims mapping to MS-DRG 236 (Coronary Bypass without Cardiac Catheterization without MCC) and 20.07% of claims mapping to MS-DRG 234 (Coronary Bypass with Cardiac Catheterization or Open Ablation without MCC).
	Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology. Per the applicant, the use of the technology is additive and would not replace existing technologies, and the financial impact of utilizing the new technology on hospital resources compared to prior technologies is minimal.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the expected hospital acquisition cost of the technology by the national cost to charge ratio of 0.160 for Operating Room from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $236,691 Final inflated average case-weighted standardized charge per case: $336,491 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the DrugSorb-ATR Device meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we agree with the applicant that the DrugSorb-ATR device meets the cost criterion and are therefore proposing to approve the DrugSorb-ATR device for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the DrugSorb-ATR device to the hospital to be $7,000 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the DrugSorb-ATR device would be $4,550 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the DrugSorb-ATR device meets the cost criterion and our proposal to approve new technology add-on payments for the DrugSorb-ATR

device for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

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

The following table summarizes the information provided in the new technology add-on payment application for the Emily's Care Nourish Test System (Model 1).

BILLING CODE 4120–01–P

	Emily's Care Nourish Test System (Model 1)	
Technology Info	**Applicant**	Lactation Lab Inc.
	Description	Per the applicant, the Emily's Care Nourish Test System (Model 1) is an FDA cleared Breakthrough Device. Per the applicant, it is an analytical system designed to measure the concentration of fat, carbohydrates (lactose), and protein in human milk at point of care using an enzyme-based test strip and a smartphone camera with an associated application.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241006EAA50
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the macronutrient breast milk test strip quantitatively measures the concentration of fat, carbohydrate, and protein in human milk. The associated smartphone app provides a calculated value for energy (calories) and is intended to be used in conjunction with other clinical assessments to aid in the nutritional management and treatment of very low birth weight (VLBW) in the NICU, for both neonates and infants less than 6 months of age.
	FDA marketing authorization indication	The Emily's Care Nourish Test System (Model 1) quantitatively measures the concentration of protein, fat (triglycerides), and carbohydrates (lactose) in human milk. It also provides calculated values for calories (energy). These measurements, in conjunction with other clinical assessments, may be used to aid in the nutritional management of newborns, including preterm, and infants.
	FDA marketing authorization information	Per the applicant, the device was not named in the Breakthrough Device designation, and the device has since been named Emily's Care Nourish Test System (Model 1).
	FDA marketing authorization date	May 3, 2024
	Commercial availability	The applicant stated the technology was not commercially available immediately after FDA clearance because the applicant is a small business that needs to raise capital for manufacturing and because of manufacturing delays. The applicant anticipates the technology will become available on May 1, 2025.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	The applicant identified 2 MS-DRGs, MS-DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome, Neonate) and MS-DRG 791 (Prematurity with Major Problems), as relevant to the cost analysis for this technology. The applicant did not provide a cost criterion codes and MS-DRGs attachment listing applicable codes used for purposes of its cost analysis.
	Claims identified	The applicant estimated there would be 25,000 claims mapping to 2 MS-DRGs, with 30% of claims mapping to MS-DRG 790 (Extreme Immaturity or Respiratory Distress Syndrome, Neonate) and 70% of claims mapping to MS-DRG 791 (Prematurity with Major Problems). To estimate the claim volume, the applicant estimated the total live births in the US was 4 million, and stated that 10.4% of infants would be premature based on data from March of Dimes. The applicant estimated that low birth weight (LBW) infants would be 8.6% of births (344,000), and VLBW infants would be 1.4% of births (56,000). The applicant stated that 50% of VLBW infants would be in MS-DRG 790 (28,000), and 50% of LBW infants would be in MS-DRG 791 (172,000), resulting in 200,000 total annual cases. The applicant estimated that initial rollout would be 25% of cases, resulting in 25,000 claims.
	Charges removed for prior technology	The applicant did not remove direct or indirect charges related to the prior technology.
	Standardized charges	For the average standardized charge per case, the applicant used the same values as the average charge per case (unstandardized with case weight).
	Inflation factor	The applicant applied an inflation factor of 1.04118% to the standardized charges.
	Charges added for the new technology	The applicant added charges for the new technology. The applicant also added indirect additional charges for training and additional time for measuring milk.
	Cost analysis results	Average case-weighted threshold amount: $52,165.00 Final inflated average case-weighted standardized charge per case: $837,658.83 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Emily's Care Nourish Test System (Model 1) meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2026. Therefore, only the use of the Emily's Care Nourish Test System (Model 1) for VLBW neonates and infants in the NICU, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2026.

We note the following concerns with respect to the cost criterion. We are unclear how the applicant identified the 25,000 claims used in its cost analysis, including the type of source data and the data year that were used to identify cases. The applicant did not provide a completed cost criterion codes and MS–DRGs worksheet and we are unclear how ICD–10–PCS and/or –CM codes were used to identify potential cases representing patients that may be eligible for use of the Emily's Care Nourish Test System (Model 1). We note that MS–DRGs 790 and 791 identified by the applicant may represent a patient population broader than those cases that would be included within the scope of the Breakthrough Device designation indication that is appropriate for consideration for new technology add-on payment under the alternative pathway criteria (VLBW neonates and infants less than 6 months of age in the NICU), and we question whether using these MS–DRGs without additional inclusion and/or exclusion criteria would be representative of cases eligible for new technology add-on payment.

Furthermore, it appears that the applicant did not identify relevant cases from a claims database such as the MedPAR file for its cost analysis, but instead calculated a case volume based on assumptions using the number of total live births in the United States. In addition, we question the assumptions used in the cost analysis regarding the potential Medicare volume for the technology. As noted in the FDA clearance letter for this device,[189] its intended patient population is newborns, including preterm, and infants. The applicant asserts that after a premature infant is delivered, the infant may be eligible for Medicare coverage if it qualifies under specific criteria, such as disability or end-stage renal disease (ESRD). Although we agree that infants may be eligible for Medicare if they have ESRD and need regular dialysis or have had a kidney transplant,[190] we note that Medicare Part A entitlement—for inpatient hospital services—based on child disability benefit entitlement can never begin before the month the person attains age 20 (or age 18 if the individual's disability is Amyotrophic Lateral Sclerosis).[191]

Furthermore, we are unclear how the average charge per case (unstandardized with no case weight) was calculated as it is unclear what claims data was used to determine the average charges for MS–DRG 790 and MS–DRG 791. We are also unclear as to the applicant's methodology for calculating the average charge per case (unstandardized with case weight), as it appears the applicant multiplied the average charge per case (unstandardized with no case weight) by 5.6671 for the charges in MS–DRG 790, and by 3.8704 for the charges in MS–DRG 791.

Although the applicant did not remove charges related to the technology being replaced, we note that the applicant stated that targeted fortification leads to a decreased length of stay (LOS) by 2.5 days, and we question if charges should be removed to account for the decreased LOS for patients using this technology.

We are also unclear as to the applicant's methodology for calculating the average standardized charge per case as the applicant used the same values from the average charge per case (unstandardized with case weight), which were the average charge per case (unstandardized with no case weight) multiplied by 5.6671 for the charges in MS–DRG 790, and by 3.8704 for the charges in MS–DRG 791.

To calculate the inflated average standardized charge per case, the applicant applied an inflation factor of 1.04118 percent. We would be interested in additional information regarding the basis for using this inflation factor and how it corresponds to the source data and year used for the cost analysis.

We note the applicant added direct and indirect charges related to the new technology. However, although the applicant identified a cost-to-charge ratio of 0.36 for intensive inpatient admission days, it is unclear how this cost-to-charge ratio was used to convert costs for the technology and indirect costs to charges, and how these charges were calculated using the costs of the device itself or costs related to additional time for training or measuring milk.

Therefore, because the applicant has not provided sufficient information as part of its cost analysis to demonstrate that the Emily's Care Nourish Test System (Model 1) meets the cost criterion, we are proposing to disapprove new technology add-on payments for the Emily's Care Nourish Test System (Model 1) for FY 2026. However, in the event we receive updated information to establish that the Emily's Care Nourish Test System (Model 1) meets the cost criterion, we are providing the following information regarding the new technology add-on payment.

We note the applicant states that the technology, which received FDA clearance on May 3, 2024, is expected to be commercially available May 1, 2025, and we would appreciate more information about the cause for any delay in the commercial availability of the device following FDA clearance.

We believe the relevant ICD–10–CM codes to identify the Breakthrough Device-designated indication for use of the technology in VLBW neonates and infants would be the following codes:

ICD–10–CM code	Description
P05.01	Newborn light for gestational age, less than 500 grams.
P05.02	Newborn light for gestational age, 500–749 grams.
P05.03	Newborn light for gestational age, 750–999 grams.
P05.04	Newborn light for gestational age, 1,000–1,249 grams.
P05.05	Newborn light for gestational age, 1,250–1,499 grams.
P05.11	Newborn small for gestational age, less than 500 grams.

[189] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K234088.pdf.*

[190] Centers for Medicare & Medicaid Services. End-stage renal disease (*https://www.medicare.gov/basics/end-stage-renal-disease*, accessed 1/16/2024).

[191] Centers for Medicare & Medicaid Services. Original Medicare (Part A and B) Eligibility and Enrollment (*https://www.cms.gov/medicare/enrollment-renewal/health-plans/original-part-a-b*, accessed 1/16/2024).

ICD–10–CM code	Description
P05.12	Newborn small for gestational age, 500–749 grams.
P05.13	Newborn small for gestational age, 750–999 grams.
P05.14	Newborn small for gestational age, 1,000–1,249 grams.
P05.15	Newborn small for gestational age, 1,250–1,499 grams.
P07.00	Extremely low birth weight newborn, unspecified weight.
P07.01	Extremely low birth weight newborn, less than 500 grams.
P07.02	Extremely low birth weight newborn, 500–749 grams.
P07.03	Extremely low birth weight newborn, 750–999 grams.
P07.14	Other low birth weight newborn, 1,000–1,249 grams.
P07.15	Other low birth weight newborn, 1,250–1,499 grams.

We are inviting public comments on the use of these ICD–10–CM diagnosis codes to identify the Breakthrough Device-designated indication for purposes of the new technology add-on payment, if approved.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost to the hospital for the Emily's Care Nourish Test System (Model 1) to be $3,000 per patient before discounts and $1,800 after discounts, based on the contents of the kit, which provides enough supplies for testing over a typical NICU stay (36 tests). The applicant stated the contents of the kit include: 36 test strips, pipettes, reference cards, 2 control solutions, and a reusable lightbox (iPhone not included). The applicant also provided additional information on the costs for the annual use of the technology to the hospital of $25,000, consisting of $10,000 for the kit including the lease of the lightbox and iPhone, and $15,000 for the device's operation (labor, testing milk, analysis interpretation, adjustment of feeding protocols). However, we note that the costs to the hospital, per patient, per inpatient stay remains unclear, and that the provided costs also include additional costs related to use of the device as well as capital costs for the lease of the lightbox and iPhone.

As we have discussed in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device (86 FR 45146). Therefore, we would not include costs of staff labor for the device's operation in the relevant costs for purposes of determining the new technology add-on payment amount.

In addition, because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). The costs to lease the lightbox and iPhone are capital costs. As such, these components would not be eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308).

Without a breakdown of the costs of this technology to the hospital, per patient, per inpatient stay, for the operating components of the kit, we are unable to identify the relevant costs for purposes of determining the new technology add-on payment amount. In addition, the applicant had indicated that the cost of the device would be discounted to hospitals, and the Medicare program expects providers to take advantage of available discounts.[192] It is unclear how potential discounts would affect the relevant estimated operating costs of the device. We would be interested in additional information regarding the current or anticipated average cost of the technology to the hospital per inpatient stay.

We invite public comments on whether the Emily's Care Nourish Test System (Model 1) meets the cost criterion and our proposal to disapprove new technology add-on payments for the Emily's Care Nourish Test System (Model 1) for FY 2026. We also invite public comments on the operating costs for the device, in the event we receive updated information to establish that the Emily's Care Nourish Test System (Model 1) meets the cost criterion.

10. Esprit™ BTK Everolimus Eluting Resorbable Scaffold System

The following table summarizes the information provided in the new technology add-on payment application for the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System.

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[192] Medicare Department of Health & Human Services (DHHS) Provider Reimbursement Manual Part 1—Chapter 8, Purchase Discounts; Allowances; Refunds of Expenses (Date: March 8, 2013) *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r456pr1.pdf.*

	Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	
Technology Info	**Applicant**	Abbott Laboratories
	Description	Per the applicant, the Esprit™ BTK Everolimus Eluting Resorbable Scaffold is a temporary scaffold that will resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb threatening ischemia (CLTI).
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241004V78CP
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Absorb GT1 BVS is a temporary scaffold that will fully resorb over time and is indicated for improving luminal diameter in infrapopliteal lesions in patients with critical limb ischemia (CLI). In all cases, the treated lesion length should be less than the total scaffolding length with a reference vessel diameter of ≥ 2.5 mm and ≤ 3.75 mm.
	FDA marketing authorization indication	The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with CLTI and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm.
	FDA marketing authorization information	Per the applicant, the primary difference in the FDA-approved indication and the Breakthrough Device indication is that the FDA-approved indication includes a total scaffolding length up to 170 mm and larger upper limit for the reference vessel diameter (≥ 2.5 mm and ≤ 4.00 mm). According to the applicant, the trade name had been updated to the Esprit™ BTK Everolimus Eluting Resorbable Scaffold System (Esprit™ BTK System).
	FDA marketing authorization date	April 26, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA approval.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant provided a list of procedure codes that, effective October 1, 2024, may be used to uniquely describe procedures involving the use of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold under the ICD-10-PCS coding system in the online application posting. X27P3TA (Dilation of right anterior tibial artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10) X27Q3TA (Dilation of left anterior tibial artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10) (X27R3TA - Dilation of right posterior tibial artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10) X27S3TA (Dilation of left posterior tibial artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10) X27T3TA (Dilation of right peroneal artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10) X27U3TA (Dilation of left peroneal artery with intraluminal device, everolimus-eluting resorbable scaffold(s), percutaneous approach, new technology group 10)
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Esprit™ BTK Everolimus Eluting Resorbable Scaffold.
	Claims identified	Scenario 1: 12,850 claims mapping to 139 MS-DRGs, with 15.86% of claims mapping to MS-DRG 271 (Other Major Cardiovascular Procedures with CC) and 15.18% of claims mapping to MS-DRG 253 (Other Vascular Procedures with CC). Scenario 2: 2,751 claims mapping to 81 MS-DRGs, with 15.92% of claims mapping to MS-DRG 271 (Other Major Cardiovascular Procedures with CC) and 13.89% of claims mapping to MS-DRG 253 (Other Vascular Procedures with CC).
	Charges removed for prior technology	To be as conservative as possible, the applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 0275, 0276, 0278 and 0624) because the device is expected to replace a portion of devices included in these claims, although it will not replace all devices, nor any medical supplies required to perform the procedure, and an estimate of the percentage of total charges that the technology would replace could not be determined. The applicant did not remove indirect charges related to the prior technology.

	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Scenario 1: - Average case-weighted threshold amount: $130,782 - Final inflated average case-weighted standardized charge per case: $227,641 Scenario 2: - Average case-weighted threshold amount: $132,247 - Final inflated average case-weighted standardized charge per case: $252,513 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the Esprit BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant has received FDA marketing authorization is included within the scope of the Breakthrough Device designation indication, it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.[193]

We agree with the applicant that the Esprit™ BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion and are therefore proposing to approve the Esprit™ BTK Everolimus Eluting Resorbable Scaffold for new technology add-on payments for FY 2026 for the indication of improving luminal diameter in infrapopliteal lesions in patients with CLTI and total scaffolding length up to 170 mm with a reference vessel diameter of ≥2.5 mm and ≤4 mm.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold to the hospital to be $6,000 per patient. According to the applicant, the costs of the technology include the Esprit™ BTK Scaffold ($2,750) and the Esprit™ BTK Delivery System ($250). The applicant stated that per the IDE Clinical Study, on average two Esprit™ BTK Everolimus Eluting Resorbable Scaffolds were used per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Esprit™ BTK Everolimus Eluting Resorbable Scaffold would be $3,900 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

11. EUROPA™ Posterior Cervical Fusion System

The following table summarizes the information provided in the new technology add-on payment application for the EUROPA™ Posterior Cervical Fusion System.

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[193] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

	EUROPA™ Posterior Cervical Fusion System	
Technology Info	**Applicant**	MiRus, LLC
	Description	Per the applicant, the EUROPA™ Posterior Cervical Fusion System is a posterior cervical screw system intended to provide structural stability and mechanical support to the cervical spine through posterior cervical fusion. Per the applicant, the EUROPA™ Posterior Cervical Fusion System implants are offered in multiple configurations and different sizes to accommodate various needs.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007BVT6M
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (C1 to C7) and the thoracic spine from T1-T3: traumatic spinal fractures and/or traumatic dislocations; instability or deformity; failed previous fusions (for example, pseudarthrosis); tumors involving the cervical/thoracic spine; and degenerative disease, including intractable radiculopathy and/or myelopathy, neck and/or arm pain of discogenic origin as confirmed by radiographic studies, and degenerative disease of the facets with instability. The EUROPA™ Posterior Cervical Fusion System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod-to-rod connectors.
	FDA marketing authorization indication	The EUROPA™ Posterior Cervical Fusion System is intended to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the following acute and chronic instabilities of the cervical spine (Cl to C7) and the upper thoracic spine (T1 to T3): * Traumatic spinal fractures and/or traumatic dislocations * Instability or deformity * Failed previous fusions (for example, pseudarthrosis) * Tumors involving the cervical/thoracic spine * Degenerative disease, including intractable radiculopathy and/or myelopathy * Neck and/or arm pain of discogenic origin as confirmed by radiographic studies * Degenerative disease of the facets with instability. The EUROPA™ Posterior Cervical Fusion System is also intended to restore the integrity of the spinal column even in the absence of fusion for a limited time period in patients with advanced stage tumors involving the cervical spine in whom life expectancy is of insufficient duration to permit achievement of fusion. In order to achieve additional levels of fixation, the EUROPA™ Posterior Cervical Fusion System may be connected to the EUROPA™ Pedicle Screw System via the rod to rod connectors.
	FDA marketing authorization date	November 19, 2024
	Commercial availability	According to the applicant, the EUROPA™ Posterior Cervical Fusion System is not commercially available, as the applicant planned to start manufacturing this technology and make available for commercial use based on project timelines after FDA clearance. The applicant anticipates the technology will become available in the fourth quarter of 2025.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the EUROPA™ Posterior Cervical Fusion System.
	Claims identified	28,953 claims mapping to 31 MS-DRGs, with 20.41% of claims mapping to MS-DRG 472 (Cervical Spinal Fusion with CC).
	Charges removed for prior technology	The applicant calculated the cost estimate for prior technology using the average price for the screws, rods, and set screws that are used during the average spinal procedure. The applicant then converted the cost for an average procedure to a charge using national cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not remove any indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule correction notice.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant calculated the cost per patient based on the prices of the implants used in a construct and weighted by the length of the construct and the percentage of those procedures across different levels of fusion. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $175,355 Final inflated average case-weighted standardized charge per case: $688,679 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the EUROPA™ Posterior Cervical Fusion System meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant has received FDA marketing authorization is

included within the scope of the Breakthrough Device designation indication, it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

According to the applicant, the technology, which received FDA clearance on November 19, 2024, is not yet available for sale due to project timelines. The applicant stated that the technology is not expected to be commercially available until the fourth quarter of 2025. We are interested in additional information regarding the cause of any delay in the technology's market availability.

We agree with the applicant that the EUROPA™ Posterior Cervical Fusion System meets the cost criterion and are therefore proposing to approve the EUROPA™ Posterior Cervical Fusion System for new technology add-on payments for FY 2026, to provide immobilization and stabilization of spinal segments as an adjunct to fusion for the acute and chronic instabilities of the cervical spine (Cl to C7) and the upper thoracic spine (T1 to T3) listed in both the Breakthrough Device designation and FDA clearance letter.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the EUROPA™ Posterior Cervical Fusion System to the hospital to be $123,920 per patient. According to the applicant, there are approximately 374 different components associated with the technology, including Pedicle Screws, Set Screws, Rods, and Connectors, all of which are operating costs and new components. The applicant stated that the majority of posterior cervical fusion procedures are inpatient Medicare procedures in most hospitals, but there may be exceptions based on individual clinical practice. Per the applicant, most of these procedures are C1–T3 or C2–T3 with some exceptions being 2–3 levels. The applicant calculated the total cost based on the unit prices of the implants used in a construct (Rod $9,000.00; Pedicle Screw $5,000.00; Smooth Shank Screw $5,000.00; Set Screw $500.00; Connector $4,000.00), weighted by the length of the construct (1- through 9-level), and the percentage of those procedures across different levels of fusion (10 percent for 2- through 4-level; 90 percent for 5 or more levels). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the EUROPA™ Posterior Cervical Fusion System would be $80,548 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the EUROPA™ Posterior Cervical Fusion System meets the cost criterion and our proposal to approve new technology add-on payments for the EUROPA™ Posterior Cervical Fusion System for FY 2026.

12. iFuse TORQ TNT™ Implant System

The following table summarizes the information provided in the new technology add-on payment application for the iFuse TORQ TNT™ Implant System.

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	iFuse TORQ TNT™ Implant System	
Technology Info	**Applicant**	SI-BONE, Inc.
	Description	Per the applicant, the iFuse TORQ TNT™ Implant System consists of a fully threaded, 3D-printed porous anatomy-specific implant with optional washers along with instruments used to place the implant under either fluoroscopic guidance or with certain navigation systems. According to the applicant, the implant has features specific to pelvic anatomy for fracture fixation or sacroiliac joint fusion.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241002J7XRV
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the iFuse TNT Implant System is indicated for fracture fixation of the pelvis, including acute, nonacute and non-traumatic fractures. The iFuse TNT Implant System is indicated for sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis. The iFuse TNT Navigation instruments are intended to be used with the iFuse TNT Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TNT Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy.
	FDA marketing authorization indication	The iFuse TORQ TNT Implant System is indicated for fracture fixation of the pelvis, including acute, non-acute and non-traumatic fractures. The iFuse TORQ TNT Implant System is indicated for sacroiliac joint fusion for: - Sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis. - Augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion. The iFuse TORQ TNT Navigation instruments are intended to be used with the iFuse TORQ TNT Implant System to assist the surgeon in precisely locating anatomical structures in iFuse TORQ TNT Implant System procedures, in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as the pelvis or vertebra, can be identified relative to the acquired image (CT, MR, 2D fluoroscopic image or 3D fluoroscopic image reconstruction) and/or an image data based model of the anatomy. iFuse TORQ TNT Navigation instruments are intended to be used with the Medtronic StealthStation System.
	FDA marketing authorization information	The applicant asserted that the same device is applicable to both the Breakthrough Device designation and the FDA marketing authorization, despite slight difference in the name of the technology. According to the applicant, the current SI-BONE labeling materials for the iFuse TORQ TNT™ Implant System include indications for use that match the Breakthrough Device designation, except for a statement which describes an "augmenting" indication. The applicant stated that only after the completion of the appropriate SI-BONE design control activities will the indications statement in the labeling materials for the iFuse TORQ TNT™ Implant System be updated to include the additional "augmenting" indication.
	FDA marketing authorization date	August 19, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA clearance.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the iFuse TORQ TNT™ Implant System.
	Claims identified	Fracture Fixation with TNT Analysis: 853 claims mapping to 43 MS-DRGs, with none of the MS-DRGs exceeding more than 12.66% of the total identified cases. SI Joint Fusion with TNT Analysis: 642 claims mapping to 21 MS-DRGs, with 28.04% of claims mapping to MS-DRG 448 (Multiple Level Spinal Fusion Except Cervical Without MCC).

	Charges removed for prior technology	The applicant removed 75% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027X, and 0624). According to the applicant, the use of the technology is expected to replace a portion of devices included in these claims, but it will not replace all devices or medical supplies required to perform the procedure. The applicant stated that the estimate of the percentage of these total charges for devices that would be replaced could not be determined. The applicant, therefore, adopted a conservative approach to removed 75% of these charges. The applicant did not remove indirect charges related to the prior technology as it stated that the financial impact of utilizing the technology on hospital resources compared to prior technologies is minimal.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology as it stated that no other hospital charges were assumed to be required for implanting the technology.
	Cost analysis results	Fracture Fixation with TNT Analysis: - Average case-weighted threshold amount: $153,117 - Final inflated average case-weighted standardized charge per case: $264,101 Fracture Fixation with TNT Analysis: - Average case-weighted threshold amount: $173,990 - Final inflated average case-weighted standardized charge per case: $201,625 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the iFuse TORQ TNT™ Implant System meets the cost criterion.

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After review of the information provided by the applicant, we note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2026. As noted by the applicant, the FDA clearance describes an additional indication for sacroiliac joint fusion for augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion, which is not included in the Breakthrough Device designation. Therefore, it appears that this indication is not relevant for purposes of the new technology add-on payment application for FY 2026.

Please see Table 10.2.—iFuse TORQ TNT™ Implant System associated with this proposed rule for the list of ICD–10–PCS procedure codes that we believe would be appropriate to exclude when reported in combination with use of the iFuse TORQ TNT™ Implant System. We are inviting public comments on the exclusion of cases reporting these ICD–10–PCS procedure codes in combination with the procedure codes that identify use of the iFuse TORQ TNT™ Implant System for augmenting immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion, which would not be eligible for new technology add-on payment, if approved.

We agree with the applicant that the iFuse TORQ TNT™ Implant System meets the cost criterion and are therefore proposing to approve the iFuse TORQ TNT™ Implant System for new technology add-on payments for FY 2026 when used for fracture fixation of the pelvis, including acute, non-acute and nontraumatic fractures and sacroiliac joint fusion for sacroiliac joint dysfunction including sacroiliac joint disruption and degenerative sacroiliitis.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the iFuse TORQ TNT™ Implant System to the hospital to be $6,573 per patient. The applicant stated that the iFuse TORQ TNT™ Implant System includes the operating unit costs of the TNT Implant ($3,150), Drill Bit ($200), Guide Pin ($100), Blunt Pin ($100), and Washer ($50). The applicant estimated the average number of each component used per case for pelvic fixation and sacroiliac joint fusion cases separately, and calculated the costs of the new technology by multiplying the component costs by the average number of components used per case. The applicant used internal sales data to estimate the percentages of pelvic fixation (80 percent) and sacroiliac joint (20 percent) fusion cases in an average hospital. The applicant then calculated the total cost of the iFuse TORQ TNT™ Implant System to the hospital by taking the weighted average of the cost per pelvic fixation case and cost per sacroiliac joint fusion case.

It appears that the TNT Implant and Washers are components of the Breakthrough device. However, the Drill Bit, Guide Pin, and Blunt Pin are instrumentation used for the implantation of the TNT Implant. As we have discussed in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device (86 FR 45146). It appears that the cost of the instrumentation (the Drill Bit, Guide Pin, and Blunt Pin) are costs related to the use of the technology, rather than a cost of the technology itself. In addition, it is not clear if the Drill Bit, Guide Pin, and Blunt Pin are new and unique components for this technology, or if they may be reused and/or may be purchased separately in support of other technologies. Therefore, it appears any add-on payment for the iFuse TORQ TNT™ Implant System would include only the weighted average cost per pelvic fixation case and cost per

sacroiliac joint fusion case of the TNT Implant and Washers ($6,093).

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the iFuse TORQ TNT™ Implant System would be $3,960.45 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the iFuse TORQ TNT™ Implant System meets the cost criterion and our proposal to approve new technology add-on payments for the iFuse TORQ TNT™ Implant System for FY 2026.

13. Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)

The following table summarizes the information provided in the new technology add-on payment application for the Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE).

BILLING CODE 4120–01–P

	Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)	
Technology Info	**Applicant**	Merit Medical
	Description	Per the applicant, the Merit Wrapsody® is a flexible self-expanding CIE to treat venous outflow circuit stenosis or occlusion in patients with hemodialysis fistula or graft. Per the applicant, FDA Breakthrough prevents transgraft cellular migration resulting in randomized controlled trial (RCT) multicenter 6-month target lesion primary patency (TLPP) (90% vs 63%) compared to percutaneous transluminal angioplasty (PTA) and equal safety.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410062MPCC
FDA Info	**Breakthrough Device designation indications**	Per the applicant, the proposed indications for use includes treatment of stenosis or occlusion within the dialysis outflow circuit, including stenosis or occlusion: • within the peripheral veins in the arm of the Arteriovenous Fistula (AVF) patients, and • within the thoracic central veins, up to the superior vena cava, in Arteriovenous Graft (AVG) patients. The proposed indications for use include treatment of stenosis or occlusion within the dialysis outflow circuit of patients with a synthetic arteriovenous graft, including stenosis or occlusion: • at the venous anastomosis and • within the peripheral veins of the outflow circuit up to but not including the subclavian vein.
	FDA marketing authorization indication	The WRAPSODY® Cell-Impermeable Endoprosthesis is a flexible, self-expanding endoprosthesis indicated for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit, including stenosis or occlusion: • In the peripheral veins of individuals with an arteriovenous (AV) fistula, • At the venous anastomosis of a synthetic AV graft.
	FDA marketing authorization information	Per the applicant, the original FDA Breakthrough Device designation indications for use (IFU) are different from the current IFU to reflect the patients enrolled for analysis in the RCT. According to the applicant, the current IFU no longer includes patients with a dysfunction within the thoracic central veins and instead reflects the predominant hemodialysis AVG dysfunction enrolled in the RCT, meeting the safety and efficacy end points. Per the applicant, the name of the technology was updated to the Merit Wrapsody® Cell Impermeable Endoprosthesis after validation of the clinical effectiveness and patent issuance.
	FDA marketing authorization date	December 19, 2024
	Commercial availability	The applicant stated the Merit Wrapsody® CIE was commercially available on 1/02/2025 with 3 purchase orders in 3 days. Per the applicant, it is marketed in accordance with the conditions of the sale and distribution restricted to prescription use in accordance with 21 CFR 801.109 and under section 515(d)(1)(B)(ii) of the Federal FDA Act (the act). The applicant noted that the device is further restricted under section 515(d)(1)(B)(ii) of the act insofar as the labeling must specify the specific training or experience practitioners need in order to use the device.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Merit Wrapsody® CIE. The applicant noted that "Set A Cost Thresh" was for its cost threshold calculations.
	Claims identified	44,393 claims mapping to 7 MS-DRGs, with 38.12% of claims mapping to MS-DRG 252 (Other Vascular Procedures with MCC).
	Charges removed for prior technology	The applicant removed charges for routine PTA catheters or stents by estimating a weighted cost based on 70% of procedures using a catheter for PTA and 30% of procedures for stent placement. The applicant then converted the cost to charges using the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used relevant values reported in the impact file and standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule and correction notice, as well as the labor share percent from the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for	The applicant added charges for the new technology by dividing the cost of the new technology by the

	the new technology	national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $115,373 Final inflated average case-weighted standardized charge per case: $161,315 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Merit Wrapsody® CIE meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, since the indication for which the applicant received PMA approval from FDA is included within the scope of the Breakthrough Device designation indication, it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We note that the application stated that commercialization of the device was initiated on January 2, 2025, with 3 purchase orders in 3 days. We are interested in additional information regarding any delay in commercial availability between its FDA approval on December 19, 2024, and the date commercialization was initiated, including if the device was available for sale prior to January 2, 2025.

We agree with the applicant that the Merit Wrapsody® CIE meets the cost criterion and are therefore proposing to approve the Merit Wrapsody® CIE for new technology add-on payments for FY 2026, for use in hemodialysis patients for the treatment of stenosis or occlusion within the dialysis access outflow circuit, including stenosis or occlusion in the peripheral veins of individuals with an AV fistula or at the venous anastomosis of a synthetic AV graft.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the cost of the Merit Wrapsody® CIE to the hospital to be $5,800 per patient, inclusive of all components and accessories. The applicant also provided an additional cost for operating room time because the facility operation room time may be 8–12 minutes greater than similar current procedures. However, as discussed in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device, such as the ongoing use of the device including maintenance and processing fees. For example, if a technology required an extra hour of operating room time, or reduced the amount of procedure time, we would neither add nor deduct costs based on this, and would only consider the actual cost of the technology at the time of purchase in our determination of the add-on payment (86 FR 45146).

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Merit Wrapsody® CIE would be $3,770 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the Merit Wrapsody® CIE meets the cost criterion and our proposal to approve new technology add-on payments for the Merit Wrapsody® CIE for FY 2026.

14. Minima Stent System

The following table summarizes the information provided in the new technology add-on payment application for the Minima Stent System.

BILLING CODE 4120–01–P

	Minima Stent System	
Technology Info	**Applicant**	Renata Medical, Inc.
	Description	Per the applicant, the Minima Stent System is the first and only stent designed, tested, clinically trialed, and FDA approved for treating coarctation of aorta and pulmonary artery stenosis in neonates, infants, and young children > 1.5 kg. Per the applicant, not only can the device be implanted that small, but it is also designed to be re-expanded over time up to adult size vessels.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241004LBYDY
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Renata Minima Stent System is indicated for use in the treatment of common congenital and post-operative discrete coarctation of the aorta without significant arch hypoplasia in patients less than 20kg and in the treatment of pulmonary artery stenoses.
	FDA marketing authorization indication	The Minima Stent System is indicated for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight.
	FDA marketing authorization date	August 28, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-PCS codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Minima Stent System.
	Claims identified	75,638 claims mapping to 6 MS-DRGs, with 26.50% of claims mapping to MS-DRG 252 (Other Vascular Procedures with MCC).
	Charges removed for prior technology	The applicant did not remove charges or indirect charges related to the prior technology as the applicant stated that the technology would not replace a device and is not expected to significantly change cost in other revenue/cost centers.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $128,762 Final inflated average case-weighted standardized charge per case: $270,295 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Minima Stent System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, since the indication for which the applicant received PMA approval from FDA is included within the scope of the Breakthrough Device designation indication, it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.[194]

With respect to the cost criterion, we note that the applicant identified 6 relevant MS–DRGs using 8 ICD–10–PCS codes that most closely resemble the procedure to insert and/or dilate the great vessels using the Minima Stent System. Per the applicant, the Minima Stent System is used in the pediatric population and no cases appear in Medicare data; therefore, the applicant used CY 2022 and CY 2023 Medicare charge and discharge data accessed via Definitive Healthcare as well as data from the AOR/BOR File published as part of the FY 2025 IPPS/LTCH PPS final rule, correction notice and interim final action with comment period Data and Supplemental Files and FY 2023 IPPS/LTCH PPS final rule and correcting amendment files. However, we question whether using the total charges for the Medicare claims within the 6 identified MS–DRGs would provide an accurate estimate for eligible cases in a pediatric patient population where the Minima Stent System would be used.

Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and are proposing to approve the Minima Stent System for new technology add-on payments for FY 2026 for use in the treatment of native or acquired pulmonary artery stenoses or coarctation of the aorta in neonates, infants, and children at least 1.5 kg in weight.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Minima Stent

[194] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

System to the hospital to be $34,900 per patient. Per the applicant, total cost per inpatient stay was calculated based on the assumption that only one unit will be used per patient for each inpatient stay. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Minima Stent System would be $22,685 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

15. MY01 Continuous Compartmental Pressure Monitor

The following table summarizes the information provided in the new technology add-on payment application for the MY01 Continuous Compartmental Pressure Monitor.

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	MY01 Continuous Compartmental Pressure Monitor	
Technology Info	**Applicant**	MY01 Inc.
	Description	Per the applicant, the MY01 Continuous Compartmental Pressure Monitor is a single-use device that measures and displays in real-time muscle compartment pressure as an aid in Compartment Syndrome diagnosis. Per the applicant, the companion Mobile App displays identical muscle pressure data together with calculated perfusion pressure using a manually entered diastolic blood pressure.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007X55AR
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the MY01 device is used for real-time and continuous measurement of muscle pressures. The measured muscle pressure can be used as an aid in the diagnosis of acute compartment syndrome (ACS). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.
	FDA marketing authorization indication	The MY01 Continuous Compartmental Pressure Monitor is used for real-time and continuous measurement of the muscle compartment pressure. The measured muscle compartment pressure can be used as an aid in diagnosis of Compartment Syndrome (Acute and Chronic). The MY01 Mobile Application is an application intended for storing and displaying identical pressure values from the MY01 Continuous Compartmental Pressure Monitor device and calculating critical muscle perfusion pressure utilizing diastolic pressure manual entry by the physician. Diagnosis should always be made in conjunction with clinical assessments.
	FDA marketing authorization information	Per the applicant, the FDA indication for use is similar to the Breakthrough Device designation, but the language was modified for clarity and accuracy. Per the applicant: the device name was changed from "MY01 device" to "MY01 Continuous Compartmental Pressure Monitor"; the term "muscle pressure" was changed to "muscle compartment pressure"; the indications were expanded from including only "acute compartment syndrome" to include both "(Acute and Chronic) [compartment syndrome]"
	FDA marketing authorization date	March 13, 2025
	Commercial availability	According to the applicant, the MY01 Mobile Application is not yet available for use because the applicant is completing final testing of the application before it is available on the Apple App Store and the Google Play App Store. The applicant anticipates the app will be available for download by April 30, 2025.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2023, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the MY01 Continuous Compartmental Pressure Monitor: XX2F3W9 (Monitoring of musculoskeletal muscle compartment pressure, micro-electro-mechanical system, percutaneous approach, new technology group 9).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the MY01 Continuous Compartmental Pressure Monitor.
	Claims identified	78,166 claims mapping to 90 MS-DRGs, with 13.69% of claims mapping to MS-DRG 563 (Fracture, Sprain, Strain and Dislocation Except Femur, Hip, Pelvis and Thigh without MCC) and 13.54% of claims mapping to MS-DRG 493 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur with CC).
	Charges removed for prior technology	The applicant conducted an analysis of sales data to collect the cost of each component of the prior technology. To calculate the charges for the prior technology, the applicant converted the cost to charge by using the national average cost-to-charge ratio of 0.297 for Supplies and Equipment from the FY 2025 IPPS/LTCH PPS final rule. The applicant estimated that the technology would be used on 50% of patients and therefore removed charges for 50% of the charges for the prior technology. The applicant did not remove charges related to the prior technology as it believed that the choice of device is the sole difference between cases treated with the MY01 Continuous Compartmental Pressure Monitor and cases treated with the prior technology. Per the applicant, besides the choice of device, the procedure is the same, and the services provided during the course of the hospitalization are also the same.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.297 for Supplies and Equipment from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology, as the services provided during the course of hospitalization are not affected by the use of the technology.

	Cost analysis results	Average case-weighted threshold amount: $86,011 Final inflated average case-weighted standardized charge per case: $112,813 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the MY01 Continuous Compartmental Pressure Monitor meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, since the indication for which the applicant has received FDA marketing authorization is included within the scope of the Breakthrough Device designation indication, it appears that the FDA marketing authorization is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.[195]

According to the applicant, the MY01 Mobile Application is not yet available for use because the applicant is completing final testing of the application before it is available for download. We are interested in additional information on when the MY01 Continuous Compartmental Pressure Monitor, which is the subject of this new technology add-on payment application, became available for sale.

We agree with the applicant that the MY01 Continuous Compartmental Pressure Monitor meets the cost criterion and are therefore proposing to approve the MY01 Continuous Compartmental Pressure Monitor for new technology add-on payments for FY 2026, for real-time and continuous measurement of the muscle compartment pressure.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the MY01 Continuous Compartmental Pressure Monitor to the hospital to be $3,250 per patient. Per the applicant, only one device is used per inpatient stay, and the companion MY01 Mobile Application is provided at no additional cost for any physician registered to use the device. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the MY01 Continuous Compartmental Pressure Monitor would be $2,112.50 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

16. Nelli Seizure Monitoring System

The following table summarizes the information provided in the new technology add-on payment application for the Nelli Seizure Monitoring System. We note that Neuro Event Labs, Inc. submitted an application for new technology add-on payments for the Nelli Seizure Monitoring System for FY 2023, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28341 through 28342), but the technology did not meet the applicable deadline for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2023 (87 FR 48960). We note that the applicant also submitted an application for new technology add-on payments for FY 2024, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26940 through 26942), that it withdrew prior to the issuance of the FY 2024 IPPS/LTCH PPS final rule (88 FR 58919).

BILLING CODE 4120–01–P

[195] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

	Nelli Seizure Monitoring System	
Technology Info	**Applicant**	Neuro Event Labs
	Description	Per the applicant, the Nelli Seizure Monitoring System is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. Per the applicant, Nelli's software is designed to automate the analysis of audio and video data to identify seizure events with a positive motor component.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241006U8AKC
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Nelli software is intended for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults. The software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate). Nelli software provides A/V data for physicians to characterize seizures and peri-ictal events.
	FDA marketing authorization information	The applicant anticipates a 510(k) clearance decision from FDA before May 1, 2025. Per the applicant, the FDA indication is currently being pursued for adults only.
	Commercial availability	Per the applicant, the technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2022, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the Nelli Seizure Monitoring System: XXE0X48 (Measurement of brain electrical activity, computer-aided semiologic analysis, new technology group 8).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Nelli Seizure Monitoring System. The applicant completed a cost analysis and a separate "imputed" analysis using the same Inclusion/Exclusion criteria. Cost Analysis: The applicant used the resulting MS-DRGs assigned to claims for hospitals with ≥11 claims. Blended Imputed Analysis: Using the same MS-DRGs identified for hospitals with ≥11 claims, the applicant performed a separate blended "imputed" analysis for cases from hospitals with <11 claims by combining this data with the original data for hospitals performing ≥11 cases.
	Claims identified	Cost Analysis: 11,215 claims mapping to 17 MS-DRGs, with 56.86% of claims mapping to MS-DRG 101 (Seizures without MCC). Blended Imputed Analysis: 22,530 claims mapping to 17 MS-DRGs, with 36.55% of claims mapping to MS-DRG 101 (Seizures without MCC).
	Charges removed for prior technology	The applicant did not remove direct or indirect charges related to the prior technology as it stated that no technology is being replaced and there is no change in other resources.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the operating expenses of the new technology by dividing the non-capital cost of the technology by the cost to charge ratio of 0.336 for Other Services from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Cost Analysis: - Average case-weighted threshold amount: $59,383 - Final inflated average case-weighted standardized charge per case: $81,595 Blended Imputed Analysis: - Average case-weighted threshold amount: $66,696 - Final inflated average case-weighted standardized charge per case: $114,010 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the Nelli Seizure Monitoring System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we agree with the applicant that the Nelli Seizure Monitoring System meets the cost

criterion and are therefore proposing to approve the Nelli Seizure Monitoring System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Nelli Seizure Monitoring System to the hospital to be $1,000 per patient for the cost of the analysis during the hospital visit. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Nelli Seizure Monitoring System would be $650 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

17. Positive Blood Culture (PBC) Separator With Selux AST System

The following table summarizes the information provided in the new technology add-on payment application for the PBC Separator with Selux AST System. We note that Selux Diagnostics, Inc. submitted an application for new technology add-on payments for the PBC Separator with Selux AST System for FY 2024 under the name Selux NGP System, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26946 through 26949), that it withdrew prior to the issuance of the FY 2024 IPPS/LTCH PPS final rule (88 FR 58919).

BILLING CODE 4120–01–P

	PBC Separator with Selux AST System	
Technology Info	**Applicant**	Selux Diagnostics, Inc.
	Description	Per the applicant, the PBC Separator with Selux AST System is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007LLY3U
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Selux Positive Blood Culture Separator and Selux System is intended for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles.
	FDA marketing authorization indication	The PBC Separator with Selux AST System is an automated inoculum preparation system that uses lysis, centrifugation and sequential optical density measurements to generate a McFarland equivalent suspension from positive blood culture samples that can be used for quantitative in vitro AST by the Selux AST System. Samples are processed directly from blood culture samples identified as positive by a continuous monitoring blood culture system. Samples should be confirmed as monomicrobial, gram negative rods by Gram stain. Organism identification is required for AST result interpretation and reporting, per the Selux AST System instructions for use.
	FDA marketing authorization information	Per the applicant, the Selux Positive Blood Culture Separator and Selux System is the same technology as the PBC Separator with Selux AST System from the FDA 510(k) clearance associated with this application. The applicant stated that during the 510(k) clearance process, FDA requested that Selux change the name to make it clear that this clearance was specific to the positive blood culture indication of the previously cleared AST system.
	FDA marketing authorization date	February 15, 2024
	Commercial availability	Per the applicant, the technology was commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2023, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the PBC Separator with Selux AST System: XXE5XY9 (Measurement of infection, other positive blood/isolated colonies bimodal phenotypic susceptibility technology, new technology group 9).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, and/or MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the PBC Separator with Selux AST System.
	Claims identified	Simulation 1: 1,319,069 claims mapping to 37 MS-DRGs, with 41.42% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC) Simulation 2: 1,793,579 claims mapping to 742 MS-DRGs, with 30.32% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC) Simulation 3: 2,117,455 claims mapping to 742 MS-DRGs, with 25.80% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC) Simulation 4: 368,389 claims mapping to 589 MS-DRGs, with 42.01% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC) Simulation 5: 1,437,546 claims mapping to 592 MS-DRGs, with 38.00% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV >96 Hours with MCC)
	Charges removed for prior technology	The applicant did not remove direct or indirect charges related to the prior technology. Per the applicant, the technology is not expected to remove the need for prior technologies or remove the costs associated with prior technologies.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.102 for Laboratory from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Simulation 1: - Average case-weighted threshold amount: $73,418 - Final inflated average case-weighted standardized charge per case: $84,339

		Simulation 2: - Average case-weighted threshold amount: $81,998 - Final inflated average case-weighted standardized charge per case: $107,616 Simulation 3: - Average case-weighted threshold amount: $78,365 - Final inflated average case-weighted standardized charge per case: $99,821 Simulation 4: - Average case-weighted threshold amount: $90,005 Final inflated average case-weighted standardized charge per case: $133,372 Simulation 5: - Average case-weighted threshold amount: $75,671 Final inflated average case-weighted standardized charge per case: $92,088 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the PBC Separator with Selux AST System meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant received 510(k) clearance from FDA is included within the scope of the Breakthrough Device designation indication, it appears that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We agree with the applicant that the PBC Separator with Selux AST System meets the cost criterion and are therefore proposing to approve the PBC Separator with Selux AST System for new technology add-on payments for FY 2026 for use as an automated inoculum preparation system that uses lysis, centrifugation and sequential optical density measurements to generate a McFarland equivalent suspension from positive blood culture samples that can be used for quantitative in vitro AST by the Selux AST System.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the PBC Separator with Selux AST System to the hospital to be $135.04 per patient. Per the applicant, the cost per patient includes $80 for the Selux AST Gram Negative and Selux AST Gram Positive AST Kit, $50 for the Selux AST Positive Blood Culture Kit, $4.79 for the Selux AST Analyzer Reagent Kit, and $0.25 for the Selux AST Waste Kit.

We note that according to the applicant, the Selux AST System has been granted multiple previous FDA clearances for a different indication and sample type.[196] However, per the applicant, the Breakthrough Device designation is for the Selux Positive Blood Culture Separator and Selux [AST] System. The previous FDA clearances for the Selux AST System were not considered Breakthrough Devices. Therefore, it appears that the components of the Selux AST System, including the Selux AST Gram Negative and Selux AST Gram Positive AST Kit, Selux AST Analyzer Reagent Kit, and Selux AST Waste Kit are eligible for new technology add-on payment only when used in conjunction with the PBC Separator on positive blood culture samples. We further note that the Selux AST System first received FDA 510(k) clearance on January 18, 2023, and therefore the components of the Selux AST System would still be new for FY 2026.

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2) we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the PBC Separator with Selux AST System would be $87.78 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

18. PearlMatrix P–15 Peptide Enhanced Bone Graft

The following table summarizes the information provided in the new technology add-on payment application for the PearlMatrix P–15 Peptide Enhanced Bone Graft.

BILLING CODE 4120–01–P

[196] *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211759.pdf* and *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211748.pdf.*

	PearlMatrix P-15 Peptide Enhanced Bone Graft	
Technology Info	**Applicant**	Cerapedics Inc.
	Description	Per the applicant, the PearlMatrix P-15 Peptide Enhanced Bone Graft is a composite bone graft material consisting of a synthetic peptide, found naturally occurring in human Type I collagen (P-15), adsorbed onto calcium phosphate particles, which are incorporated into a fibrous collagen matrix putty as an inert carrier.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241003MHP1H
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the P-15L Bone Graft is indicated for intervertebral body fusion of the spine in skeletally mature patients. The P-15L Bone Graft is intended to be used in conjunction with a TLIF Fusion Device and supplemental internal spinal fixation systems cleared by FDA for use in the lumbosacral spine. The system is to be used in patients who have had at least six months of non-operative treatment. The P-15L Bone Graft is intended for use at one level in the lumbar spine (L2-S1) for the treatment of degenerative disc disease (DDD) with up to Grade I spondylolisthesis. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies.
	FDA marketing authorization information	The applicant anticipates a PMA decision from FDA before May 1, 2025. Per the applicant, the device name of P-15L Bone Graft was used in the application for the Breakthrough Device designation. The applicant stated that Indications for Use statement in the Breakthrough Device designation was broader to encompass the initial product approval as well as future potential indication expansions, but the expected FDA indication would be specific to the clinical study data gathered within the Investigational Device Exemption study for FDA approval.
	Commercial availability	The applicant stated that it anticipates the technology will be available on the market immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the PearlMatrix P-15 Peptide Enhanced Bone Graft.
	Claims identified	6,902 claims mapping to 2 MS-DRGs, with 94.73% of claims mapping to MS-DRG 451 (Single Level Spinal Fusion Except Cervical without MCC).
	Charges removed for prior technology	The applicant removed 50% of charges associated with implantable devices (revenue centers 0278 and 0624). The applicant stated that this approach reflects a conservative estimate because the PearlMatrix P-15 Peptide Enhanced Bone Graft is used in conjunction with other implantable devices, including PEEK TLIF fusion device and posterior pedicle screw fixation. Per the applicant, this approach is supported by its literature review, which shows the percentage of costs associated with bone graft products as of total implantable devices ranges from 13% to 37%. The applicant did not remove any indirect charges as the applicant believed that the PearlMatrix P-15 Peptide Enhanced Bone Graft is anticipated to use a similar level of medical resources as the previous technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file and standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology as the applicant believed that the PearlMatrix P-15 Peptide Enhanced Bone Graft is anticipated to use a similar level of medical resources as the previous technology.
	Cost analysis results	Average case-weighted threshold amount: $127,054 Final inflated average case-weighted standardized charge per case: $145,497 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the PearlMatrix P-15 Peptide Enhanced Bone Graft meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we agree with the applicant that the PearlMatrix P–15 Peptide Enhanced Bone Graft

meets the cost criterion and are therefore proposing to approve the PearlMatrix P–15 Peptide Enhanced Bone Graft for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the PearlMatrix P–15 Peptide Enhanced Bone Graft to the hospital to be $6,500 per patient, for one 10 cc kit used per inpatient stay. The applicant provided the following cost breakdown of each component: bone graft peptide ($3,120 operating cost and $780 capital cost), porcine anorganic bone mineral ($780 operating cost and $195 capital cost), and fibrous collagen matrix ($1,300 operating cost and $325 capital cost). Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (86 FR 45145). As noted, the applicant stated, there are capital costs of $1,300 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix. Therefore, it appears that these costs are not eligible for new technology add-on payment because, as discussed in prior rulemaking and as noted, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). We note that any new technology add-on payment for the PearlMatrix P–15 Peptide Enhanced Bone Graft would include only the operating costs of $5,200 for the bone graft peptide, porcine anorganic bone mineral, and fibrous collagen matrix. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Any new technology add-on payment for the PearlMatrix P–15 Peptide Enhance Bone Graft would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the PearlMatrix P–15 Peptide Enhanced Bone Graft would be $3,380 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

19. Provizio® SEM Scanner

The following table summarizes the information provided in the new technology add-on payment application for the Provizio® SEM Scanner.

BILLING CODE 4120–01–P

	Provizio® SEM Scanner	
Technology Info	**Applicant**	Bruin Biometrics, LLC
	Description	Per the applicant, the Provizio® SEM Scanner is a wireless, hand-held, bedside device with a touch-screen interface. Per the applicant, the technology is non-invasive and detects, measures, and monitors sub-epidermal moisture (SEM), persistent focal edema, or localized edema to detect early-stage pressure injuries/ulcers (PI/PUs) and deep tissue pressure injuries (DTPIs).
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410076TVHF
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Provizio SEM Scanner S is intended to measure and monitor changes in subepidermal moisture (SEM), representing localized edema or persistent focal edema, for the detection of pressure induced and deep tissue damage when scanning the heels and sacrum of patients who are at risk of developing pressure ulcers and deep tissue injuries. Results from the Provizio SEM Scanner S are intended to direct clinical decision making in providing earlier, anatomy - specific interventions to treat raised levels of SEM while the skin is still intact. When used as intended by healthcare professionals, results from the Provizio SEM Scanner S are clinically actionable and aid in the prevention of chronic pressure ulcers (Stages 2, 3 and 4) and deep tissue injuries.
	FDA marketing authorization information	The applicant anticipates a De Novo Classification decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation.
	Commercial availability	The applicant anticipates the technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	Effective April 1, 2024, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the Provizio® SEM Scanner: XX2KXP9 (Monitoring of interstitial fluid volume, sub-epidermal moisture using electrical biocapacitance).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the list of ICD-10-CM codes used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Provizio® SEM Scanner. The applicant used FY 2023 MedPAR data to identify cases used in the cost analysis.
	Claims identified	10,249 claims mapping to 444 MS-DRGs, with none exceeding more than 7.86% of the total identified cases.
	Charges removed for prior technology	The applicant did not remove charges as the applicant stated there is no current technology for prevention of pressure ulcers and the new technology is additive to current practice. The applicant removed indirect charges to account for fewer supplies used to treat an active pressure ulcer and a lower length of stay if a pressure ulcer was prevented. The applicant analyzed the MedPAR data and compared the length of stay and supply charges for patients without pressure ulcers to cases for patients who developed sacral and heel pressure ulcers during the stay. The applicant reduced supply charges by 18% and reduced accommodation charges associated with 59% reduction in length of stay.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule and standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the estimated cost of the technology per day by the national average cost-to-charge ratio of 0.297 for Supplies & Equipment from the FY 2025 IPPS/LTCH PPS final rule to estimate charges per day. The applicant then multiplied this charge by the estimated length of stay after reducing the length of stay by 59% to bring in line with the length of stay for patients without pressure ulcers. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $137,789 Final inflated average case-weighted standardized charge per case: $232,164 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Provizio® SEM Scanner meets the cost criterion.

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After review of the information provided by the applicant, we agree with the applicant that the Provizio® SEM Scanner meets the cost criterion and are therefore proposing to approve the Provizio® SEM Scanner for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Provizio® SEM Scanner to the hospital to be $631.84 per patient, based on the cost of the

Single-Use Disposable Provizio® SEM Sensor ($17.95) with a two-scan frequency per day, and an anticipated average length of stay (LOS) of 17.6 days. Per the applicant, the average LOS was determined by analyzing the FY2023 MedPAR data, and the weighted average LOS for all MS–DRGs (765 DRGs) was 5.1 days. According to the applicant, the average LOS for MS–DRGs (444 MS–DRGs) with patients who developed sacral and heel pressure ulcers (PUs) during the stay was 24.9 days, and the average LOS for the same MS–DRGs for cases without PUs was 10.3 days. The applicant expected that the LOS for these MS–DRGs would be reduced from 24.9 to 10.3 days for patients using the device. The applicant noted that the MedPAR data describes the number of cases with PUs, and that it is possible that individual patients may have multiple PUs, such as at the sacrum and heel. Per the applicant, in these cases, the scanner would be used on the remaining anatomies at risk of PUs through the average LOS of 24.9 days. Per the applicant, the midpoint between the average LOS for cases without PUs and cases with PUs is 17.6 days. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Any new technology add-on payment for the Provizio® SEM Scanner would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Provizio® SEM Scanner would be $410.70 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

20. RECELL® Autologous Cell Harvesting Device

The following table summarizes the information provided in the new technology add-on payment application for the RECELL® Autologous Cell Harvesting Device.

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	RECELL® Autologous Cell Harvesting Device	
Technology Info	**Applicant**	AVITA Medical
	Description	Per the applicant, the RECELL® Autologous Cell Harvesting Device is a stand-alone, single-use, battery-powered medical device that is used to process and apply a skin cell suspension autograft for the treatment of thermal burn wounds and full thickness skin defects. Per the applicant, this NTAP application is for the full thickness skin defects indication.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007VBAM0
FDA Info	**Breakthrough Device designation Indication**	Per the applicant, the proposed indication for use is for the treatment of patients with acute nonthermal full thickness skin wounds after traumatic avulsion, surgical excision (for example, necrotizing soft tissue infection), or resection (for example, skin cancer), in combination with meshed autografting.
	FDA marketing authorization indication	The RECELL® Autologous Cell Harvesting Device is used by an appropriately licensed and trained healthcare professional at the patient's point-of-care to prepare autologous Spray-On Skin Cells for direct application to acute partial-thickness thermal burn wounds in patients 18 years of age or older, or application in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (for example, degloving) or surgical excision (for example, necrotizing soft tissue infection) or resection (for example, skin cancer) in patients 15 years of age and older.
	FDA marketing authorization information	The applicant stated that the following FDA-approved indication is the subject of the new technology add-on payment application: for the use of the RECELL® Autologous Cell Harvesting Device in combination with meshed autografting for full thickness skin defects resulting from traumatic avulsion (for example, degloving), surgical excision (for example, necrotizing soft tissue infection), or resection (for example, skin cancer) in patients 15 years of age and older.
	FDA marketing authorization date	June 7, 2023
	Commercial availability	Per the applicant, the RECELL® Autologous Cell Harvesting Device was commercially available immediately after FDA approval for the indication of full thickness skin defects.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant provided a list of procedure codes that, effective October 1, 2019, may be used to uniquely identify procedures involving the use of the RECELL® Autologous Cell Harvesting Device under the ICD-10-PCS coding system in the online application posting.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and list of MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the RECELL® Autologous Cell Harvesting Device.
	Claims identified	Cost Analysis 1: 17,183 claims mapping to 11 MS-DRGs, with 36.87% of claims mapping to MS-DRG 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connectivity Tissue Disorders with CC). Cost Analysis 2: 13,539 claims mapping to 4 MS-DRGs, with 46.79% of claims mapping to MS-DRG 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connectivity Tissue Disorders with CC). Cost Analysis 3: 17,183 claims mapping to 11 MS-DRGs, with 36.87% of claims mapping to MS-DRG 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connectivity Tissue Disorders with CC).
	Charges removed for prior technology	According to the applicant, the RECELL® Autologous Cell Harvesting Device is a novel device and does not replace any prior technology. Therefore, the applicant did not remove any direct charges for prior technology being replaced. The applicant stated that the RECELL® Autologous Cell Harvesting Device is indicated for use in combination with the standard of care, split-thickness skin grafting (STSG), for full-thickness skin defects, complementing but not replacing the STSG procedure. The applicant believed the same resources required for a standard STSG are also needed when the RECELL® Autologous Cell Harvesting Device is used. Therefore, the applicant did not remove any indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.

	Inflation factor	Cost analysis 1 and 2: The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule. Cost analysis 3: The applicant did not apply an inflation factor to the standardized charges.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology because it believed the same resources required for a standard STSG are also needed when the RECELL® Autologous Cell Harvesting Device is used.
	Cost analysis results	Cost Analysis 1: - Average case-weighted threshold amount: $114,718 - Final inflated average case-weighted standardized charge per case: $175,809 Cost Analysis 2: - Average case-weighted threshold amount: $113,758 - Final inflated average case-weighted standardized charge per case: $172,998 Cost Analysis 3: - Average case-weighted threshold amount: $114,718 - Final inflated average case-weighted standardized charge per case: $159,065 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all analyses, the applicant asserted that the RECELL® Autologous Cell Harvesting Device meets the cost criterion.

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After review of the information provided by the applicant, we note that the RECELL® Autologous Cell Harvesting Device is also indicated for acute partial-thickness thermal burn wounds and acute full-thickness thermal burn wounds. However, we note that under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2026. Therefore, only the use of the RECELL® Autologous Cell Harvesting Device for acute nonthermal full thickness skin wounds after traumatic avulsion, surgical excision (for example, necrotizing soft tissue infection), or resection (for example, skin cancer), and the FDA Breakthrough Device designation it received for those uses, are relevant for purposes of the new technology add-on payment application for FY 2026.

Please see Table 10.1.A.-RECELL® Autologous Cell Harvesting Device associated with this proposed rule for the list of relevant ICD–10–CM diagnosis codes that we believe would identify the Breakthrough Device-designated indication of acute nonthermal full thickness skin wounds after traumatic avulsion. Please see Table 10.1.B.-RECELL® Autologous Cell Harvesting Device associated with this proposed rule for the list of relevant ICD–10–PCS procedure codes that we believe would be appropriate to report in combination with use of the RECELL® Autologous Cell Harvesting Device to identify use of the technology for the Breakthrough Device-designated indication of acute nonthermal full thickness skin wounds after surgical excision (for example, necrotizing soft tissue infection) or resection (for example, skin cancer). We are inviting public comments on the use of these ICD–10–CM diagnosis and ICD–10–PCS procedure codes to identify use of the technology for the Breakthrough Device-designated indications for purposes of the new technology add-on payment, if approved.

We agree with the applicant that the RECELL® Autologous Cell Harvesting Device meets the cost criterion and are therefore proposing to approve the RECELL® Autologous Cell Harvesting Device for new technology add-on payments for FY 2026, when used in combination with meshed autografting for acute full-thickness thermal burn wounds in pediatric and adult patients and full-thickness skin defects after traumatic avulsion (for example, degloving) or surgical excision (for example, necrotizing soft tissue infection) or resection (for example, skin cancer).

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the RECELL® Autologous Cell Harvesting Device to the hospital to be $7,500 per device. The applicant estimated that, on average, one device is used per inpatient stay for patients with a full-thickness skin defect. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the RECELL® Autologous Cell Harvesting Device would be $4,875 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

21. Restor3d TIDAL™ Fusion Cage

The following table summarizes the information provided in the new

technology add-on payment application for the restor3d TIDAL™ Fusion Cage. We note that restor3d submitted an application for new technology add-on payments for the restor3d TIDAL™ Fusion Cage for FY 2025, as summarized in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36124 through 36125), that it withdrew prior to the issuance of the FY 2025 IPPS/LTCH PPS final rule (89 FR 69204).

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	restor3d TIDAL™ Fusion Cage	
Technology Info	**Applicant**	restor3d
	Description	Per the applicant, the restor3d TIDAL™ Fusion Cages are additively manufactured porous cages intended to be used as an accessory to an intramedullary nail for internal bone fixation for bone fractures, bone voids, or surgical resections in the hindfoot and tibia.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410022M84U
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the restor3d Fusion Cage System is intended for tibiotalocalcaneal arthrodesis (fusion) to provide stabilization of the hindfoot and ankle with critical size bone defect, in lieu of bulk allograft in procedures such as: post-traumatic and degenerative arthritis; post-traumatic or primary arthrosis involving both ankle and subtalar joints; revision after failed ankle arthrodesis with subtalar involvement; failed total ankle arthroplasty; non-union ankle arthrodesis; rheumatoid hindfoot; talectomy; avascular necrosis of the talus; neuroarthropathy; neuromuscular disease and severe deformity; osteoarthritis; Charcot foot; and previously infected arthrosis, second degree.
	FDA marketing authorization information	The applicant anticipates a 510(k) clearance decision from FDA before May 1, 2025, consistent with its Breakthrough Device designation. Per the applicant, the proposed FDA indications are a subset of the indications from the Breakthrough Designation and that the restor3d TIDAL™ Fusion Cage indications have been restricted to use the DynaNail, with indications limited to revision applications for patients at risk of limb loss.
	Commercial availability	The applicant anticipates the technology will be immediately available for sale after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2024, the following ICD-10-PCS codes may be used to uniquely describe procedures involving use of the restor3d TIDAL™ Fusion Cage: XRGK0CA (Fusion of left ankle joint using gyroid-sheet lattice design internal fixation device, open approach), XRGM0CA (Fusion of left tarsal joint using gyroid-sheet lattice design internal fixation device, open approach), XRGJ0CA (Fusion of right ankle joint using gyroid-sheet lattice design internal fixation device, open approach), and XRGL0CA (Fusion of right tarsal joint using gyroid-sheet lattice design internal fixation device, open approach).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the list of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the restor3d TIDAL™ Fusion Cage. The applicant used FY 2022 MedPAR data to identify cases used in the cost analysis.
	Claims identified	14,247 claims mapping to 24 MS-DRGs, with 15.82% of claims mapping to MS-DRG 617 (Amputation of Lower Limb for Endocrine, Nutritional and Metabolic Disorders With CC) and 15.61% of claims mapping to MS-DRG 853 (Infectious and Parasitic Diseases with O.R. Procedures with MCC).
	Charges removed for prior technology	The applicant removed charges for the prior technology by estimating the cost of the technology being replaced using market intelligence data and the CMS Public Data file. The applicant then calculated charges for the technology by using the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file and standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 17.52% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant added indirect charges related to the new technology by using market intelligence data to estimate the cost related to use of the technology. The applicant then calculated charges using the Implantable Devices cost-to-charge ratio (0.259).
	Cost analysis results	Average case-weighted threshold amount: $113,613 Final inflated average case-weighted standardized charge per case: $320,053 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the restor3d TIDAL™ Fusion Cage meets the cost criterion.

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After review of the information provided by the applicant, we agree with the applicant that the restor3d TIDAL™ Fusion Cage meets the cost criterion and are therefore proposing to approve the restor3d TIDAL™ Fusion

Cage for new technology add-on payments for FY 2026 subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the cost of the restor3d TIDAL™ Fusion Cage to the hospital to be $27,995 per patient. In addition, the applicant noted the costs related to the technology for required supporting instruments and materials consist of one unit each of the Instrument Kit ($6,995), TTC Fusion Nail ($7,500), and Graft Material ($1,500). The applicant estimated the total cost to the hospital to be $43,990 for each procedure per patient, including the related cost of the technology. As we discussed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36125) and in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device (86 FR 45146). Based on the information provided by the applicant, the cost of the Instrument Kit is included in the costs of the supporting instruments and materials for each procedure related to the use of the technology, rather than the cost of the technology itself. In addition, it appears that the TTC Fusion Nail and Bone Graft are not new and unique components for this technology and can be purchased separately in support of other technologies. Furthermore, we note that the Instrument Kit is not included in the Breakthrough Device designation, and it therefore appears that only the restor3d TIDAL™ Fusion Cage would be designated as the Breakthrough Device once market authorized and would be eligible for new technology add-on payments under the alternative pathway. Therefore, it appears any add-on payment for the restor3d TIDAL™ Fusion Cage would include only the cost of the restor3d TIDAL™ Fusion Cage ($27,995).

We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the restor3d TIDAL™ Fusion Cage would be $18,196.75 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

22. ShortCut™

The following table summarizes the information provided in the new technology add-on payment application for the ShortCut™.

BILLING CODE 4120–01–P

	ShortCut™	
Technology Info	Applicant	Pi-Cardia Ltd
	Description	Per the applicant, the ShortCut™ is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk of coronary obstruction.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410045YWFH
FDA Info	Breakthrough Device designation indication	Per the applicant, the ShortCut™ is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction.
	FDA marketing authorization indication	The ShortCut™ is indicated for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction.
	FDA marketing authorization date	September 27, 2024
	Commercial availability	The applicant stated that the technology was commercially available immediately after FDA market authorization.
Coding	Unique ICD-10-PCS Code(s)	Effective October 1, 2024, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the ShortCut™: X28F3VA (Division of aortic valve using intraluminal bioprosthetic valve leaflet splitting technology in existing valve, percutaneous approach, new technology group 10).
	ICD-10-CM Code(s)	The applicant stated the ICD-10-CM code I35.0 (Nonrheumatic aortic (valve) stenosis) may be used to currently identify the indication under the ICD-10-CM coding system.
Cost Criterion	Inclusion/exclusion criteria	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the ShortCut™. The applicant used FY 2023 MedPAR data to identify cases used in the cost analysis.
	Claims identified	39,533 claims mapping to 2 MS-DRGs, with 68.3% of claims mapping to MS-DRG 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC).
	Charges removed for prior technology	The applicant did not remove charges or indirect charges related to prior technology as the applicant stated there is no existing technology to be replaced.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.297 for Supplies & Equipment from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Average case-weighted threshold amount: $192,802 Final inflated average case-weighted standardized charge per case: $275,030 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the ShortCut™ meets the cost criterion.

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After review of the information provided by the applicant, we agree with the applicant that the ShortCut™ meets the cost criterion and are therefore proposing to approve the ShortCut™ for new technology add-on payments for FY 2026 for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk for coronary obstruction.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the ShortCut™ to the hospital to be $15,000 per patient. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the ShortCut™ would be $9,750 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the ShortCut™ meets the cost criterion and our proposal to approve new technology add-on payments for the ShortCut™ for FY 2026.

23. Spur Peripheral Retrievable Stent System

The following table summarizes the information provided in the new technology add-on payment application for the Spur Peripheral Retrievable Stent System.

BILLING CODE 4120–01–P

	Spur Peripheral Retrievable Stent System	
Technology Info	**Applicant**	Reflow Medical, Inc.
	Description	Per the applicant, the Spur Peripheral Retrievable Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal diameter. Per the applicant, it places a temporary stent within the lesion and is removed during the procedure.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241004UTR2W
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Bare Temporary Spur Stent System is intended for the treatment of de novo or restenotic lesions of the infrapopliteal arteries to increase luminal gain.
	FDA marketing authorization information	The applicant stated that it anticipates a De Novo Classification decision from FDA before May 1, 2025. Per the applicant, the expected FDA indication has verbiage regarding increasing luminal diameter, which is similar to the Breakthrough Device designation indication verbiage regarding increasing luminal gain. Per the applicant, both indications are consistent in that the device is intended for patients with de novo or restenotic lesions in the infrapopliteal arteries. According to the applicant, the Bare Spur Stent System named in the Breakthrough Device designation letter is the same device as the Spur Peripheral Retrievable Stent System named in the De Novo application.
	Commercial availability	The applicant stated that it anticipates the technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Spur Peripheral Retrievable Stent System.
	Claims identified	14,511 claims mapping to 152 MS-DRGs, with 15.22% of claims mapping to MS-DRG 253 (Other Vascular Procedures with CC).
	Charges removed for prior technology	The applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). Per the applicant, the use of the Spur Peripheral Retrievable Stent System is expected to replace a portion of devices included in these claims, although it will not replace all devices, nor any medical supplies required to perform the procedure. However, an estimate of the percentage of these total charges for devices that would be replaced could not be determined by the applicant. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant did not add charges or indirect charges for the new technology.
	Cost analysis results	Average case-weighted threshold amount: $130,537 Final inflated average case-weighted standardized charge per case: $187,119 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Spur Peripheral Retrievable Stent System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, with regard to the cost criterion, we note that the applicant provided a list of ICD–10–CM codes to identify indications relevant to use of the technology for patients with de novo or restenotic lesions in the infrapopliteal arteries. However, in the cost analysis, the applicant used only ICD–10–PCS codes to identify eligible cases. We question whether using a combination of ICD–10–CM and ICD–10–PCS codes would more accurately identify eligible cases.

Subject to the applicant adequately addressing this concern, we would agree that the Spur Peripheral Retrievable Stent System meets the cost criterion and are therefore proposing to approve the Spur Peripheral Retrievable Stent System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

The applicant has not provided an estimate for the cost of the Spur Peripheral Retrievable Stent System at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the Spur Peripheral Retrievable Stent System would be subject to our policy under § 412.88(a)(2) where we limit new

technology add-on payment to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case.

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

24. The WiSE CRT System

The following table summarizes the information provided in the new technology add-on payment application for The WiSE CRT System.

BILLING CODE 4120–01–P

	The WiSE CRT System	
Technology Info	**Applicant**	EBR Systems, Inc
	Description	Per the applicant, The WiSE CRT System is indicated for patients who meet current guidelines for cardiac resynchronization therapy (CRT) with previously acute or chronic failed implants or patients that are high-risk upgrades to a traditional CRT device.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410056PHBK
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the WiSE CRT System is indicated for patients who meet current guidelines for CRT device implantation and satisfy at least one of the following criteria: patients with previously implanted CRT device, who have not responded to CRT – referred to as "non-responders;" patients in whom previous coronary sinus lead implantation procedure was unsuccessful, or where an implanted lead has been turned off – referred to as "previously untreatable;" and patients with previously implanted pacemakers or ICD's in whom standard CRT upgrade is not advisable due to known relative contraindications for CS lead or CRT device implantation – referred to as "high-risk upgrades."
	FDA marketing authorization information	The applicant stated that it anticipates a PMA decision from FDA before May 1, 2025. According to the applicant, the proposed FDA indication includes two of the three indications for which Breakthrough Device Designation was approved, specifically patients that are "previously untreatable" and "high-risk upgrades."
	Commercial availability	The applicant anticipates The WiSE CRT System will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for The WiSE CRT System.
	Claims identified	Scenario 1: 396 claims mapping to 2 MS-DRGs, with 53.79% of claims mapping to MS-DRG 229 (Other Cardiothoracic Procedures without MCC). Scenario 2: 934 claims mapping to 2 MS-DRGs, with 64.45% of claims mapping to MS-DRG 229 (Other Cardiothoracic Procedures without MCC).
	Charges removed for prior technology	The applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624), because the technology is expected to replace a portion of devices included in these claims (although it will not replace all devices, nor any medical supplies required to perform the procedure) and an estimate of the percentage of total charges that the technology would replace could not be determined. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule correcting amendment.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Scenario 1: - Average case-weighted threshold amount: $156,573 - Final inflated average case-weighted standardized charge per case: $362,465 Scenario 2: - Average case-weighted threshold amount: $150,937 - Final inflated average case-weighted standardized charge per case: $356,495 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that The WiSE CRT System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we agree with the applicant that The WiSE CRT System meets the cost criterion and are therefore proposing to approve The WiSE CRT System for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of The WiSE CRT System to the hospital to be $63,300 per patient. The components include the electrode

and catheter ($21,970), the delivery sheath ($2,590), the battery ($12,870), and the transmitter ($25,870). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS-DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of The WiSE CRT System would be $41,145 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

25. TriVerity Test

The following table summarizes the information provided in the new technology add-on payment application for the TriVerity Test.

BILLING CODE 4120–01–P

	TriVerity Test	
Technology Info	**Applicant**	Inflammatix, Inc.
	Description	Per the applicant, the TriVerity test is a blood test that rapidly "reads" the body's immune response to infection using machine learning-derived algorithms. Per the applicant, the test informs on the presence of infection and risk of progression to severe illness in adult patients suspected of acute infection or sepsis in the emergency department.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007260BW
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the TriVerity Test is an automated, semi-quantitative in vitro diagnostic test that measures the relative expression levels of host response genes in RNA isolated from whole blood collected in the PAXgene Blood RNA tube using reverse transcription loop-mediated isothermal amplification (RT-LAMP) on the Myrna instrument. The results are generated using two fixed classifiers. The TriVerity Test is indicated for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as the likelihood of disease progression in adult patients with suspected acute infection or sepsis presenting to the emergency department. The test generates three scores that fall within one of five discrete interpretation bands based on the likelihoods of: 1) bacterial infection, 2) viral infection, and 3) severe illness, as defined by the need for mechanical ventilation, vasopressors, and/or renal replacement therapy (RRT) within seven days.
	FDA marketing authorization information	The TriVerity test is an automated, semi-quantitative in vitro diagnostic test that measures the relative expression levels of host response genes in RNA isolated from whole blood collected in the PAXgene Blood RNA tube using reverse transcription loop-mediated isothermal amplification (RT-LAMP) on the Myrna instrument. The TriVerity test is indicated for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as to determine the likelihood of 7-day need for mechanical ventilation, vasopressors, and/or renal replacement therapy in adult patients with suspected acute infection or suspected sepsis presenting to the emergency department. The test generates three scores that each fall within one of five discrete interpretation bands based on the increasing likelihood of 1) bacterial infection, 2) viral infection, and 3) severe illness, as defined by the need for mechanical ventilation, vasopressors, and/or renal replacement therapy (RRT) within seven days.
	FDA marketing authorization date	January 10, 2025
	Commercial availability	Per the applicant, the technology was not commercially available immediately after FDA marketing authorization because it is working to transition its test system manufacturing to be able to roll out TriVerity cartridges for routine clinical use including: (1) updating labeling, (2) build-up of TriVerity cartridge inventory, and (3) updating documents within its QMS. Per the applicant, its target date for commercial availability is March 6, 2025.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a diagnosis code that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and/or MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the TriVerity Test.
	Claims identified	Cost Analysis 1: 1,321,764 claims mapping to 42 MS-DRGs, with 39.73% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC). Cost Analysis 2: 2,269,088 claims mapping to 727 MS-DRGs, with 23.05% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC).
	Charges removed for prior technology	The applicant stated that the TriVerity Test is expected to be used as an aid in the Emergency Department to help identify which patients should receive antibiotics, undergo further diagnostic testing, and be admitted for further treatment, and would be additive to the cases identified. Therefore, the applicant did not remove any direct or indirect charges for prior technologies being replaced.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant did not add direct or indirect charges related to the new technology.
	Cost analysis results	Cost Analysis 1: - Average case-weighted threshold amount: $67,984 - Final inflated average case-weighted standardized charge per case: $70,025 Cost Analysis 2: - Average case-weighted threshold amount: $73,258 - Final inflated average case-weighted standardized charge per case: $81,393 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the TriVerity Test meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we note the applicant stated that the technology was not commercially available immediately

after FDA clearance. We are interested in additional information regarding the cause of any delay in the technology's commercial availability, including the significance of building up TriVerity cartridge inventory on its availability for routine clinical use.

With regard to the cost criterion, the applicant stated the technology is used as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as the likelihood of disease progression in adult patients. However, the applicant included diagnosis codes related to sepsis of newborn in the second cost criterion analysis. We question whether diagnosis codes related to newborns are applicable to this technology because it is indicated for use in adult patients, and whether the applicant should remove these diagnosis codes to identify eligible cases more accurately.

Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and propose to approve the TriVerity Test for new technology add-on payments for FY 2026, for use in conjunction with clinical assessments and other laboratory findings as an aid to differentiate bacterial infections, viral infections, and non-infectious illness, as well as to determine the likelihood of 7-day need for mechanical ventilation, vasopressors, and/or renal replacement therapy in adult patients with suspected acute infection or suspected sepsis presenting to the emergency department.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the TriVerity Test to the hospital to be $388 per patient. The applicant stated that there would be two components for the operating cost of the technology: the TriVerity Cartridge ($375) and the PAXgene Blood RNA Tube ($13). Per the applicant, the PAXgene Blood RNA Tube is an FDA-cleared tube distributed by BD and is a necessary component for hospitals to use the TriVerity Test. The applicant stated that hospitals can purchase the PAXgene Blood RNA Tubes directly from BD or from the applicant. Although the applicant stated that the PAXgene Blood RNA Tube is a new component of the device, we note that the PAXgene Blood RNA Tube is also commercially available for other uses as a standalone sample collection device, and received FDA marketing authorization as early as April 18, 2005.[197] Therefore, it appears that only the cost of the TriVerity Cartridge is appropriate for consideration for new technology add-on payment. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the TriVerity Test would be $243.75 for FY 2026 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the TriVerity Test meets the cost criterion and our proposal to approve new technology add-on payments for the TriVerity Test for FY 2026.

[197] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN050003.*

26. Ventura® Interatrial Shunt System

The following table summarizes the information provided in the new technology add-on payment application for the Ventura® Interatrial Shunt System.

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	Ventura® Interatrial Shunt System	
Technology Info	**Applicant**	V-Wave, Inc.
	Description	Per the applicant, the Ventura® Interatrial Shunt System includes the Ventura® Interatrial Shunt and delivery system. Per the applicant, it is indicated to reduce morbidity and mortality in NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy and have a left ventricular ejection fraction of ≤40%.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241004DLXGV
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the V-Wave Shunt is a permanent implant, which is designed to enable shunting of blood from the left to the right atrium and by that, improve symptoms in NYHA Class III and ambulatory Class IV heart failure patients, with reduced or preserved left ventricular systolic function.
	FDA marketing authorization information	The applicant anticipates a PMA decision from FDA before May 1, 2025. Per the applicant, the Breakthrough Device designation is broader than the proposed FDA indication submitted for FDA marketing authorization because the Breakthrough device indication includes both NYHA Class III and ambulatory Class IV heart failure patients, with reduced or preserved left ventricular systolic function, while the proposed FDA indication is for NYHA Class III heart failure patients who remain symptomatic despite guideline directed medical therapy and have a left ventricular ejection fraction (LVEF) of ≤40%. According to the applicant, the V-Wave Shunt named in the Breakthrough designation letter is now called Ventura® Interatrial Shunt System.
	Commercial availability	The applicant anticipates the technology will be commercially available immediately after FDA marketing authorization.
Coding	**Unique ICD-10-PCS Code(s)**	According to the applicant, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the Ventura® Interatrial Shunt System: 02173J6 (Bypass left atrium to right atrium with synthetic substitute, percutaneous approach).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the Ventura® Interatrial Shunt System.
	Claims identified	Medical MS-DRG analysis: 13,345 claims mapping to 10 MS-DRGs, with 40.66% of claims mapping to MS-DRG 291 (Heart Failure and Shock with MCC). Surgical MS-DRG analysis: 975 claims mapping to 3 MS-DRGs, with 83.28% of claims mapping to MS-DRG 270 (Other Major Cardiovascular Procedures with MCC).
	Charges removed for prior technology	Medical MS-DRG analysis: The applicant did not remove charges for prior technology because the applicant selected the currently medically managed cases that the Ventura® Interatrial Shunt System will be used to treat. Per the applicant, the new technology is additive to current practice. The applicant did not remove indirect charges related to the new technology. Surgical MS-DRG analysis: The applicant removed supplies and implant charges associated with similarly resourced surgical procedures performed in the catheterization lab. According to the applicant, this technology would not be used in conjunction with any other procedure. The applicant did not remove indirect charges related to the new technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule and in the standardization file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.259 for Implantable Devices from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Scenario 1: - Average case-weighted threshold amount: $53,467 - Final inflated average case-weighted standardized charge per case: $185,373 Scenario 2: - Average case-weighted threshold amount: $170,001 - Final inflated average case-weighted standardized charge per case: $293,772 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the Ventura® Interatrial Shunt System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, we note that with regard to the unique ICD–10–PCS procedure code used to identify the use

of this technology, the applicant stated that ICD–10–PCS procedure code 02173J6 (Bypass left atrium to right atrium with synthetic substitute, percutaneous approach) describes implantation of an interatrial shunt. The applicant stated that it expects the Ventura® Interatrial Shunt System to be the first interatrial shunt to receive FDA approval and that it therefore will be the only technology reported under this code. However, we believe that other technologies currently in clinical trials may also be able to be reported using this code. Therefore, we believe that the ICD–10–CM diagnosis code Z00.6 (Encounter for examination for normal comparison and control in clinical research program) should be used in combination with the ICD–10–PCS procedure code 02173J6 to exclude new technology add-on payment for cases involving technologies that are used in clinical trial settings, as costs for the investigational item or service, itself unless otherwise covered outside of the clinical trial, are not covered by Medicare under the routine costs of a clinical trial.[198] We are inviting public comments on the use of this ICD–10–CM diagnosis code to exclude cases involving technologies that are used in clinical trial settings, which would not be eligible for the new technology add-on payment, if approved.

We agree with the applicant that the Ventura® Interatrial Shunt System meets the cost criterion and are therefore proposing to approve the Ventura® Interatrial Shunt System for new technology add-on payments for FY 2026 subject to the technology receiving FDA marketing authorization for the indication corresponding to the Breakthrough Device designation by May 1, 2025.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Ventura® Interatrial Shunt System to the hospital to be $34,000 per device, and one unit of the shunt system would be furnished during an inpatient stay. The components include the Ventura® Interatrial Shunt ($32,000) and the Ventura® Interatrial Shunt Delivery System ($2,000). We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the Ventura® Interatrial Shunt System would be $22,100 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

27. VITEK® REVEAL™ AST System

The following table summarizes the information provided in the new technology add-on payment application for the VITEK® REVEAL™ AST System.

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[198] Routine Costs in Clinical Trials 310.1 (Effective Date of this Version 05/27/2024) *https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=1&ncdver=3&*.

	VITEK® REVEAL™ AST System	
Technology Info	**Applicant**	bioMerieux
	Description	Per the applicant, the VITEK® REVEAL™ Antimicrobial Susceptibility Testing (AST) System is an in vitro diagnostic (IVD) automated system for the quantitative AST of organisms from positive blood culture. Per the applicant, test results are intended to be used in conjunction with Gram stain, organism identification and other clinical findings to inform antibiotic therapy treatment decisions.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241007GL4LH
FDA Info	**Breakthrough Device designation indication**	Per the applicant, the Reveal Rapid AST System is indicated for use as an IVD automated system for quantitative AST of organisms direct from positive blood culture or isolate dilution. The Reveal GN BC AST Assay is indicated for susceptibility testing of specific gram-negative pathogenic bacteria commonly associated with or causing bacteremia. Results are intended to be used in conjunction with Gram stain, organism identification and other clinical laboratory findings.
	FDA marketing authorization indication	The VITEK® REVEAL™ AST System is an automated system for quantitative and qualitative AST of organisms direct from positive blood culture. The VITEK® REVEAL™ AST System does not provide organism identification. The VITEK® REVEAL™ AST System is an automated system that uses an array of sensors to detect volatile organic compounds emitted by growing bacteria for the IVD quantitative and qualitative determination of antimicrobial susceptibility. The VITEK® REVEAL™ GN AST Assay is indicated for susceptibility testing direct from positive blood culture samples signaled positive by a continuous monitoring blood culture system and confirmed to contain gram-negative bacilli by Gram stain. Organism identification is required for the AST result interpretation and reporting.
	FDA marketing authorization information	Per the applicant, the FDA-cleared device name is slightly different than the Breakthrough Device name, as the word "Rapid" was removed from the name by FDA as a condition of clearance. The applicant stated that the FDA-cleared device name is VITEK® REVEAL™ AST System.
	FDA marketing authorization date	June 20, 2024
	Commercial availability	According to the applicant, the VITEK® REVEAL™ AST System became commercially available on October 21, 2024. Per the applicant, there was a delay in market availability due to lead times in the supply chain and implementation of system modifications due to FDA requirements.
Coding	**Unique ICD-10-PCS Code(s)**	Effective October 1, 2024, the following ICD-10-PCS code may be used to uniquely describe procedures involving the use of the VITEK® REVEAL™ AST System: XXE5X4A (Measurement of infection, positive blood culture small molecule sensory array technology, new technology group 10).
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for the VITEK® REVEAL™ AST System.
	Claims identified	Simulation 1: 1,417,026 claims mapping to 579 MS-DRGs, with 35.52% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Simulation 2: 619,445 claims mapping to 3 MS-DRGs, with 81.25% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Simulation 3: 417,648 claims mapping to 585 MS-DRGs, with 49.81% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC) Simulation 4: 798,340 claims mapping to 44 MS-DRGs, with 61.16% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC)
	Charges removed for prior technology	Per the applicant, the technology is not expected to remove the need for prior technologies or remove the costs associated with prior technologies. Therefore, the applicant did not remove any direct or indirect charges for prior technologies being replaced.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2025 IPPS/LTCH PPS final rule.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.

	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.102 for Laboratory from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Simulation 1: - Average case-weighted threshold amount: $81,102 - Final inflated average case-weighted standardized charge per case: $104,143 Simulation 2: - Average case-weighted threshold amount: $76,738 - Final inflated average case-weighted standardized charge per case: $87,170 Simulation 3: - Average case-weighted threshold amount: $78,518 - Final inflated average case-weighted standardized charge per case: $94,050 Simulation 4: - Average case-weighted threshold amount: $81,248 - Final inflated average case-weighted standardized charge per case: $93,942 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the VITEK® REVEAL™ AST System meets the cost criterion.

BILLING CODE 4120–01–C

After review of the information provided by the applicant, since the indication for which the applicant received 510(k) clearance is included within the scope of the Breakthrough Device designation indication, it appears that the FDA-cleared indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.[199]

We note the applicant stated the device was not commercially available until October 21, 2024, due to lead times in the supply chain and implementation of system modifications due to FDA requirements. We are interested in additional information regarding the cause for any delay in the technology's commercial availability, as it received FDA clearance on June 20, 2024, and it is not clear how lead times in the supply chain affected its availability on the market and what system modifications were required.

We agree with the applicant that the VITEK® REVEAL™ AST System meets the cost criterion and are therefore proposing to approve the VITEK® REVEAL™ AST System for new technology add-on payments for FY 2026, indicated for susceptibility testing direct from positive blood culture samples signaled positive by a continuous monitoring blood culture system and confirmed to contain gram-negative bacilli by Gram stain.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the VITEK® REVEAL™ AST System to the hospital to be $125 per patient for the VITEK® REVEAL™ Sensor Array. Per the applicant, while there are additional capital costs for the technology, these costs were not included in the device's cost to the hospital per patient per inpatient stay. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of the VITEK® REVEAL™ AST System would be $81.25 for FY 2026 (that is, 65 percent of the average cost of the technology).

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

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

1. EMBLAVEO™ (Aztreonam-Avibactam)

The following table summarizes the information provided in the new technology add-on payment application for EMBLAVEO™ (also referred to as ATM–AVI).

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[199] Breakthrough Devices Program *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

	EMBLAVEO™ (aztreonam-avibactam)	
Technology Info	**Applicant**	AbbVie
	Description	Per the applicant, ATM-AVI is an intravenous antibiotic treatment for infections caused by Gram-negative bacteria with limited treatment options. Per the applicant, it combines aztreonam, a monobactam β-lactam, with avibactam, a potent broad-spectrum β-lactamase inhibitor.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP241005WY6F6
FDA Info	**QIDP designation indication**	Per the applicant, ATM-AVI is designated as a QIDP for treatment of complicated intra-abdominal infections (cIAI), complicated urinary tract infections (cUTI), and hospital-acquired bacterial pneumonia (HABP)/ventilator-associated bacterial pneumonia (VABP).
	FDA marketing authorization indication	Emblaveo, in combination with metronidazole, is indicated in patients 18 years and older who have limited or no alternative options for the treatment of complicated intraabdominal infections (cIAI) including those caused by the following susceptible gram-negative microorganisms: *Escherichia coli, Klebsiella pneumoniae, Klebsiella oxytoca, Enterobacter cloacae complex, Citrobacter freundii complex*, and *Serratia marcescens*.
	FDA marketing authorization date	February 7, 2025
	Commercial availability	The applicant anticipates EMBLAVEO™ will be available for use and purchase in the United States by quarter 3 (Q3) of calendar year (CY) 2025 due to product availability.
Coding	**Unique ICD-10-PCS Code(s)**	The applicant submitted a request for approval for a unique ICD-10-PCS procedure code beginning in FY 2026.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes, ICD-10-PCS codes, and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for EMBLAVEO™ (aztreonam-avibactam).
	Claims identified	57,785 claims mapping to 369 MS-DRGs, with 18.17% of claims mapping to MS-DRG 853 (Infectious and Parasitic Diseases with O.R. Procedures with MCC).
	Charges removed for prior technology	The applicant did not remove any charges for drugs from the identified cases because the technology is expected to be additive to current treatments. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant did not add direct or indirect charges related to the technology.
	Cost analysis results	Average case-weighted threshold amount: $126,084 Final inflated average case-weighted standardized charge per case: $195,074 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that EMBLAVEO™ meets the cost criterion.

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After review of the information provided by the applicant, since the indication for which the applicant received NDA approval is included within the scope of the QIDP designation indication, it appears that the FDA-approved indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

We note that the applicant stated that the technology is expected to be commercially available by Q3 of CY 2025 due to product availability. We are interested in additional information regarding the cause for any delay in the technology's market availability as the technology received FDA approval on February 7, 2025.

We agree with the applicant that EMBLAVEO™ meets the cost criterion and are therefore proposing to approve EMBLAVEO™ for new technology add-on payments for FY 2026 for use in patients 18 years and older who have limited or no alternative options for the treatment of cIAI.

The applicant has not provided an estimate for the cost of EMBLAVEO™ at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for EMBLAVEO™ would be subject to our policy under § 412.88(a)(2)(ii)(B) where we limit new technology add-on payment for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case.

We invite public comments on whether EMBLAVEO™ meets the cost criterion and our proposal to approve new technology add-on payments for EMBLAVEO™ for FY 2026.

2. CONTEPO™ (Fosfomycin)

The following table summarizes the information provided in the new technology add-on payment application for CONTEPO™ (fosfomycin). We note

that Nabriva Therapeutics submitted an application for CONTEPO™ for FY 2021 and FY 2022, as summarized in the FY 2021 and FY 2022 IPPS/LTCH PPS proposed rules (85 FR 32682 through 32683; 86 FR 25390 through 25392), and received conditional approval subject to the technology receiving FDA marketing authorization before July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (85 FR 58723 through 58725; 86 FR 45154 through 45155). CONTEPO™ did not receive FDA marketing authorization by the applicable July 1 deadlines, and was therefore not eligible for new technology add-on payments for FY 2021 or FY 2022 (86 FR 44972; 87 FR 48909).

Per the applicant, Meitheal Pharmaceuticals Inc. has acquired the rights to CONTEPO™ in the U.S. and is submitting the new technology add-on payment application for FY 2026.

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	CONTEPO™ (fosfomycin)	
Technology Info	**Applicant**	Meitheal Pharmaceuticals Inc.
	Description	Per the applicant, CONTEPO™ for injection is a broad spectrum intravenous antibiotic for the treatment of complicated urinary tract infection (cUTI), including acute pyelonephritis, due to difficult to treat Gram-negative and Gram-positive bacteria.
	Online application	https://mearis.cms.gov/public/publications/ntap/NTP2410073U85N
FDA Info	**QIDP designation Indication**	Per the applicant, ZTI-01 (fosfomycin disodium) is designated for IV use as a QIDP for cUTI.
	FDA marketing authorization information	The applicant anticipates an NDA decision from FDA before July 1, 2025, consistent with its QIDP designation. According to the applicant, the QIDP designation indication refers to ZTI-01 and the generic name fosfomycin disodium, as the brand name CONTEPO™ was not yet established at the time of QIDP designation.
	Commercial availability	According to the applicant, CONTEPO™ is expected to be commercially available within 3 months of FDA approval due to manufacturing scheduling, final label implementation and printing and supply chain fulfilment.
Coding	**Unique ICD-10-PCS Code(s)**	A code proposal in association with the Spring 2025 ICD-10 Coordination and Maintenance Committee Update regarding a unique procedure code beginning in FY 2026 was made available in the ICD-10-PCS Topics Open for Public Comment materials located at: https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials.
	ICD-10-CM Code(s)	The applicant provided a list of diagnosis codes that may be used to currently identify the indication under the ICD-10-CM coding system in the online application posting.
Cost Criterion	**Inclusion/exclusion criteria**	For the Inclusion/Exclusion criteria used in the Cost Analysis, including the data source and lists of ICD-10-CM codes and MS-DRGs used by the applicant, see the cost criterion codes and MS-DRGs attachment included in the online posting for CONTEPO™.
	Claims identified	Cost Analysis 1: 528,518 claims mapping to 575 MS-DRGs, with 15.84% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC). Cost Analysis 2: 396,786 claims mapping to 559 MS-DRGs, with 16.81% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC). Cost Analysis 3: 371,862 claims mapping to 20 MS-DRGs, with 22.51% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC). Cost Analysis 4: 319,332 claims mapping to 10 MS-DRGs, with 26.22% of claims mapping to MS-DRG 871 (Septicemia or Severe Sepsis without MV>96 Hours with MCC).
	Charges removed for prior technology	Per the applicant, it is likely that CONTEPO™ will replace other antibiotics during some patients' inpatient stays, but it is difficult to identify the exact differences in drug regimen that patients treated with CONTEPO™ would receive, both before and in conjunction with treatment with CONTEPO™. Therefore, to make the estimate conservative, the applicant removed all drug charges on the original claims. The applicant stated that this is likely an overestimation of the charges of the drugs that will be replaced, as patients may receive drugs in addition to CONTEPO™ for care during their hospitalization. The applicant did not remove indirect charges related to the prior technology.
	Standardized charges	The applicant used the standardization formula provided in Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2025 IPPS/LTCH PPS interim final action with comment period.
	Inflation factor	The applicant applied an inflation factor of 12.87% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2025 IPPS/LTCH PPS final rule.
	Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.178 for Drugs and Cellular Therapies from the FY 2025 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.
	Cost analysis results	Cost Analysis 1: - Average case-weighted threshold amount: $71,141 - Final inflated average case-weighted standardized charge per case: $132,960 Cost Analysis 2: - Average case-weighted threshold amount: $66,939

		- Final inflated average case-weighted standardized charge per case: $ 115,271 Cost Analysis 3: - Average case-weighted threshold amount: $67,176 - Final inflated average case-weighted standardized charge per case: $124,459 Cost Analysis 4: - Average case-weighted threshold amount: $65,055 - Final inflated average case-weighted standardized charge per case: $ 121,799 Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all analyses, the applicant asserted that CONTEPO™ meets the cost criterion.

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After review of the information provided by the applicant, we note the applicant states that the technology is expected to be commercially available within 3 months of FDA approval, and we would appreciate more information on the reasons for any delay in the commercial availability of CONTEPO™ following FDA approval.

We agree with the applicant that CONTEPO™ meets the cost criterion and are therefore proposing to approve CONTEPO™ for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization for the indication corresponding to the QIDP designation by July 1, 2025. As an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), CONTEPO™ is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by July 1, 2025, provided that the technology receives FDA marketing authorization before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2026), as provided in § 412.87(f)(3). If CONTEPO™ receives FDA marketing authorization before July 1, 2026, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2026, no new technology add-on payments would be made for cases involving the use of CONTEPO™ for FY 2026.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipates the total cost of CONTEPO™ to the hospital to be $11,700 per patient. The applicant estimated that each vial costs $325 and that 3 doses are needed each day for an average treatment duration of 12 days. We note that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2)(ii)(B), we limit new technology add-on for technologies designated as QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are proposing that the maximum new technology add-on payment for a case involving the use of CONTEPO™ would be $8,775 for FY 2026 (that is, 75 percent of the average cost of the technology).

We invite public comments on whether CONTEPO™ meets the cost criterion and our proposal to approve new technology add-on payments for CONTEPO™ for FY 2026, subject to the technology receiving FDA marketing authorization consistent with its QIDP designation by July 1, 2025.

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

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the proposed FY 2026 hospital wage index based on the statistical areas appears under section III.B. of the preamble of this proposed rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, IV. The aforementioned information collection requirements are in Worksheet S–3, Parts II, III, IV. of the information collection request titled ''Hospitals and Health Care Complex Cost Report (CMS Form 2552–10)''. The information collection request is currently approved under OMB control number is 0938–0050 and has a September 30, 2025, expiration date. We plan to submit the information collection request to OMB for reapproval in the near future. In accordance with the PRA, the resubmission process will be announced in the **Federal Register** providing the public with the requisite notice and comment periods which will be separate from those associated with this rulemaking. Section 1886(d)(3)(E) of the Act also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The proposed adjustment for FY 2026 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The proposed budget neutrality adjustment for FY 2026 is discussed in section II.A.4.b. of the Addendum to this proposed rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program to construct an occupational mix adjustment to the wage index. The information collection request is currently approved under OMB control number is 0938–0907 and has a September 30, 2025, expiration date. We plan to submit the information collection request to OMB for reapproval in the near future. In accordance with the PRA, the resubmission process will be announced in the **Federal Register** providing the public with the requisite notice and comment periods which will be separate from those associated with this rulemaking. A discussion of the occupational mix adjustment that we are proposing to apply to the FY 2026 wage index appears under section III.E. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed FY 2026 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005 (69 FR 49026 through 49032), we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey (ACS). In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. The current statistical areas (which were implemented beginning with FY 2025) are based on revised OMB delineations issued on July 21, 2023, in OMB Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, the ACS, and Census Population Estimates Program data) (we refer to these revised OMB delineations as the ''new OMB delineations'' in this proposed rule). A copy of OMB Bulletin No. 23–01 may be obtained at *https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266) for a full discussion of our implementation of the new OMB delineations for the FY 2025 wage index. For FY 2026, we are proposing to continue using the new OMB delineations that we adopted beginning with FY 2025 to calculate the area wage indexes and the transition periods, which we discuss below.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The Federal Information Processing Standard (FIPS) county codes are maintained by the U.S. Census Bureau. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to use the FIPS county codes for purposes of crosswalking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes. For FY 2026, we are proposing to continue to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2026, Tables 2 and 3 associated with this proposed rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS county code updates.

B. Worksheet S–3 Wage Data for the FY 2026 Wage Index

1. Cost Reporting Periods Beginning in FY 2022 for FY 2026 Wage Index

The proposed FY 2026 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2022 (the FY 2025 wage indexes were based on data from cost reporting periods beginning during FY 2021).

The proposed FY 2026 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours including direct patient care (which includes nursing), certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

Consistent with the wage index methodology for FY 2025, the proposed wage index for FY 2026 excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to Graduate Medical Education (GME) (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The proposed FY 2026 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs), because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, as explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398), salaries, hours, and wage-related costs of Critical Access Hospitals (CAHs) are excluded from the wage index as we believe that removing CAHs from the wage index is prudent policy, given the substantial negative impact these hospitals have on the wage indexes in the areas where they are located and the minimal impact they have on the wage indexes of other areas. We refer the reader to the FY 2004 IPPS final rule (68 FR 45397 through 45398) for a complete discussion regarding the exclusion of CAHs from the wage index. Similar to our treatment of CAHs, as discussed later in this section, we exclude Rural Emergency Hospitals (REHs) from the wage index.

For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract

labor costs, are excluded from the calculation of the wage index.

2. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note, in the calendar year (CY) 2025 ESRD PPS final rule (89 FR 89097–89116), CMS finalized a new ESRD PPS-specific wage index that will be used to adjust ESRD PPS payments for geographic differences in area wages. We refer the reader to the CY 2025 ESRD PPS final rule for complete details regarding ESRD wage index. We further note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers.

3. Verification of Worksheet S–3 Wage Data

The wage data for the proposed FY 2026 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2025) for cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022. For wage index purposes, we refer to cost reports beginning on or after October 1, 2021, and before October 1, 2022, as the ''FY 2022 cost report,'' the ''FY 2022 wage data,'' or the ''FY 2022 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, Sections 4005.2 through 4005.4. The data file used to construct the FY 2026 wage index includes FY 2022 data submitted to us as of January 31, 2025. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

We note, in previous fiscal years, we reviewed and evaluated the audited wage data, and the impacts of the COVID–19 PHE on such data. For FY 2026, we have not identified any significant issues with the FY 2022 wage data itself in terms of our audits of this data. As usual, the data was audited by the Medicare Administrative Contractors (MACs), and there were no significant issues reported across the data for all hospitals.

We requested that our Medicare Administrative Contractors (MACs) revise or verify data elements that resulted in specific edit failures. For the proposed FY 2026 wage index, we identified and excluded 79 providers with aberrant data that should not be included in the wage index. If data elements for some of these providers are corrected, we intend to include data from those providers in the final FY 2026 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their verification of questionable data elements and to transmit any changes to the wage data no later than March 21, 2025.

In constructing the proposed FY 2026 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2022, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages.

As discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398) and FY 2025 IPPS/LTCH final rule (89 FR 69268), any hospital that is designated as a CAH or REH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index.

For the proposed FY 2026 wage index, we removed 7 hospitals that converted to CAH status and 5 hospitals that converted to REH status on or after January 24, 2024, the cut-off date for CAH and REH exclusion from the FY 2025 wage index, and through and including January 24, 2025, the cut-off date for CAH and REH exclusion from the FY 2026 wage index. In summary, we calculated the FY 2026 wage index using the Worksheet S–3, Parts II and III wage data of 3,027 hospitals.

For the proposed FY 2026 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2026 wage index associated with this proposed rule (available via the internet on the CMS website), includes separate wage data for the campuses of 29 multicampus hospitals. The following chart lists the multicampus hospitals by CMS certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

CCN of main campus of multicampus hospital	Full-time equivalent percentage of main campus	CCN of sub campus of multicampus hospital	Full-time equivalent percentage of sub campus	CCN of second sub campus of multicampus hospital	Full-time equivalent percentage of second sub campus
050121	0.86	05B121	0.14	.....	.....
070010	0.85	07B010	0.15	.....	.....
070022	0.99	07B022	0.01	.....	.....
100029	0.52	10B029	0.48	.....	.....
140010	0.81	14B010	0.19	.....	.....
220074	0.9	22B074	0.1	.....	.....
310069	0.17	31B069	0.83	.....	.....
330103	0.69	33B103	0.31	.....	.....
330195	0.9	33B195	0.1	.....	.....
330214	0.77	33B214	0.23	.....	.....
330234	0.79	33B234	0.21	.....	.....
340040	0.93	34B040	0.07	.....	.....
340115	0.82	34B115	0.13	34C115	0.05

CCN of main campus of multicampus hospital	Full-time equivalent percentage of main campus	CCN of sub campus of multicampus hospital	Full-time equivalent percentage of sub campus	CCN of second sub campus of multicampus hospital	Full-time equivalent percentage of second sub campus
360020	0.97	36B020	0.03	.....	.....
390115	0.82	39B115	0.18	.....	.....
390142	0.83	39B142	0.17	.....	.....
390307	0.89	39B307	0.11	.....	.....
420004	0.96	42B004	0.04	.....	.....
450033	0.96	45B033	0.04	.....	.....
450330	0.96	45B330	0.04	.....	.....
460051	0.77	46B051	0.23	.....	.....
510022	0.94	51B022	0.06	.....	.....
520009	0.72	52B009	0.28	.....	.....
520030	0.98	52B030	0.02	.....	.....
520189	0.72	52B189	0.28	.....	.....
670062	0.84	67B062	0.16	.....	.....
670102	0.68	67B102	0.32	.....	.....
670107	0.69	67B107	0.31	.....	.....
670116	0.66	67B116	0.34	.....	.....

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other variable digits in the CCN. We also note that provider 340115 has an additional second sub campus located in a different CBSA then the main campus and its other sub campus. Therefore, in order to uniquely identify this second sub campus, we have placed a ''C'' in the third position of the CCN.

4. Process for Requests for Wage Index Data Corrections

a. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files for the proposed FY 2026 wage index were made available on May 23, 2024, through the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2026-wage-index-home-page*. The FY 2026 preliminary Worksheet S–3 wage data file inadvertently contained cost report data with a begin date before 10/01/2021 and cost report data with a begin date after 10/01/2022. We removed these cost reports and added cost reports that were inadvertently omitted from the file originally posted on May 23. Therefore, on June 20, 2024, we posted an updated FY 2026 preliminary Worksheet S–3 wage data file.

On January 31, 2025, we posted a public use file (PUF) at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2026-wage-index-home-page* containing FY 2026 wage index data available as of January 31, 2025. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2021, through September 30, 2022; that is, FY 2022 wage data), a tab with the occupational mix data (which includes data from the CY 2022 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 31, 2025 wage data PUF, and a tab containing the CY 2022 occupational mix data of the hospitals deleted from the January 31, 2025 occupational mix PUF. In a memorandum dated January 31, 2025, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 31, 2025, wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2026 Hospital Wage Index Development Time Table available at *https://www.cms.gov/files/document/fy-2026-hospital-wage-index-development-time-table.pdf*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated April 17, 2024, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2022 occupational mix survey data files posted on May 23, 2024, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 23, 2024, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 3, 2024. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs.

November 1, 2024, was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2025. CMS published the wage index PUFs that included hospitals' revised wage index data on January 31, 2025. Hospitals had until February 18, 2025, to submit requests to the MACs to correct errors in the January 31, 2025, PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 31, 2025, PUF.

Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must have been received by the MAC by the February deadline (that is, by February 18, 2025, for the FY 2026 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 21, 2025. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) is April 4, 2025. Data that were incorrect in the preliminary or January 31, 2025, wage index data PUFs, but for which no correction request was received by the February 18, 2025, deadline, are not considered for correction at this stage. In addition, April 4, 2025, is the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 31, 2025, PUF and at least 14 calendar days prior to April 4, 2025 (that is, March 21, 2025), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 4, 2025, for the FY 2026 wage index). We refer readers to the FY 2026 Hospital Wage Index Development Time Table for complete details.

Hospitals are given the opportunity to examine Table 2 associated with this proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2026-wage-index-home-page*. Table 2 associated with the proposed rule contains each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2026 wage index, which was constructed from FY 2022 data. We note that the proposed hospital average hourly wages shown in Table 2 only reflect changes made to a hospital's data that were transmitted to CMS by late January 2025.

We plan to post the final wage index data PUFs on April 30, 2025, on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/wage-index-files/fy-2026-wage-index-home-page*. The April 2025 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process (the process for disputing revisions submitted to CMS by the MACs by March 21, 2025, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier), as previously described.

After the release of the April 2025 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 21, 2025.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 31, 2025, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2025 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital is required to send its request to CMS and to the MAC so that it is received no later than May 30, 2025. May 30, 2025, is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is notified on or after 13 calendar days prior to April 4, 2025 (that is, March 22, 2025), and at least 14 calendar days prior to May 30, 2025 (that is, May 16, 2025), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital is notified on or after 13 calendar days prior to May 30, 2025 (that is, May 17, 2025), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2026 Hospital Wage Index Development Time Table posted on the CMS website at *https://www.cms.gov/files/document/fy-2026-hospital-wage-index-development-time-table.pdf*, the May appeals are required to be submitted to CMS through an online submission process or through email. We refer readers to the FY 2026 Hospital Wage Index Development Time Table for complete details.

Verified corrections to the wage index data received timely (that is, by May 30, 2025) by CMS and the MACs will be incorporated into the final FY 2026 wage index, which will be effective October 1, 2025.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2026 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2025, they have an opportunity to detect any data entry or

tabulation errors made by the MAC or CMS before the development and publication of the final FY 2026 wage index by August 2025, and the implementation of the FY 2026 wage index on October 1, 2025. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 30, 2025, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with § 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 30, 2025, for the FY 2026 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised § 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 30, 2025, deadline for the FY 2026 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 30, 2025 deadline for the FY 2026 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS' or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in § 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

b. Process for Data Corrections by CMS After the January 31, 2025, Public Use File (PUF)

The process set forth with the wage index timetable discussed in section III.C.4. of the preamble of this proposed rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 31, 2025, PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data the need for which may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965

through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error, and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 31, 2025, PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency in instances where CMS makes data corrections after the January 31, 2025 PUF and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are described earlier and in the FY 2026 Hospital Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

C. Method for Computing the Proposed FY 2026 Unadjusted Wage Index

The method used to compute the proposed FY 2026 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761), and we are not proposing any changes to this methodology. We have restated our methodology in this section the preamble of this proposed rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2026, these were data from cost reports for cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022). In addition, we included data from hospitals that had cost reporting periods beginning prior to the October 1, 2021, begin date and extending into FY 2022 but that did not have any cost report with a begin date on or after October 1, 2021, and before October 1, 2022. We include this data because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as data applicable to the fiscal year wage data being used to compute the wage index for those hospitals. We note that, if a hospital had more than one cost reporting period beginning during FY 2022 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2021, and before October 1, 2022), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. (We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following: ((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula: (Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43). We then compute the amounts of overhead

salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following: (Lines 26 through 43 − Lines 28, 33 and 35)/ ((((Line 1 + Lines 28, 33, 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).
- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2021, through April 15, 2023, for private industry hospital workers from data obtained from the Bureau of Labor Statistics' (BLS') Office of Compensation and Working Conditions. We use the ECI because it reflects the price increase associated with total compensation (salaries plus fringe benefits) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing to make any changes to the usage of the ECI for FY 2026. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this proposed rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the Nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSAs' wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306). We believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the proposed FY 2026 wage index, we note there is one urban CBSA for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website and contains the area wage indexes), we include a footnote to indicate to which CBSA this policy applies. This CBSA's wage index is calculated as described, based on the FY 2020 IPPS/LTCH PPS final rule methodology (84 FR 42305). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded.

We refer readers to section II. of Appendix B of this proposed rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website.

The following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and

adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the ECI for compensation for each 30-day increment from October 14, 2021, through April 15, 2023, for private industry hospital workers from the BLS' Office of Compensation and Working Conditions data. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we are not proposing any changes to the usage of the ECI for FY 2026. The factors used to adjust the hospital's data were based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment factor
10/14/2021	11/15/2021	1.07227
11/14/2021	12/15/2021	1.06742
12/14/2021	01/15/2022	1.06250
01/14/2022	02/15/2022	1.05755
02/14/2022	03/15/2022	1.05259
03/14/2022	04/15/2022	1.04772
04/14/2022	05/15/2022	1.04303
05/14/2022	06/15/2022	1.03854
06/14/2022	07/15/2022	1.03412
07/14/2022	08/15/2022	1.02967
08/14/2022	09/15/2022	1.02518
09/14/2022	10/15/2022	1.02072
10/14/2022	11/15/2022	1.01637
11/14/2022	12/15/2022	1.01212
12/14/2022	01/15/2023	1.00797
01/14/2023	02/15/2023	1.00393
02/14/2023	03/15/2023	1.00000
03/14/2023	04/15/2023	0.99617

For example, the midpoint of a cost reporting period beginning January 1, 2022, and ending December 31, 2022, is June 30, 2022. An adjustment factor of 1.03412 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of Division O, Title VI (section 601) of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2026, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously described methodology, the proposed FY 2026 unadjusted national average hourly wage is the following:

Proposed FY 2026 Unadjusted National Average Hourly Wage: $57.70

D. Proposed Occupational Mix Adjustment to the FY 2026 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2022 Medicare Wage Index Occupational Mix Survey for the FY 2026 Wage Index

Section 304(c) of Appendix F, Title III of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program and to measure the earnings and paid hours of employment for such hospitals by occupational category. As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69275 through 69278), we collected data in 2022 to compute the occupational mix adjustment for the FY 2025, FY 2026, and FY 2027 wage indexes.

The FY 2026 occupational mix adjustment is based on a calendar year (CY) 2022 survey. Hospitals were required to submit their completed 2022 surveys (Form CMS–10079, OMB Control 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 2026 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2026

For FY 2026, we are proposing to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2026 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the

cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this proposed rule (which is available via the internet on the CMS website), which contains the proposed FY 2026 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this proposed rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the proposed FY 2026 wage index. For the proposed FY 2026 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,029 hospitals, and we used the occupational mix surveys of 2,945 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (2,945/3,029). For the proposed FY 2026 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2026 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2026 Occupational Mix Adjusted National Average Hourly Wage: $57.63

3. Proposed Occupational Mix Adjustment and the Proposed FY 2026 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed rule, for FY 2026, we are applying the occupational mix adjustment to 100 percent of the FY 2026 wage index. We calculated the occupational mix adjustment using data from the 2022 occupational mix survey, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582–51586).

Based on the 2022 occupational mix survey data, the proposed FY 2026 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational mix nursing subcategory	Average hourly wage
National RN	$60.47
National LPN and Surgical Technician	35.06
National Nurse Aide, Orderly, and Attendant	23.53
National Medical Assistant	23.15
National Nurse Category	50.12

The proposed national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2022 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category: 45%

National Percentage of Hospital Employees in the All Other Occupations Category: 55%

E. Hospital Redesignations and Reclassifications

The following sections III.E.1 through III.E.4 discuss revisions to the wage index based on hospital redesignations and reclassifications. Specifically, hospitals may have their geographic area changed for wage index payment by applying for urban to rural reclassification under section 1886(d)(8)(E) of the Act (implemented at § 412.103), reclassification by the Medicare Geographic Classification Review Board (MGCRB) under section 1886(d)(10) of the Act, Lugar status redesignations under section 1886(d)(8)(B) of the Act, or a combination of the foregoing.

1. Urban to Rural Reclassification Under Section 1886(d)(8)(E) of the Act, Implemented at § 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at § 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act (such hospitals are referred to herein as ''§ 412.103 hospitals''). The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977) for a review of our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004) to calculate the rural floor with the wage data of urban hospitals reclassifying to rural areas under § 412.103, and discussion of our modification to the calculation of the rural wage index and its implications for the rural floor.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at §§ 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural

under § 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain Sole Community Hospital (SCH), Rural Referral Center (RRC), or Medicare Dependent Hospital (MDH) status, or rural reclassification under § 412.103, independently or separately from its remote location(s), and vice versa. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012 and 49013), we added § 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS' longstanding policy to assign that remote location a wage index based on its own geographic area to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSAs on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for these remote locations in Table 2 with a ''B'' in the 3rd position of the CCN. These remote locations of hospitals with § 412.103 rural reclassification status in a different CBSA are identified in Table 2, and hospitals should evaluate potential wage index outcomes for their remote location(s) when withdrawing or terminating MGCRB reclassification, or canceling § 412.103 rural reclassification status.

We also note that in the FY 2025 IPPS/LTCH PPS Final Rule (89 FR 69279 through 69280), we reminded hospitals located in rural areas becoming urban under the adoption of the revised OMB delineations in FY 2025 that if they have SCH, MDH, or RRC status, they may choose to apply for a § 412.103 urban to rural reclassification if qualifying criteria are met to maintain the SCH, MDH, or RRC status. We advised hospitals to evaluate their options and if desired, apply for § 412.103 urban to rural reclassification before the beginning of FY 2025, to avoid a lapse in SCH, MDH, or RRC status at the beginning of FY 2025. We note that the ''Am I Rural'' tool currently available on the Rural Health Information Hub [200] website at *https://www.ruralhealthinfo.org/am-i-rural* was updated on November 21, 2024, based on data provided by the Federal Office of Rural Health Policy which is available at *https://www.hrsa.gov/rural-health/about-us/what-is-rural/data-files*. As discussed at § 412.103(f), the duration of an approved rural reclassification remains in effect without need for reapproval unless there is a change in the circumstances under which the classification was approved. If a hospital located in an urban area was approved for a rural reclassification under § 412.103(a)(1), that reclassification would no longer be valid if the hospital is no longer located within a rural census tract of an MSA as determined by the Federal Office of Rural Health Policy (FORHP) of the Health Resources and Services Administration (HRSA). Therefore, we encourage all hospitals and CAHs with active rural reclassifications under section 1886(d)(8)(E) of the Act to review their original reclassification application and determine whether the reclassification status would still apply.

Finally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69280), CMS finalized a policy regarding terminated or ''tied-out'' hospitals, to address our concerns regarding the impacts these hospitals would have on rural wage index values. Specifically, we finalized a policy that § 412.103 reclassifications would be considered cancelled for the purposes of calculating the area wage index for any hospital with a CCN listed as terminated or ''tied-out'' as of the date that the hospital ceased to operate with an active CCN. We stated that we would obtain and review the best available CCN termination status lists as of the § 412.103(b)(6) ''lock-in'' date (60 days after the proposed rule for the FY is displayed in the **Federal Register**), consistent with the wage index development timeline. The lock-in date is used to determine whether a hospital has been approved for § 412.103 reclassification in time for that status to be included in the upcoming year's wage index development.

We noted that our policy to consider § 412.103 reclassifications cancelled for the purposes of calculating area wage index for any hospital with a CCN listed as terminated or ''tied-out'' is not intended to alter or affect the qualification for Critical Access Hospital (CAH), Sole Community Hospital (SCH), or Rural Emergency Hospital (REH) statuses or to have other effects unrelated to hospital wage index calculations. The rural reclassification status would remain in effect for any period that the original PPS hospital remains in operation with an active CCN. For REH qualification requirement purposes, this would include the date of enactment of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which was December 27, 2020.

[200] The Rural Health Information Hub is supported by the Health Resources and Services Administration (HRSA) of HHS under Grant Number U56RH05539 (Rural Assistance Center for Federal Office of Rural Health Policy Cooperative Agreement). Any information, content, or conclusions on this website are those of the authors and should not be construed as the official position or policy of, nor should any endorsements be inferred by HRSA, HHS or the U.S. Government.

2. General Policies and Effects of MGCRB Reclassification and Treatment of Dual Reclassified Hospitals

Under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions not later than the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in §§ 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under § 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under § 412.103 from the calculation of the rural floor, but we reverted to the pre-FY 2020 policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004). Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of § 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 urban to rural and MGCRB reclassifications. Prior to this amendment to the regulations, hospitals had to choose between a § 412.103 urban to rural reclassification which confers other rural benefits (Medicare provisions such as payments to disproportionate share hospitals (DSHs), and non-Medicare payment provisions, such as the 340B Drug Pricing Program administered by HRSA) besides the wage index under section 1886(d) of the Act or a reclassification under the MGCRB to solely increase its wage index. Under the amended regulations, a hospital that has an active MGCRB reclassification and is then approved for an urban to rural reclassification under § 412.103 will not lose its MGCRB reclassification. Additionally, a hospital is no longer required to cancel its § 412.103 reclassification in order to be approved for an MGCRB reclassification. By amending the regulations and allowing a hospital to pursue reclassification under the MGCRB while also maintaining a rural reclassification under § 412.103, hospitals are accorded the benefits of a § 412.103 urban to rural reclassification and the ability to use distance and average hourly wage criteria designated for rural hospitals to obtain a higher wage index value through an MGCRB reclassification. We note, for wage index calculation and payment purposes, when there is both a § 412.103 reclassification and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes.

Prior to FY 2024, we excluded hospitals with § 412.103 urban to rural redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved and is not withdrawn or terminated by the hospital within the established timelines, we considered the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016, IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016, IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For FY 2024 and subsequent years, we refer readers to the FY 2024 IPPS/LTCH PPS final rule for discussion of our policy to include hospitals with a § 412.103 reclassification that also have an active MGCRB reclassification to another area in the calculation of the reclassified rural wage index (88 FR 58971 through 58977).

3. MGCRB Reclassification Issues for FY 2026

a. FY 2026 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. There are 639 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2026. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2026, hospitals reclassified beginning in FY 2024 or FY 2025 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 280 hospitals approved for wage index reclassifications in FY 2024 that will continue for FY 2026, and 278 hospitals approved for wage index reclassifications in FY 2025 that will continue for FY 2026. Of all the hospitals approved for reclassification for FY 2024, FY 2025, and FY 2026, 1,197 hospitals (approximately 36 percent of IPPS hospitals) are in a MGCRB reclassification status for FY 2026 (with 279 of these hospitals reclassified back to their urban geographic location). We note that several of the 639 hospitals approved for MGCRB reclassifications beginning in FY 2026 may opt to withdraw this status after the final rule, and a prior year reclassification may become effective in its place. We refer readers to section III.F.3.b. of the preamble of this proposed rule for information on the effects of implementation of new OMB labor market area delineations on reclassified hospitals.

Under the regulations at § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.273, whichever is later.

For information about the current process for withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as section III.E.3.b. of the preamble of this proposed rule, and the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations was included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

Applications for FY 2027 reclassifications are due to the MGCRB by September 2, 2025 (Note: While the deadline for reclassification applications is not later than 13 months prior to the start of the fiscal year for which reclassification is sought, usually by September 1, the Board has historically allowed submission up to the first business day in September, which is September 2, 2025, due to Labor Day). This is also the current deadline for canceling a previous wage index reclassification withdrawal or termination under § 412.273(d) for the FY 2026 cycle.

Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2025 via the internet on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/geographic-classification-review-board*. This collection of information was previously approved under OMB Control Number 0938–0573, which expired on January 31, 2021. A reinstatement of this PRA package is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

b. Proposed Revisions to § 412.273 To Simplify MGCRB Reinstatements

As discussed in the previous section, under the regulations at § 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the

MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.273, whichever is later. Hospitals may also terminate an existing approved reclassification, effective for the second and third year of the three year reclassification period or both, provided the request for termination is received by the MGCRB within 45 days of the date of filing for public inspection of the proposed rule at the website of the Office of the Federal Register, or within 7 calendar days of receiving a decision of the Administrator's in accordance with § 412.273, whichever is later.

Furthermore, these withdrawal and termination requests may be cancelled by submitting a request by the next application deadline for MGCRB application, reinstating the withdrawn or terminated reclassification for the remaining years of the reclassification.

We believe this process allows hospitals to maintain flexibility in choosing the optimal reclassification status for any given fiscal year, while balancing the need for consistency and predictability of the wage index system. However, we also believe the regulations § 412.273 can be confusing and contain complicated definitions and language. We are proposing revisions to multiple paragraphs of § 412.273 to clarify current policy and revise definitions in a more straightforward and understandable manner.

The first consideration is CMS's definitions of a withdrawal and a termination in § 412.273(a). *Termination* refers to the termination of an already existing 3-year MGCRB reclassification where such reclassification has already been in effect for 1 or 2 years, and there are 1 or 2 years remaining on the 3-year reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered. *Withdrawal* refers to the withdrawal of a 3-year MGCRB reclassification that has not yet gone into effect or where the MGCRB has not yet issued a decision on the application.

Stated generally, a withdrawal is an action taken upon a reclassification that has either not yet been reviewed by the MGCRB, or an approved reclassification due to go into effect in that upcoming fiscal year, and a termination is an action taken on an approved reclassification that has already gone into effect. There are policy considerations for defining withdrawals and terminations separately. For example, county group reclassification withdrawals must include all parties to the application, while a termination may be submitted by any individual hospital that is party to the application. For reasons discussed later in this section, we continue to believe this is the appropriate policy. However, we believe that specifically citing this policy exception in regulation is more straightforward than maintaining differing definitions for substantially similar actions. Therefore, for consistency and simplicity we are proposing to modify the definition of a withdrawal to only include requests made prior to a decision being made by the MGCRB. The definition of termination would encompass all post-decision actions to forgo the upcoming years of an approved reclassification. Specifically, we are proposing to modify § 412.273(a) to provide that a *termination* refers to the termination of an approved 3-year MGCRB reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered. We would also specify that a *withdrawal* refers to the withdrawal of a 3-year MGCRB reclassification where the MGCRB has not yet issued a decision on the application.

We are also proposing to remove § 412.273(c)(1)(i) and (ii) and revise paragraph (c)(1) to indicate that a request for withdrawal must be received by the MGCRB at any time before the MGCRB issues a decision on the application.

There is also a current process for cancelling an eligible withdrawal or termination in order to make the reclassification effective for any remaining years of the 3-year reclassification period. We note that this process is widely referring to as a request for ''reinstatement.'' To provide clarity and consistency, we are proposing to modify several references in § 412.273(d) from ''cancelling'' or a ''cancellation'' to ''reinstating'' or ''reinstatement.'' As we are proposing that withdrawals be limited to applications prior to approval, a proposed reinstatement would only apply to the proposed modified definition of a termination. Therefore, we are proposing to delete the references to withdrawals from § 412.273(d)(1).

As discussed earlier in this section, we continue to believe that all parties to a county group reclassification must participate on any action prior to the effective date of a group reclassification. Under current policy, this would include whether to withdraw a reclassification in the timeframe described at § 412.273(c)), and whether to cancel an approved reclassification withdrawal request to reinstate the remaining second and third year of the approved group reclassification, as described at § 412.273(d)(2). We believe that requiring these actions to include all parties to the group reclassification reduces the possibility of one or more parties withdrawing from a reclassification to the benefit or detriment of other hospitals reclassified to that labor market area. For example, a hospital may be incentivized to withdraw a potentially beneficial reclassification if the exclusion of its wage data in the reclassified area would increase the wage index value. This type of manipulation of reclassification policy does not encourage stability or predictability of wage index system and is contrary to the concept of providing hospitals in a county an opportunity to obtain a reclassification that they may not be able to obtain through an individual reclassification. Therefore, we are proposing to continue the current policy by modifying the current regulation to explicitly state that the proposed modified withdrawal requests and proposed modified termination and reinstatement requests made prior to the effective date of the reclassification (that is, any request made prior to the first year the reclassification goes into effect), must include all parties to the application. Specifically, we are proposing to modify § 412.273(e), by modifying paragraph (e)(2) to state that a request to terminate an approved individual reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB and adding a new paragraph (e)(3) specifying that a request to terminate or reinstate an approved group reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB. A request to terminate or reinstate an approved group reclassification that has not yet gone into effect must include all hospitals party to the reclassification. Termination requests for group reclassification for the second or third year of the 3-year wage index reclassification period and reinstatement requests for a group reclassification effective for the third

year of the 3-year wage index reclassification period may be submitted by any individual hospital that is party to the reclassification.

We believe that this proposal to explicitly state this policy regarding county group reclassification in regulation reduces confusion for hospitals and more clearly addresses our intent.

To provide clarity, we are also proposing to state that a termination of a 3-year reclassification defined at § 412.273(d)(4) is not eligible to be reinstated. This type of termination of an approved reclassification occurs when a hospital receives a different MGCRB reclassification in a subsequent fiscal year. Under current policy, hospitals may effectively choose between accepting a newly approved reclassification, or to withdraw it and ''fallback'' to a previously approved reclassification. We believe this provides sufficient flexibility for hospitals to obtain the most beneficial reclassification. However, once an approved reclassification goes into effect, we believe it is appropriate to permanently terminate other previously approved reclassifications. Doing so provides a degree of predictability and consistency in the wage index calculations by limiting hospitals to a total of two potential MGCRB reclassification options. This is the current policy of CMS and the current practice of the MGCRB. We are proposing specifically state this policy in regulation by providing in § 412.273(d)(4) that the terminated reclassification in such a case is not eligible for reinstatement.

We are proposing the preceding changes to become effective for requests made beginning in FY 2026. The current policies and definitions will continue for the remainder of FY 2025. We note that hospitals currently use the Office of Hearings Case and Document Management System (OH CDMS) to enter and maintain their MGCRB cases, and to correspond with the Office of Hearings. We are aware that the proposed changes will require system changes to the OH CDMS, and there could be some delay in revising certain terminology. However, nothing in the section is intended to significantly modify current policies and practices. Instead, it serves to clarify and simplify the process of determining whether an approved reclassification should be accepted and applied in a given fiscal year. We also believe that in making these changes, the regulation will provide clearer instructions to hospitals.

Finally, we note that under the current and proposed policies, there is no negative effect for a hospital to reinstate (cancel a withdrawal or termination) for a subsequent year, as the reclassification could be terminated in the following year, and hospitals are eligible to reapply for wage index reclassification to a different labor market area. When eligible, a large majority of hospitals already do this, as it provides greater flexibility and options for wage index reclassification. Before the introduction of the OH CDMS, these reinstatement requests were often submitted simultaneously with a withdrawal or termination request. However, in the online system, the option to reinstate is typically only made available after all withdrawal and termination requests have been processed. We have considered a policy modification to make termination requests effective for only one fiscal year. That is, all requests to withdraw or terminate a reclassification made in the timeframe specified at § 412.273(c) would automatically be reinstated for any remaining fiscal years, without the need of a second action to reinstate it. We have not fully evaluated the impact of such a policy but may consider it in future rulemaking.

4. Redesignations Under Section 1886(d)(8)(B) of the Act

a. Lugar Status Determinations

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the issuance of the proposed rule in the **Federal Register**) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital would no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of the issuance of the proposed rule in the **Federal Register** for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests. When applicable, this election would result in a cancelation of a hospital's rural reclassification status under § 412.103, effective October 1, 2025. We also inform hospitals that for the request to be approved, the hospital must withdraw or terminate any active MGCRB reclassification. All requests, once approved, will remain in effect for the remainder of the 3-year out-migration adjustment period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the outmigration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an outmigration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the outmigration adjustment would be denied, and the hospital would be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values would be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section

1886(d)(8)(B) of the Act, it would be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

F. Wage Index Adjustments: Rural Floor, Imputed Floor, State Frontier Floor, Out-Migration Adjustment, Low Wage Index Hospital, and Cap on Wage Index Decrease Policies

The following adjustments to the wage index are listed in the order that they are generally applied. First, the rural floor, imputed floor, and state frontier floor provide a minimum wage index. The rural floor at section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that the wage index for hospitals in urban areas of a State may not be less than the wage index applicable to hospitals located in rural areas in that State. The imputed floor at section 1886(d)(3)(E)(iv) of the Act provides a wage index minimum for all-urban states. The state frontier floor at section 1886(d)(3)(E)(iii) of the Act requires that hospitals in frontier states cannot be assigned a wage index of less than 1.0000. Next, the out-migration adjustment at section 1886(d)(13)(A) of the Act is applied, potentially increasing the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county or counties with a higher wage index. For FY 2026 and subsequent fiscal years, as discussed later in this section, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy. Because we are proposing to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we would no longer apply a low wage index budget neutrality factor to the standardized amounts. Finally, all hospital wage index decreases are capped at 95 percent of the hospital's final wage index in the prior fiscal year, according to the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

1. Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor. Based on the FY 2026 wage index associated with this proposed rule (which is available on the CMS website), and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103, we estimate that 565 hospitals would receive the rural floor in FY 2026. The budget neutrality impact of the proposed application of the rural floor is discussed in section II.A.4.e. of Addendum A of this proposed rule.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48784), CMS finalized a policy change to calculate the rural floor in the same manner as we did prior to the FY 2020 IPPS/LTCH PPS final rule, in which the rural wage index sets the rural floor. We stated that for FY 2023 and subsequent years, we would include the wage data of § 412.103 hospitals that have no Medicare Geographic Classification Review Board (MGCRB) reclassification in the calculation of the rural floor, and include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

In the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy change beginning that year to include the data of *all* § 412.103 hospitals, even those that have an MGCRB reclassification, in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. We explained that after revisiting the case law, prior public comments, and the relevant statutory language, we agreed that the best reading of section 1886(d)(8)(E)'s text that CMS ''shall treat the [§ 412.103] hospital as being located in the rural area'' is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation.

Accordingly, in the FY 2024 IPPS/LTCH PPS final rule, we finalized a policy to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) that are implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. (For additional information on these changes, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58971 through 58977).)

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all-urban States that have stated that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at § 412.64(h)(4). For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Section 1886(d)(3)(E)(iv)(IV) of the Act provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section

1886 of the Act if it is assigned the State's rural area wage index value.

Effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstated the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178) for further discussion of the original imputed floor calculation methodology implemented in FY 2005 and the alternative methodology implemented in FY 2013.

Based on data available for this proposed rule, States that will be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States that will be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2026, are identified in Table 3 (which is available on the CMS website) associated with this proposed rule.

The regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor will continue to be applied for FY 2026 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

3. State Frontier Floor for FY 2026

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at § 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) We are not proposing any changes to the frontier floor policy for FY 2026. In this proposed rule, 40 hospitals would receive the frontier floor value of 1.0000 for their FY 2026 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000.

The areas affected by the rural and frontier floor policies for the proposed FY 2026 wage index are identified in Table 3 associated with this proposed rule, which is available via the internet on the CMS website.

4. Proposed Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census Bureau used at that time, and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, we have applied the same policies, procedures, and computations since FY 2012. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source. We also stated that we would consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

As discussed above in section III.A.2., in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69253 through 69266), CMS adopted revised delineations from the OMB Bulletin 23–01, published July 21, 2023. The revised delineations incorporated population estimates based on the 2020 decennial census, as well as updated journey-to-work commuting data. The Census Bureau once again worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked, for use in developing a new out-migration adjustment based on new commuting patterns. We analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, utilizing 2016 through 2020 data. The Census Bureau produces county level commuting flow tables every 5 years using non-overlapping 5-year ACS estimates. The data include demographic characteristics, home and work locations, and journey-to-work travel flows. The custom tabulation requested by CMS was specific to general medical and surgical hospital and specialty (except psychiatric and substance use disorder treatment) hospital employees (hospital sector Census code 8191/NAICS code 6221 and 6223) who worked in the 50 States, Washington, DC, and Puerto Rico and, therefore, provided information about commuting patterns of workers at the county level for residents of the 50 States, Washington, DC, and Puerto Rico.

For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. The ACS samples approximately 3.5 million resident addresses per year.[201] The results of the ACS are used to formulate descriptive population estimates, and, as such, the sample on which the dataset is based represents the actual figures that would be obtained from a complete count.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301), we finalized that for

[201] According to the Census Bureau, the effects of the public health emergency (PHE) on ACS activities in 2020 resulted in a lower number of addresses (~2.9 million) in the sample, as well as fewer interviews than a typical year.

FY 2025 and subsequent years, the out-migration adjustment would be based on the data derived from the previously discussed custom tabulation of the ACS utilizing 2016 through 2020 (5-year) Microdata. As discussed earlier, we believe that these data are the most appropriate to establish qualifying counties, because they are the most accurate and up-to-date data that are available to us. For FY 2026, we are not proposing any changes to the methodology or data source for calculating the out-migration adjustment. Specifically, we are proposing that the FY 2026 out-migration adjustments continue to be based on the same policies, procedures, and computation that were used for the FY 2012 out-migration adjustment. We have applied these same policies, procedures, and computations since FY 2012, and we believe they continue to be appropriate for FY 2026. We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602). Table 2 of this proposed rule (which is available on the CMS website) lists the proposed out-migration adjustments for the FY 2026 wage index. In addition, Table 4A associated with this proposed rule, ''List of Counties Eligible for the Out Migration Adjustment under Section 1886(d)(13) of the Act'' (also available on the CMS website), consists of the following: A list of counties that are eligible for the outmigration adjustment for FY 2026 identified by FIPS county code, the proposed FY 2026 out-migration adjustment, and the number of years the adjustment will be in effect. We refer readers to section V.I. of the Addendum of this proposed rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this proposed rule.

5. Discontinuation of the Low Wage Index Hospital Policy and Budget Neutrality Adjustment

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to address increasing wage index disparities, based in part on comments we received in response to our request for information included in our FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372 through 20377). Accordingly, we finalized a policy that provided certain low wage index hospitals with an opportunity to increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index (as they would expect to do if not for the lag). We accomplished this by temporarily increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We increased the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year 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).

When we adopted the low wage index hospital policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328), we stated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We also stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. For FY 2024, we continued to apply the low wage index hospital policy and the related budget neutrality adjustment (88 FR 58977 through 58980). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301 through 69308), we adopted an extension of the low wage index hospital policy and the related budget neutrality adjustment effective for at least three more years, beginning in FY 2025, in order for sufficient wage data from after the end of the COVID–19 Public Health Emergency to become available.

On July 23, 2024, the Court of Appeals for the D.C. Circuit held that the Secretary lacked authority under section 1886(d)(3)(E) of the Act or under the ''adjustments'' language of section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020, and that the policy and related budget neutrality adjustment must be vacated.[202] After considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* in the interim final action with comment period (IFC) titled ''Medicare Program; Changes to the Fiscal Year 2025 Hospital Inpatient Prospective Payment System (IPPS) Rates Due to Court Decision'' (referred to herein as the FY 2025 IFC) (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. We refer the reader to the applicable year final rule discussions (FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339); FY 2024 IPPS/LTCH PPS final rule (88 FR 58977 through 58980)) regarding the implementation of the low wage index hospital policy and the FY 2025 IFC for a complete discussion regarding the removal of the low wage index hospital policy for FY 2025.

For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy. Because we are proposing to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we would no longer apply a low wage index budget neutrality factor to the standardized amounts.

6. Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a wage index cap policy and associated budget neutrality adjustment for FY 2023 and subsequent fiscal years. Under this policy, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. If a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index will not be less than 95 percent of the hospital's capped wage index in the prior FY. We note, the FY 2025 wage index was established in the FY 2025 Interim Final Action with Comment (IFC) which removed the low wage index hospital policy (89 FR 80405 through 80421). Therefore, for FY 2026, the prior year wage index for purposes of the cap would be based on the wage index established in the IFC. We also note that in that same IFC, we established a transitional payment exception for FY 2025. The 5-percent cap for FY 2026 would be applied irrespective of the FY 2025 transitional payment exception. We finally note, as discussed below, that for FY 2026 we are also proposing a transitional payment exception that addresses the effects of the removal of the low wage index hospital policy. This proposed transitional payment exception would be applied after the application of the 5-percent cap.

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

Except for newly opened hospitals, we apply the cap for a FY using the final wage index applicable to the hospital on the last day of the prior FY. A newly opened hospital will be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it will not receive a cap for that first year, because it will not have been assigned a wage index in the prior year. The wage index cap policy is reflected at § 412.64(h)(7). We apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. For more information about the wage index cap policy and associated budget neutrality adjustment, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

For FY 2026, we would apply the wage index cap and associated budget neutrality adjustment in accordance with the policies adopted in the FY 2023 IPPS/LTCH PPS final rule. We note that the budget neutrality adjustment will be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this proposed rule for further information regarding the budget neutrality calculations.

7. Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy

As discussed above, in the FY 2025 IFC we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, consistent with the FY 2025 IFC, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy. Because we are proposing to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we would no longer apply the low wage index budget neutrality factor to the standardized amounts.

In the past, we have established temporary transition policies when there have been significant changes to payment policies, and we have limited the duration of each transition in order to phase in the effects of those payment policy changes. In taking this temporary approach in the past, we have sought to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under prospective payment systems. For example, CMS has recognized that hospitals in certain areas may experience a negative impact on their IPPS payment due to the adoption of revised OMB delineations for wage index purposes and has finalized transition policies to mitigate negative financial impacts and provide stability to year-to-year wage index variations. We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49956 through 49962) for a discussion of the transition period finalized when CMS adopted revised OMB delineations after the 2010 decennial census. For FY 2025, consistent with our past practice, we established an interim transition policy for hospitals significantly impacted by the removal of the FY 2025 low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act. Specifically, the transitional payment exception for FY 2025 for those hospitals is equal to the additional FY 2025 amount a hospital would have been paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index. For a discussion of the removal of the low wage index hospital policy and the establishment of the interim transition policy, we refer readers to the FY 2025 IFC (89 FR 80405 through 80421).

We currently have a wage index cap policy at 42 CFR 412.64(h)(7), under which we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY in a budget neutral manner, regardless of the circumstances causing the decline, so that a hospital's final wage index for the upcoming fiscal year will not be less than 95 percent of its final wage index from the prior fiscal year. In accordance with 42 CFR 412.64(e)(1)(ii), CMS applies a budget neutrality adjustment to offset the increase in total payments resulting from the application of that cap.

Some hospitals that previously benefitted from the low wage index hospital policy would experience decreases of 10 percent or more over the two years from their FY 2024 wage index (with the low wage index hospital policy applied) to their proposed FY 2026 wage index (that is, approximately 5 percent or more per year over that time period). Similar to how 42 CFR 412.64(h)(7) would operate, and how our interim transitional policy established in the FY 2025 IFC for these hospitals operates in FY 2025, we are proposing to establish a narrow transitional exception to the calculation of FY 2026 payments for these hospitals.

As described above, if the combined payment effect of the FY 2025 wage index and the transitional payment exception for FY 2025 had been attributable solely to the FY 2025 wage index, then the wage index cap policy at 42 CFR 412.64(h)(7) would have mitigated these FY 2026 wage index decreases and would have done so in a budget neutral manner under our current regulations. As discussed in the FY 2025 IFC (89 FR 80407–80408), while CMS is not necessarily required by the statute to budget neutralize every exception or adjustment under section 1886(d)(5)(I), it has often done so by exercising its discretion under section 1886(d)(5)(I) of the Act twice: first to adopt an exception or adjustment, and then again to make that exception or adjustment budget neutral.[203] For the FY 2025 interim transition policy, under the unique circumstances and due to the timing of the appellate court's decision in *Bridgeport Hosp.* v. *Becerra* so close to the beginning of FY 2025, we declined to exercise our discretion to budget neutralize that interim FY 2025 transition policy. We stated that unlike most policies relevant to the calculation of the hospital wage index, the timing of the court's decision shortly before the beginning of the fiscal year necessitated swift action by the agency via an IFC, rather than providing for prior notice and opportunity for comment. The agency's action in that IFC was intended to promote certainty regarding FY 2025 IPPS payments in light of the reasoning of *Bridgeport,* which risked creating ongoing confusion for hospitals extending into FY 2025 about the amount of their IPPS payments. In that circumstance, the lack of an opportunity to notify interested parties in a notice of proposed rulemaking about changes to their wage index that would result from budget neutralizing the transition policy, and for the agency to consider before the policy's effective date issues hospitals might raise when commenting on those changes, weighed in favor of an approach that did not adversely affect the significant majority of hospitals. For these reasons, and as discussed in the IFC, we declined to budget neutralize the interim FY 2025 transition policy.

In contrast, we are proposing the FY 2026 transition policy under very different circumstances. We are not facing the timing constraints of a court decision issued shortly before the beginning of a fiscal year that necessitated swift action through an IFC to promote certainty and prevent ongoing confusion by hospitals. Rather,

[203] For example, CMS has stated in the past that it would exercise its discretion under section 1886(d)(5)(I) of the Act to make the low wage index hospital policy budget neutral even if budget neutrality were not required by statute (88 FR 58979).

we are proposing the FY 2026 transition policy through the normal course of our annual rulemaking for the IPPS, which will allow both for advance notice of the policy and for us to consider issues interested parties might raise in comments on this proposed rule. We are proposing to make this policy budget neutral through an adjustment applied to the standardized amount for all hospitals because (1) the wage index cap policy at 42 CFR 412.64(h)(7) would have mitigated these FY 2026 wage index decreases had the combined payment effect of the FY 2025 wage index and the transitional payment exception been reflected solely in the FY 2025 wage index, and it would have done so in a budget neutral manner under our current regulations, and (2) the circumstances described above that caused us to decline to budget neutralize the interim FY 2025 transition policy are not applicable to the proposed FY 2026 transition policy. In addition, we note that implementing the proposed FY 2026 transition policy in a budget neutral manner would be consistent with past practice. For example, we budget neutralized the FY 2015 wage index transition budget neutrality policy discussed earlier (79 FR 49956 through 49962). As we have discussed in other instances (89 FR 19398), we believed, and continue to believe, that transition policies should not increase estimated aggregate Medicare payments beyond the payments that would be made had we never proposed these transition policies. Therefore, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we are proposing to adopt a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy. Second, we are exercising our authority again to do so in a budget neutral manner.[204] [205] We refer the reader to section II.A.4.g. of the Addendum of this proposed rule for complete details regarding the application of the proposed transition for the discontinuation of the low wage index hospital policy budget neutrality factor.

The transitional exception policy we are proposing applies to hospitals that benefitted from the FY 2024 low wage index hospital policy. For those hospitals, we compare the hospital's proposed FY 2026 wage index to the hospital's FY 2024 wage index. If the hospital is significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed FY 2026 wage index is decreasing by more than 9.75 percent [206] from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2026 for that hospital would be equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent [207] of its FY 2024 wage index.[208] We note this proposed transitional payment exception would be applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7). For example, assume the FY 2024 wage index for a hospital that benefitted from the low wage index hospital policy is 0.7600, and the hospital's proposed FY 2026 wage index is 0.6500. (If applicable, this proposed FY 2026 wage index value would include the 5-percent cap based on a comparison of the hospital's FY 2026 wage index prior to application of the 5-percent cap, to the hospital's FY 2025 wage index. We note the FY 2025 wage index that will be used in this comparison is generally the FY 2025 wage index listed in Table 2 from the FY 2025 IFC in the column labeled ''FY 2025 Wage Index With Cap''. We note all hospitals, regardless of whether the cap was applied to their FY 2025 wage index, have a value in the column ''FY 2025 Wage Index With Cap''. Hospitals that did not have a cap applied to their FY 2025 wage index will display a wage index in this column without the cap.) The hospital's proposed FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index [that is, 0.6500 < 0.6859 where 0.6859 = (0.9025 times 0.7600)]. The proposed transitional payment exception for FY 2026 for this hospital is equal to the additional amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 0.6859, which is 90.25 percent of 0.7600, its FY 2024 wage index.

Under the capital IPPS, the adjustment for local cost variation is based on the hospital wage index value that is applicable to the hospital under the operating IPPS. We adjust the capital standard Federal rate so that the effects of the annual changes in the geographic adjustment factor (GAF) are budget neutral. The low wage index hospital policy has been reflected in the capital IPPS GAFs since FY 2020 (84 FR 42638). The removal of the low wage index hospital policy for FY 2025 also affects the FY 2025 GAFs. Because we are now no longer applying the low wage index hospital policy in FY 2025, we are also no longer making an adjustment to the FY 2025 capital standard Federal rate to ensure budget neutrality for the low wage index hospital policy.

As discussed previously, for FY 2025 we believe it is appropriate to establish a transition policy for low wage hospitals significantly impacted by the removal of the low wage index hospital policy.

As discussed in the FY 2025 IFC (89 FR 80408), since FY 2023, the GAFs reflect the wage index cap policy that limits any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline, to 95 percent of its prior year value. As described previously, some hospitals that previously benefitted from the low wage index hospital policy would experience decreases of 10 percent or more over the two years from their FY 2024 wage index (with the low wage index hospital policy applied) to their proposed FY 2026 wage index (that is, approximately 5 percent or more per year over that time period). As such, similar to the FY 2025 interim transition policy established in the FY 2025 IFC, we are proposing to make a budget neutral

[204] We note that even more so than was the case for the FY 2025 interim transition policy, the scope and magnitude of the proposed FY 2026 transitional policy are much smaller than the low wage index hospital policy. As discussed in section VI. of the preamble of this proposed rule, we estimate only 52 hospitals out of the over 3,000 hospitals paid under the IPPS would receive proposed FY 2026 transitional exception payments, and the total payment impact of the proposed transitional policy is an increase in IPPS operating payments by approximately $27 million. For the FY 2025 interim transition policy the corresponding figures were 113 hospitals and an increase in IPPS operating payments by approximately $37 million (89 FR 80417).

[205] We note that because creating an exception to the calculation of the FY 2026 payments is in this circumstance functionally equivalent to adjusting the FY 2026 payments, the proposed transitional exception can be alternatively considered a proposed transitional adjustment.

[206] Under the wage index cap policy at 42 CFR 412.64(h)(7), a hospital's wage index for a FY cannot be lower than 0.95 * its wage index from the prior FY. Over a 2-year period if its wage index were decreasing by more than 5 percent each year, this would mean a hospital's wage index for a FY cannot be lower than (0.95*0.95) times its wage index from two years earlier. Similarly for our proposed FY 2026 transitional exception policy, we are proposing that a hospital is significantly impacted by the discontinuation of the low wage index hospital policy if its FY 2026 wage index is less than (0.95*0.95) of its FY 2024 wage index, which equates to a decrease of more than 9.75 percent.

[207] 90.25 percent = 95 percent for FY 2025 * 95 percent for FY 2026.

[208] We note that we are not proposing to change the FY 2026 wage index values under section 1886(d)(3)(E) for hospitals eligible for the proposed FY 2026 transitional exception policy on the basis of the exception; the proposed change would be applied as a separate step only for purposes of determining the hospitals' FY 2026 IPPS payments.

equivalent exception under the capital IPPS.

G. FY 2026 Wage Index Tables

In this FY 2026 IPPS/LTCH PPS proposed rule, we have 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).'' We refer readers to section VI. of the Addendum to this proposed rule for a discussion of the wage index tables for FY 2026.

H. Proposed Labor-Related Share for the FY 2026 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share results in a higher payment.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45208), we rebased and revised the hospital market basket to a 2018-based IPPS hospital market basket, which replaced the 2014-based IPPS hospital market basket, effective beginning October 1, 2021. Using the 2018-based IPPS market basket, we finalized a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. In addition, in FY 2022, we implemented this revised and rebased labor-related share in a budget neutral manner (86 FR 45193, 86 FR 45529 through 45530). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

As described in section IV. of the preamble of this proposed rule, effective beginning FY 2026, we are proposing to rebase and revise the IPPS market basket to reflect a 2023 base year. We also are proposing to recalculate the labor-related share for discharges occurring on or after October 1, 2025, using the proposed 2023-based IPPS market basket. As discussed in Appendix A of this proposed rule, we are proposing this rebased and revised labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we would not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. As described in section IV. of the preamble of this proposed rule, beginning with FY 2026, we are proposing to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2023-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services as measured in the proposed 2023-based IPPS market basket. Therefore, for FY 2026, we are proposing to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025.

As discussed in section V.B. of the preamble of this proposed rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2026, we are not proposing a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflect the national labor-related share. Table 1C, in section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflects the national labor-related share for hospitals located in Puerto Rico. For FY 2026, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2026, we are proposing to apply the wage index to a labor-related share of 66.0 percent of the national standardized amount.

IV. Rebasing and Revising of the Hospital Market Baskets for Acute Care Hospitals

A. Background

Effective for cost reporting periods beginning on or after July 1, 1979, we developed and adopted a hospital input price index (that is, the hospital market basket for operating costs). Although ''market basket'' technically describes the mix of goods and services used in providing hospital care, this term is also commonly used to denote the input price index (that is, cost category weights and price proxies combined) derived from that market basket. Accordingly, the term ''market basket'' as used in this document refers to the hospital input price index.

The percentage change in the market basket reflects the average change in the price of goods and services hospitals purchase in order to provide inpatient care. We first used the market basket to adjust hospital cost limits by an amount that reflected the average increase in the prices of the goods and services used to provide hospital inpatient care. This approach linked the increase in the cost limits to the efficient utilization of resources.

Since the inception of the IPPS, the projected change in the hospital market basket has been the integral component of the update factor by which the prospective payment rates are updated every year. An explanation of the hospital market basket used to develop the prospective payment rates was published in the **Federal Register** on September 1, 1983 (48 FR 39764). We also refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207) in which we discussed the most recent previous rebasing of the hospital input price index.

The hospital market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres-type price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to the base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (in this proposed rule, we propose to use 2023 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive spending categories, with the proportion of total costs that each category represents being calculated. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a ''price proxy.'' In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an earlier period produces a rate of growth in the input price index over that timeframe.

As previously noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide hospital services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, a hospital hiring more nurses to accommodate the needs of patients would increase the volume of goods and services purchased by the hospital but would not be factored into the price change measured by a fixed-weight hospital market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that hospitals purchase (hospital inputs) to furnish inpatient care between base periods.

We last rebased the hospital market basket cost weights effective for FY 2022 (86 FR 45194 through 45207), with 2018 data used as the base period for the construction of the market basket cost weights. For this FY 2026 IPPS/LTCH PPS proposed rule, we propose to rebase the IPPS operating market basket to reflect the 2023 cost structure for IPPS hospitals and to revise applicable cost categories and price proxies used to determine the IPPS market basket, as discussed in this proposed rule. We also propose to rebase and revise the Capital Input Price Index (CIPI) as described in section IV.D. of the preamble of this proposed rule.

In the following section, we provide an overview of the proposed IPPS market basket, describe the proposed methodologies for developing the cost weights, and provide information on the proposed price proxies. Then, we present the proposed FY 2026 market basket update and labor-related share based on the proposed 2023-based IPPS market basket.

B. Rebasing and Revising the IPPS Market Basket

The terms ''rebasing'' and ''revising,'' while often used interchangeably, actually denote different activities. ''Rebasing'' means moving the base year for the structure of costs of an input price index (for example, in this proposed rule, we propose to shift the base year cost structure for the IPPS hospital index from 2018 to 2023). ''Revising'' means changing data sources or price proxies used in the input price index. As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket. We established a rebasing frequency of every 4 years and, therefore, we propose to rebase and revise the IPPS market basket effective for the FY 2026 IPPS update since it was last rebased effective for the FY 2022 IPPS update (the base year for the cost weights is being updated from 2018 to 2023). We invite public comments on our proposed methodology discussed in this section of this proposed rule, for deriving the proposed 2023-based IPPS market basket.

1. Development of Cost Categories and Weights

a. Use of Medicare Cost Report Data

The major source of expenditure data for developing the proposed rebased and revised hospital market basket cost weights is the 2023 Medicare cost reports. These 2023 Medicare cost reports are for cost reporting periods beginning on and after October 1, 2022, and before October 1, 2023. We propose to use 2023 as the base year because we believe that the 2023 Medicare cost reports represent the most recent, complete set of Medicare cost report data available to develop cost weights for IPPS hospitals at the time of rulemaking. As was done in previous rebasings, these cost reports are from IPPS hospitals only (hospitals excluded from the IPPS (including CAHs and rural emergency hospitals) are not included) and are based on IPPS Medicare-allowable operating costs. IPPS Medicare-allowable operating costs are costs that are eligible to be paid under the IPPS. For example, the IPPS market basket excludes home health agency (HHA) costs as these costs would

be paid under the HHA PPS and, therefore, these costs are not IPPS Medicare-allowable costs.

The current set of instructions for the Medicare cost reports for hospitals (Form 2552–10, OMB Control Number 0938–0050) can be found in Chapter 40 at the following website (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Paper-Based-Manuals-Items/CMS021935*).

The major types of costs underlying the proposed 2023-based IPPS market basket are derived from the Medicare cost reports (Form 2552–10, OMB Control Number 0938–0050). Specifically, we propose to use the Medicare cost reports for seven specific types of costs: Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (Malpractice), Blood and Blood Products, and Home Office/Related Organization Contract Labor. A residual category is then estimated and reflects all remaining costs not captured in the seven types of costs identified previously. The 2018-based IPPS market basket similarly used the Medicare cost reports.

In order to create a market basket that is representative of IPPS hospitals serving Medicare patients and to help ensure the major cost weights accurately reflect the percent of total Medicare-allowable operating costs, as defined in this proposed rule, we propose to apply edits to remove reporting errors and outliers. Specifically, the IPPS Medicare cost reports used to calculate the market basket cost weights exclude any providers that reported costs less than or equal to zero for the following categories: total Medicare inpatient costs (Worksheet D–1, Part II, column 1, line 49); Medicare PPS payments (Worksheet E, Part A, column 1, line 59); Total salary costs (Worksheet S–3, Part II, column 2, line 1). We also limited our sample to providers that had a Medicare cost reporting period that was between 10 and 14 months. The final sample used includes roughly 2,900 Medicare cost reports (about 93 percent of the universe of IPPS Medicare cost reports for 2023). The sample of providers is representative of the national universe of providers by ownership-type (proprietary, nonprofit, and government) and by urban/rural status.

In this proposed rule, we calculate total Medicare-allowable operating costs for each hospital to be equal to noncapital costs (Worksheet B, Part I, column 26 less Worksheet B, Part II, column 26) that are attributable to the Medicare-allowable cost centers of the hospital. We propose that Medicare-allowable cost centers are lines 30 through 35, 50 through 60, 62 through 76, 90, 91, 92.01, 93, 96 and 97. This is the same methodology that was used for the 2018-based IPPS market basket.

(1) Wages and Salaries Costs

To derive wages and salaries costs for the Medicare-allowable cost centers, we propose to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, Part II, column 4, line 1. We then propose to remove the wages and salaries attributable to non-Medicare-allowable cost centers (that is, excluded areas) as well as a portion of overhead wages and salaries attributable to these excluded areas. This is the same methodology that was used to derive wages and salaries costs for the 2018-based IPPS market basket.

Specifically, we propose to calculate excluded area wages and salaries as equal to the sum of Worksheet S–3, Part II, column 4, lines 3, 4.01, 5, 6, 7, 7.01, 8, 9, and 10 less Worksheet A, column 1, lines 20 and 23. Overhead wages and salaries are attributable to the entire IPPS facility. Therefore, we propose to only include the proportion attributable to the Medicare-allowable cost centers. Specifically, we propose to estimate the proportion of overhead wages and salaries that are not attributable to Medicare-allowable cost centers (that is, excluded areas) by first calculating the ratio of total Medicare-allowable operating costs (as previously defined) to total facility operating costs (Worksheet B, Part I, column 26, line 202 less Worksheet B, Part I, column 0, lines 1 and 2). We then propose to multiply this ratio by total overhead wages and salaries (Worksheet S–3, Part II, column 4, lines 26, 27, 29 through 32, 34, and 36 through 43) to estimate Medicare allowable overhead wages and salaries. The difference between total overhead wages and salaries and Medicare allowable overhead wages and salaries is equal to the overhead wages and salaries attributable to the excluded areas.

Therefore, we propose wages and salaries costs used for the 2023-based IPPS market basket are equal to total wages and salaries costs less: (a) excluded area wages and salaries costs; and (b) overhead wages and salaries costs attributable to the excluded areas.

(2) Employee Benefits Costs

We propose to derive employee benefits costs using a similar methodology as the wages and salaries costs; that is, reflecting employee benefits costs attributable to the Medicare-allowable cost centers. First, we calculate total unadjusted employee benefits costs as the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 20, 22, and 25.52.

We then exclude those employee benefits attributable to the overhead wages and salaries for the non-Medicare-allowable cost centers (that is, excluded areas). Employee benefits attributable to the non-Medicare-allowable cost centers are derived by multiplying the ratio of total employee benefits (equal to the sum of Worksheet S–3, Part II, column 4, lines 17, 18, 19, 20, 21, 22, 22.01, 23, 24, 25, 25.50, 25.51, 25.52, and 25.53) to total wages and salaries (Worksheet S–3, Part II, column 4, line 1) (which we hereafter refer to as the ''IPPS benefits ratio'') by excluded overhead wages and salaries (as previously described in section IV.B.1.a.(1) of the preamble of this proposed rule for wages and salaries costs). The same methodology was used in the 2018-based IPPS market basket.

Therefore, we propose employee benefit costs used for the 2023-based IPPS market basket are equal to total employee benefit costs less: (a) excluded area benefit costs; and (b) overhead benefit costs attributable to the excluded areas.

(3) Contract Labor Costs

Contract labor costs are primarily associated with direct patient care services. Contract labor costs for services such as accounting, billing, and legal are estimated using other government data sources as described in this proposed rule. We propose to derive contract labor costs for the 2023-based IPPS market basket as the sum of Worksheet S–3, Part II, column 4, lines 11, 13, and 15. The same methodology was used in the 2018-based IPPS market basket.

(4) Professional Liability Insurance Costs

We propose that professional liability insurance (PLI) costs (often referred to as malpractice costs) be equal to premiums, paid losses, and self-insurance costs reported on Worksheet S–2, Part I, columns 1 through 3, line 118.01. The same methodology was used for the 2018-based IPPS market basket.

(5) Pharmaceuticals Costs

We propose to calculate pharmaceuticals costs as total costs reported for the Pharmacy cost center (Worksheet B, Part I, column 0, line 15) and Drugs Charged to Patients cost center (Worksheet B, Part I, column 0, line 73) less wages and salaries attributable to these two cost centers

(Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73) less estimated employee benefits attributable to these two cost centers. We propose to estimate the employee benefits costs by multiplying the IPPS benefits ratio as described in section IV.B.1.a.(2) of the preamble of this proposed rule by total wages and salaries costs for the Pharmacy and Drugs Charged to Patients cost centers (equal to the sum of Worksheet S–3, Part II, column 4, line 40 and Worksheet A, column 1, line 73). The same methodology was used for the 2018-based IPPS market basket.

(6) Blood and Blood Products Costs

We propose to calculate blood and blood products costs as total costs reported for the Whole Blood & Packed Red Blood Cells cost center (Worksheet B, Part I, column 0, line 62) and the Blood Storing, Processing, & Transfusing cost center (Worksheet B, Part I, column 0, line 63) less wages and salaries attributable to these two cost centers (Worksheet A, column 1, lines 62 and 63) less estimated employee benefits attributable to these two cost centers. We estimate these employee benefits costs by multiplying the IPPS benefits ratio as described in section IV.B.1.a.(2) of the preamble of this proposed rule by total wages and salaries for the Whole Blood & Packed Red Blood Cells and Blood Storing, Processing, & Transfusing cost centers (equal to the sum of Worksheet A, column 1, lines 62 and 63). The same methodology was used for the 2018-based IPPS market basket.

(7) Home Office/Related Organization Contract Labor Costs

We propose to determine home office/related organization contract labor costs using data reported on Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51. The same methodology was used for the 2018-based IPPS market basket.

b. Final Major Cost Category Computation

After we derived costs for the major cost categories for each provider using the Medicare cost report data as previously described, we propose to address data outliers using the following steps.

First, for each of the major cost weights except the Home Office/Related Organization Contract Labor cost weight, we propose to trim the data to remove outliers (a standard statistical process) by: (step 1) requiring that major expenses (such as Wages and Salaries costs) and total Medicare-allowable operating costs be greater than zero; (step 2) dividing the costs for each of the six categories (calculated as previously described in this section) by total Medicare-allowable operating costs to obtain cost weights for each PPS hospital; and (step 3) excluding the top and bottom five percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare-allowable operating costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2018-based IPPS market basket.

For the Home Office/Related Organization Contract Labor cost weight, we propose to exclude outliers using a slightly different method by (step 1) requiring that total Medicare-allowable operating costs are greater than zero; (step 2) dividing the home office/related organization contract labor costs (calculated as previously described in this section) by total Medicare-allowable operating costs to obtain a cost weight for each PPS hospital; and (step 3) applying a trim that excludes those reporters with a Home Office/Related Organization Contract Labor cost weight above the 99th percentile. This allows all providers' Medicare-allowable costs to be included, even if their home office/related organization contract labor costs were reported to be zero. The Medicare cost report data (Worksheet S–2, Part I, line 140) indicate that not all hospitals have a home office. IPPS hospitals without a home office would report administrative costs that might typically be associated with a home office in the Wages and Salaries and Employee Benefits cost weights, or these costs would be reflected in the residual cost weight if they purchased these types of services from external contractors. We believe the trimming methodology that excludes those who report a Home Office/Related Organization Contract Labor cost weight above the 99th percentile is appropriate as it removes extreme outliers while also allowing providers with zero home office/related organization contract labor costs to be included in the Home Office/Related Organization Contract Labor cost weight calculation.

After the outliers have been removed, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare-allowable operating costs across all remaining providers to obtain a cost weight for the proposed 2023-based IPPS market basket for the given category. This is the same methodology used for the 2018-based IPPS market basket.

The trimming process is done individually for each cost category so that providers excluded from one cost weight calculation are not automatically excluded from another cost weight calculation. We note that these proposed trimming methods are the same types of edits performed for the 2018-based IPPS market basket, as well as other PPS market baskets (including but not limited to SNF market basket and home health market basket). We note that for each of the cost weights we evaluated the distribution of providers and costs by ownership-type, and by urban/rural status. For all of the cost weights, the trimmed sample was nationally representative.

Finally, we calculate the residual ''All Other'' cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. Table IV–01 shows the major cost categories and their respective cost weights as derived from the Medicare cost reports.

TABLE IV–01—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major cost categories	2018-based IPPS market basket	Proposed 2023-based IPPS market basket
Wages and Salaries	39.7	37.8
Employee Benefits	11.3	9.8
Contract Labor	2.0	3.6
Professional Liability Insurance (Malpractice)	1.0	1.0
Pharmaceuticals	7.1	7.4
Blood and Blood Products	0.6	0.5
Home Office/Related Organization Contract Labor	5.9	6.7

TABLE IV–01—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS—Continued

Major cost categories	2018-based IPPS market basket	Proposed 2023-based IPPS market basket
All Other	32.4	33.2

From 2018 to 2023, the Wages and Salaries and Employee Benefits cost weights as calculated directly from the Medicare cost reports decreased by 1.9 percentage points and 1.5 percentage points, respectively, while the Contract Labor cost weight increased by 1.6 percentage points.

As we did for the 2018-based IPPS market basket (86 FR 45198), we propose to allocate contract labor costs to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The contract labor allocation proportion for wages and salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. Using the 2023 Medicare cost report data, this percentage is 79 percent. Therefore, we propose to allocate approximately 79 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 21 percent to the Employee Benefits cost weight. The 2018-based IPPS market basket allocated 78 percent of the Contract Labor cost weight to the Wages and Salaries cost weight.

Table IV–02 shows the Wages and Salaries and Employee Benefits cost weights after contract labor allocation for the 2018-based IPPS market basket and the proposed 2023-based IPPS market basket. In aggregate, the Compensation cost weight (calculated using more detailed decimal places) decreased from 53.0 percent to 51.1 percent, or 1.9 percentage points.

TABLE IV–02—WAGES AND SALARIES AND EMPLOYEE BENEFITS COST WEIGHTS AFTER CONTRACT LABOR ALLOCATION

Major cost categories	2018-based IPPS market basket	Proposed 2023-based IPPS market basket
Total Compensation	53.0	51.1
Wages and Salaries	41.2	40.6
Employee Benefits	11.7	10.5

Note: Detail may not add to total due to rounding.

c. Derivation of the Detailed Cost Weights

To further divide the ''All Other'' residual cost weight estimated from the 2023 Medicare cost report data into more detailed cost categories, we propose to use the 2017 Benchmark I–O, ''The Use Table (Supply-Use Framework),'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). These data are publicly available at the following website: *https://www.bea.gov/industry/input-output-accounts-data*. The BEA Benchmark I–O data are generally scheduled for publication every 5 years on a lagged basis, with the most recent data available for 2017. The 2017 Benchmark I–O data are derived from the 2017 Economic Census and are the building blocks for BEA's economic accounts. Therefore, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.[209] BEA also produces Annual I–O estimates. However, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data become available. Instead of using the less detailed Annual I–O data, we propose to inflate the detailed 2017 Benchmark I–O data forward to 2023 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2017 Benchmark I–O data and calculated the cost shares that each cost category represents using the inflated data. These resulting 2023 cost shares were applied to the residual ''All Other'' cost weight to obtain the detailed cost weights for the proposed 2023-based IPPS market basket. For example, the cost for Food: Direct Purchases represents 4.0 percent of the sum of the residual ''All Other'' 2017 Benchmark I–O Hospital Expenditures inflated to 2023. Therefore, the Food: Direct Purchases cost weight represents 4.0 percent of the proposed 2023-based IPPS market basket's ''All Other'' cost category (33.2 percent), yielding a Food: Direct Purchases proposed cost weight of 1.3 percent in the proposed 2023-based IPPS market basket (0.040×33.2 percent = 1.3 percent). For the 2018-based IPPS market basket (86 FR 45198), we used the same methodology utilizing the 2012 Benchmark I–O data (aged to 2018).

Using this methodology, we propose to derive 17 detailed cost categories from the proposed 2023-based IPPS market basket residual cost weight (33.2 percent). These categories are: (1) Fuel: Oil and Gas; (2) Electricity and Other Non-Fuel Utilities; (3) Food: Direct Purchases; (4) Food: Contract Services; (5) Chemicals; (6) Medical Instruments; (7) Rubber and Plastics; (8) Paper and Printing Products; (9) Miscellaneous Products; (10) Professional Fees: Labor-Related; (11) Administrative and Facilities Support Services; (12) Installation, Maintenance, and Repair Services; (13) All Other: Labor-Related Services; (14) Professional Fees: Nonlabor-Related; (15) Financial Services; (16) Telephone Services; and (17) All Other: Nonlabor-Related Services. We note that these are the same categories that were used in the 2018-based IPPS market basket.

2. Selection of Proposed Price Proxies

After computing the proposed 2023 cost weights for the IPPS market basket, it was necessary to select appropriate wage and price proxies to reflect the rate of price change for each expenditure category. With the exception of the

[209] *https://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

proxy for professional liability insurance (PLI), all the proxies we are proposing are based on Bureau of Labor Statistics (BLS) data and are grouped into one of the following BLS categories:

- Producer Price Indexes—Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (*https://www.bls.gov/ppi/*).
- Consumer Price Indexes—Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (*https://www.bls.gov/cpi/*). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.
- Employment Cost Indexes—Employment Cost Indexes (ECIs) measure the rate of change in employee wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- Reliability. Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the entire population.)
- Timeliness. Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market basket levels are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.
- Availability. Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.
- Relevance. Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied.

We believe the proposed PPIs, CPIs, and ECIs selected meet these criteria. Therefore, we believe that they continue to be the best proxy of price changes for the cost categories to which they would be applied.

In this proposed rule, we present a detailed explanation of the price proxies that we propose for each cost category weight.

a. Wages and Salaries

We propose to use the ECI for Wages and Salaries for All Civilian Workers in Hospitals (BLS series code CIU1026220000000I) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

b. Employee Benefits

We propose to use the ECI for Total Benefits for All Civilian Workers in Hospitals to proxy the price growth of this cost category. This ECI is calculated using the ECI for Total Compensation for All Civilian Workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2018-based IPPS market basket.

c. Fuel: Oil and Gas

For the proposed 2023-based IPPS market basket, we propose to use a blend of the PPI Industry for Petroleum Refineries (NAICS 3241), PPI for Other Petroleum and Coal Products (NAICS 32419) and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2017 Benchmark I–O data for NAICS 622000 Hospitals shows that Petroleum Refineries expenses account for approximately 86 percent, Other Petroleum and Coal Products expenses account for about 7 percent and Natural Gas expenses account for approximately 7 percent of Hospitals' (NAICS 622000) total Fuel: Oil and Gas expenses. Therefore, we propose to use a blend of 86 percent of the PPI Industry for Petroleum Refineries (BLS series code PCU324110324110), 7 percent of the PPI for Other Petroleum and Coal Products (BLS series code PCU32419) and 7 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. The 2018-based IPPS market basket used a 90/10 blend of the PPI Industry for Petroleum Refineries and PPI Commodity for Natural Gas, reflecting the 2012 I–O data (86 FR 45199). We believe that the three proposed price proxies are the most technically appropriate indices available to proxy the price growth of the Fuel: Oil and Gas cost category in the proposed 2023-based IPPS market basket.

d. Electricity and Other Non-Fuel Utilities

We propose to use the PPI Commodity for Commercial Electric Power (BLS series code WPU0542) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

e. Professional Liability Insurance

We propose to proxy price changes in hospital professional liability insurance premiums (PLI) using percentage changes as estimated by the CMS Hospital Professional Liability Index. To generate these estimates, we collect commercial insurance medical liability premiums for a fixed level of coverage while holding nonprice factors constant (such as a change in the level of coverage). This is the same price proxy used in the 2018-based IPPS market basket.

f. Pharmaceuticals

We propose to use the PPI Commodity for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

g. Food: Direct Purchases

We propose to use the PPI Commodity for Processed Foods and Feeds (BLS series code WPU02) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

h. Food: Contract Services

We propose to use the CPI for Food Away From Home (All Urban Consumers) (BLS series code

CUUR0000SEFV) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

i. Chemicals

Similar to the 2018-based IPPS market basket, we propose to use a four-part blended PPI as the proxy for the Chemicals cost category in the proposed 2023-based IPPS market basket. The proposed blend is composed of the PPI Industry for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI Industry for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518–32518), the PPI Industry for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519–32519), and the PPI Industry for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). For the proposed 2023-based IPPS market basket, we propose to derive the weights for the PPIs using the 2017 Benchmark I–O data. The 2018-based IPPS market basket used the 2012 Benchmark I–O data to derive the weights for the four PPIs (86 FR 45200).

Table IV–03 shows the proposed weights for each of the four PPIs used to create the blended index compared to those used for the 2018-based IPPS market basket.

TABLE IV–03—BLENDED CHEMICAL PPI WEIGHTS

NAICS	Name	2018-based IPPS weights (%)	Proposed 2023-based IPPS weights (%)
325120	PPI Industry for Industrial Gas Manufacturing	19	26
325180	PPI Industry for Other Basic Inorganic Chemical Manufacturing	13	10
325190	PPI Industry for Other Basic Organic Chemical Manufacturing	60	49
325998	PPI Industry for Other Miscellaneous Chemical Product Manufacturing	8	15

j. Blood and Blood Products

We propose to use the PPI Industry for Blood and Organ Banks (BLS series code PCU621991621991) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

k. Medical Instruments

We propose to use a blended price proxy for the Medical Instruments category, as shown in Table IV–04. The 2017 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112—Surgical and medical instrument manufacturing costs (approximately 64 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 36 percent). To proxy the price changes associated with NAICS 339112, we propose using the PPI Commodity for Surgical and medical instruments (BLS series code WPU1562). To proxy the price changes associated with NAICS 339113, we propose to use a 50/50 blend of the PPI Commodity for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI Commodity for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571). We propose to include the latter price proxy as it would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2017 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by IPPS hospitals. These are the same price proxies used in the 2018-based IPPS market basket.

TABLE IV–04—BLENDED MEDICAL INSTRUMENTS PPI WEIGHTS

NAICS	Name	2018-based IPPS weights (%)	Proposed 2023-based IPPS weights (%)
339112	PPI Commodity for Surgical and medical instruments	56	64
339113	PPI—Commodity for Medical and surgical appliances and supplies	22	18
	PPI Commodity for Miscellaneous products, Personal safety equipment and clothing	22	18

l. Rubber and Plastics

We propose to use the PPI Commodity for Rubber and Plastic Products (BLS series code WPU07) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

m. Paper and Printing Products

We propose to use a 61/39 blend of the PPI Commodity for Publications Printed Matter and Printing Material (BLS Series Code WPU094) and the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) to proxy the price growth of this cost category. The 2017 Benchmark I–O data shows that 61 percent of paper and printing expenses are for Printing (NAICS 323110) and the remaining expenses are for Paper manufacturing (NAICS 322). The 2018-based IPPS market basket (86 FR 45201) used the PPI Commodity for Converted Paper and Paperboard Products (BLS series code WPU0915) as this comprised the majority of expenses as reported in the 2012 Benchmark I–O data.

n. Miscellaneous Products

We propose to use the PPI Commodity for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

o. Professional Fees: Labor-Related

We propose to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to proxy the price growth of this category. It includes occupations such as legal, accounting, and engineering services. This is the same price proxy used in the 2018-based IPPS market basket.

p. Administrative and Facilities Support Services

We propose to use the ECI for Total Compensation for Private Industry Workers in Office and Administrative Support (BLS series code CIU2010000220000I) to proxy the price growth of this category. This is the same price proxy used in the 2018-based IPPS market basket.

q. Installation, Maintenance, and Repair Services

We propose to use the ECI for Total Compensation for All Civilian Workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to proxy the price growth of this cost category. This is the same proxy used in the 2018-based IPPS market basket.

r. All Other: Labor-Related Services

We propose to use the ECI for Total Compensation for Private Industry Workers in Service Occupations (BLS series code CIU2010000300000I) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

s. Professional Fees: Nonlabor-Related

We propose to use the ECI for Total Compensation for Private Industry Workers in Professional and Related (BLS series code CIU2010000120000I) to proxy the price growth of this category. This is the same price proxy that we proposed to use for the Professional Fees: Labor-Related cost category and the same price proxy used in the 2018-based IPPS market basket.

t. Financial Services

We propose to use the ECI for Total Compensation for Private Industry Workers in Financial Activities (BLS series code CIU201520A000000I) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

u. Telephone Services

We propose to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to proxy the price growth of this cost category. This is the same price proxy used in the 2018-based IPPS market basket.

v. All Other: Nonlabor-Related Services

We propose to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to proxy the price growth of this cost category. We believe that using the CPI for All Items Less Food and Energy avoids double counting of changes in food and energy prices as they are already captured elsewhere in the market basket. This is the same price proxy used in the 2018-based IPPS market basket.

Table IV–05 sets forth the proposed 2023-based IPPS market basket, including the cost categories and their respective weights and price proxies. For comparison purposes, the corresponding 2018-based IPPS market basket cost weights also are listed.

TABLE IV–05—2023-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO 2018-BASED IPPS MARKET BASKET COST WEIGHTS

Cost categories	2018-based IPPS market basket cost weights	Proposed 2023-based IPPS market basket cost weights	Proposed 2023-based IPPS market basket price proxies
1. Compensation	53.0	51.1	
A. Wages and Salaries [1]	41.2	40.6	ECI for Wages and Salaries for All Civilian Workers in Hospitals.
B. Employee Benefits [1]	11.7	10.5	ECI for Total Benefits for All Civilian Workers in Hospitals.
2. Utilities	2.3	1.8	
A. Electricity and Other Non-Fuel Utilities	1.5	1.5	PPI Commodity for Commercial Electric Power.
B. Fuel: Oil and Gas	0.8	0.4	Blend of PPIs.
3. Professional Liability Insurance	1.0	1.0	CMS Hospital Professional Liability Insurance Premium Index.
4. All Other	43.8	46.0	
A. All Other Products	18.4	20.5	
(1.) Pharmaceuticals	7.1	7.4	PPI Commodity for Pharmaceuticals for Human Use, Prescription.
(2.) Food: Direct Purchases	1.6	1.3	PPI Commodity for Processed Foods and Feeds.
(3.) Food: Contract Services	1.8	2.2	CPI for Food Away From Home.
(4.) Chemicals	0.6	0.6	Blend of PPIs.
(5.) Blood and Blood Products	0.6	0.5	PPI Industry for Blood and Organ Banks.
(6.) Medical Instruments	4.1	5.3	Blend of PPIs.
(7.) Rubber and Plastics	0.6	0.7	PPI Commodity for Rubber and Plastic Products.
(8.) Paper and Printing Products	0.9	0.9	Blend of PPIs.
(9.) Miscellaneous Products	1.2	1.5	PPI Commodity for Finished Goods less Food and Energy.
B. Labor-Related Services	14.7	14.8	
(1.) Professional Fees: Labor-Related	8.6	10.0	ECI for Total Compensation for Private Industry Workers in Professional and Related.
(2.) Administrative and Facilities Support Services.	1.1	0.8	ECI for Total Compensation for Private Industry Workers in Office and Administrative Support.
(3.) Installation, Maintenance and Repair Services.	2.4	1.5	ECI for Total Compensation for Civilian Workers in Installation, Maintenance, and Repair.
(4.) All Other: Labor-Related Services	2.6	2.6	ECI for Total Compensation for Private Industry Workers in Service Occupations.
C. Nonlabor-Related Services	10.7	10.7	
(1.) Professional Fees: Nonlabor-Related	7.0	7.0	ECI for Total Compensation for Private Industry Workers in Professional and Related.

TABLE IV–05—2023-BASED IPPS MARKET BASKET COST CATEGORIES, COST WEIGHTS, AND PRICE PROXIES COMPARED TO 2018-BASED IPPS MARKET BASKET COST WEIGHTS—Continued

Cost categories	2018-based IPPS market basket cost weights	Proposed 2023-based IPPS market basket cost weights	Proposed 2023-based IPPS market basket price proxies
(2.) Financial Services	1.4	1.8	ECI for Total Compensation for Private Industry Workers in Financial Activities.
(3.) Telephone Services	0.4	0.3	CPI for Telephone Services.
(4.) All Other: Nonlabor-Related Services	1.8	1.5	CPI for All Items less Food and Energy.
Total	100.0	100.0	

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and, therefore, the detail may not add to the total due to rounding.

[1] Contract labor is distributed to wages and salaries and employee benefits based on the share of total compensation that each category represents.

Table IV–06 compares both the historical and forecasted percent changes in the 2018-based IPPS market basket and the proposed 2023-based IPPS market basket. The forecasted growth rates in Table IV–06 are based on IHS Global Inc.'s (IGI's) fourth quarter 2024 forecast with historical data through third quarter 2024.

TABLE IV–06—2018-BASED AND PROPOSED 2023-BASED IPPS HOSPITAL MARKET BASKET PERCENT CHANGE, FY 2021 THROUGH FY 2028

Fiscal year (FY)	2018-based IPPS market basket percent change	Proposed 2023-based IPPS market basket percent change
Historical data:		
FY 2021	3.0	2.8
FY 2022	5.7	5.3
FY 2023	4.8	4.9
FY 2024	3.6	3.7
Average FYs 2021–2024	4.3	4.2
Forecast:		
FY 2025	3.4	3.5
FY 2026	3.3	3.2
FY 2027	3.1	3.0
FY 2028	2.9	2.9
Average FYs 2025–2028	3.2	3.2

Source: IHS Global, Inc., 4th Quarter 2024 forecast.

The average percent change of the proposed 2023-based IPPS market basket is 0.1 percentage point lower than the average percent change of the 2018-based IPPS market basket over the FY 2021 through FY 2024 time period. For FY 2026, the proposed 2023-based IPPS market basket is projected to increase 3.2 percent, which is 0.1 percentage point lower than the FY 2026 projected increase of the 2018-based IPPS market basket. The lower projected increase of the proposed 2023-based IPPS market basket compared to the 2018-based IPPS market basket is primarily a result of the lower compensation cost weight in the proposed 2023-based IPPS market basket. The compensation cost weights in the proposed 2023-based and 2018-based IPPS market basket were calculated from the hospital Medicare cost reports using the same methodology.

3. Labor-Related Share

Under section 1886(d)(3)(E) of the Act, the Secretary estimates from time to time the proportion of payments that are labor-related. Section 1886(d)(3)(E) of the Act states that the Secretary shall adjust the proportion, (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs, of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.''

The labor-related share is used to determine the proportion of the national PPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are *labor intensive* and *vary with the local labor market.* For this proposed rule, we propose to include in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the proposed 2023-based IPPS market basket: Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, and All Other: Labor-Related Services, as we did in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204).

Similar to the 2018-based IPPS market basket, for the proposed 2023-based IPPS market basket we propose to classify expenses into the Professional Fees: Labor-Related cost category using the Benchmark I–O data, and then for this rebasing supplement these estimates with data obtained from the Medicare hospital cost report regarding the proportion of expenses classified as professional fees (for example, advertising, legal services, accounting and auditing, engineering, and

management consulting) that are purchased within the local area labor market. The 2018-based IPPS market basket (86 FR 45204 through 45205) used a survey of hospitals conducted by CMS in 2008 (OMB Control Number 0938–1036) to supplement the Benchmark I–O data and determine this proportion. Effective for transmittal 18 (*https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i*), the hospital Medicare cost report (CMS Form 2552–10, OMB No. 0938–0050) Worksheet S–2, Part I collects information on whether a hospital purchased professional services (for example, legal, accounting, tax preparation, bookkeeping, payroll, advertising, and management/consulting services or both) from an unrelated organization and if the majority of these expenses were purchased from unrelated organizations located outside of the main hospital's local area labor market.

For the proposed 2023-based IPPS market basket, we propose to determine the proportion of expenses classified as professional fees that meet our definition of labor-related services based on the Medicare cost report data. Based on these data, approximately 73 percent of IPPS hospitals (approximately 2,100) purchased professional services from an unrelated organization in 2023 as reported on Worksheet S–2, Part I, column 1, line 123 (that is, answered Yes) and also indicated whether the majority of these expenses are purchased outside their local labor market (reported Yes or No on Worksheet S–2, Part I, column 2, line 123). Of those hospitals, 37 percent of them purchased the majority of these expenses from unrelated organizations located in a CBSA outside of the main hospital CBSA as reported on Worksheet S–2, Part I, column 2, line 123. For these reporters (which accounted for 32 percent of total Medicare allowable operating costs) that indicated they purchased the majority of these services outside of the local labor market, we need to estimate a specific proportion of these services that are purchased inside the local labor market. For these reporters, we use 25 percent (the median of 1 percent to 49 percent range) to estimate of the proportion of these services that are purchased inside of the local labor market. For the remaining reporters (which accounted for 68 percent of total Medicare allowable operating costs) that indicated they purchased the majority of these services inside the local labor market we use 75 percent (the median of 51 percent to 100 percent). To estimate the overall proportion of expenses classified as professional fees that meet our definition of labor-related services (that is, reflects services purchased inside of the local labor market), for the first group of reporters we multiply 32 percent times 25 percent, which yields an estimate of 8 percent, and for the second group of reporters multiply 68 percent times 75 percent, which yields an estimated proportion of 51 percent. Combining these two measures yields 59 percent (8 percent plus 51 percent), which reflects the overall proportion of total Medicare allowable operating expenses that are purchased inside the local labor market and would be reflected in our labor-related measure. Therefore, we propose to allocate 59 percent of the Benchmark I–O expenses classified as professional fees to estimate Professional Fees: Labor-Related cost weight, and 41 percent of the Benchmark I–O expenses classified as professional fees to estimate Professional Fees: Nonlabor-Related cost weight.

In the proposed 2023-based IPPS market basket, expenses classified as professional fees that are subject to allocation represent approximately 9.8 percent of total operating costs. Based on the Medicare cost report results, we propose to apportion 5.8 percentage points of the 9.8 percentage point figure into the Professional Fees: Labor-Related cost category (59 percent of 9.8 percent) and designate the remaining approximately 4.0 percentage points into the Professional Fees: Nonlabor-Related cost category (41 percent of 9.8 percent). We note that in the 2018-based IPPS market basket given the data available from the 2008 survey, we classified some expenses from the 2012 Benchmark I–O data as Professional Fees: Labor-Related, some expenses as Professional Fees: Nonlabor-Related, and some expenses as professional fees subject to allocation based on the survey. We then applied the 2008 survey results to the following specific categories of expenses: Legal services, Accounting, tax preparation, bookkeeping, and payroll services, Architectural, engineering and related services, and Management consulting services. However, for the 2023-based IPPS market basket, we are proposing to revise the methodology to now use the data as reported on the Medicare cost reports (Worksheet S–2, Part I) to allocate all of the expenses we propose to classify as professional fees costs from the 2017 Benchmark I–O data. The impact of this proposed change is an increase in the proposed 2023-based Professional Fees: Labor-Related cost weight of about one percentage point.

In addition to the professional services listed earlier, we also classify a proportion of the Home Office/Related Organization Contract Labor cost weight into the Professional Fees: Labor-Related cost category as was done in the previous rebasing. We believe that many of these costs are labor-intensive and vary with the local labor market. However, data indicate that not all IPPS hospitals with home offices have home offices located in their local labor market. Therefore, we propose to include in the labor-related share only a proportion of the Home Office/Related Organization Contract Labor cost weight based on the methodology described in this proposed rule.

For the proposed 2023-based IPPS market basket, based on Medicare cost report data, we found that approximately 71 percent of IPPS hospitals reported some type of home office information on their Medicare cost report for 2023 (for example, city, State, and zip code). Using the data reported on the Medicare cost report, we compared the location of the hospital with the location of the hospital's home office. We then determined the proportion of home office/related organization contract labor cost that should be allocated to the labor-related share based on the percent of the home office/related organization contract labor costs for those hospitals that had home offices located in their respective local labor markets—defined as being in the same MSA. We determined a hospital's and home office's MSAs using their zip code information from the Medicare cost report.

Based on these data, we determined the proportion of costs that should be allocated to the labor-related share based on the percent of hospital home office/related organization contract labor costs (equal to the sum of Worksheet S–3, Part II, column 4, lines 14.01, 14.02, 25.50, and 25.51). Using this methodology, we determined that 62 percent of hospitals' home office compensation costs were for home offices located in their respective local labor markets. Therefore, we propose to allocate 62 percent of Home Office/Related Organization Contract Labor cost weight to the labor-related share. The 2018-based IPPS market basket used a 60 percent proportion, which was based on the same methodology and the 2018 Medicare cost report data.

In the proposed 2023-based IPPS market basket, the Home Office/Related Organization Contract Labor cost weight that is subject to allocation based on the home office allocation methodology

represented 6.7 percent of total operating costs. Based on the results of the home office analysis, as previously discussed, we apportioned approximately 4.2 percentage points of the 6.7 percentage points figure into the Professional Fees: Labor-Related cost category and designated the remaining approximately 2.6 percentage points into the Professional Fees: Nonlabor-Related cost category.[210] In summary, based on the two previously mentioned allocations, we apportioned 10.0 percentage points (sum of the professional fees (5.8 percentage points) and Home Office/Related Organization Contract Labor cost weight (4.2 percentage points)) into the Professional Fees: Labor-Related cost category. Using these two methods, we then apportion 6.6 percentage points (sum of the professional fees (4.0 percentage points) and Home Office/Related Organization Contract Labor cost weight (2.6 percentage points)) to the Professional Fees: Nonlabor-related cost category to be included with other costs classified as Professional Fees: Nonlabor-Related (approximately 0.4 percentage point), resulting in a proposed Professional Fees: Nonlabor-related cost weight of 7.0 percent. The resulting proposed 2023-based Professional Fees: Labor-related cost weight is about 1.4 percentage points higher than the 2018-based Professional Fees: Labor-related cost weight.

Table IV–07 presents a comparison of the proposed 2023-based labor-related share and the 2018-based labor-related share. As discussed in section IV.B.1.b. of the preamble of this proposed rule, the Wages and Salaries and Employee Benefits cost weights reflect contract labor costs.

TABLE IV–07—COMPARISION OF THE 2018-BASED LABOR-RELATED SHARE AND THE PROPOSED 2023-BASED LABOR-RELATED SHARE

	2018-based IPPS market basket cost weights	Proposed 2023-based IPPS market basket cost weights
Wages and Salaries	41.2	40.6
Employee Benefits	11.7	10.5
Professional Fees: Labor-Related	8.6	10.0
Administrative and Facilities Support Services	1.1	0.8
Installation, Maintenance, and Repair Services	2.4	1.5
All Other: Labor-Related Services	2.6	2.6
Total Labor-Related Share	67.6	66.0

Note: Detail may not add to total due to rounding.

Using the cost category weights from the proposed 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, 1.6 percentage points lower than the current labor-related share of 67.6 percent. This downward revision to the labor-related share is primarily the result of incorporating the more recent 2023 Medicare cost report data for Wages and Salaries, Employee Benefits, and Contract Labor costs. This is partially offset by an increase in the Professional Fees: Labor-Related cost weight.

Therefore, we propose to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025. We continue to believe, as we have stated in the past, that these operating cost categories are related to, influenced by, or vary with the local markets. Therefore, our definition of the labor-related share continues to be consistent with section 1886(d)(3) of the Act. We note that section 403 of Public Law 108–173 amended sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless 62 percent would result in lower payments to a hospital than would otherwise be made.

C. Market Basket for Certain Hospitals Presently Excluded From the IPPS

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs.

Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating market basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. Effective for the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating market basket to a 2018 base year. Therefore, we used the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years.

As discussed in this section IV. of the preamble of this proposed rule, we propose to rebase and revise the IPPS operating market basket to a 2023 base year. We continue to believe that it is appropriate to use the increase in the IPPS operating market basket to update the target amounts for these excluded facilities, as discussed in prior rulemaking. Therefore, we propose to use the percentage increase in the proposed 2023-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern

[210] **Note:** The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

Mariana Islands, and American Samoa for FY 2026 and subsequent fiscal years. Accordingly, for FY 2026, the rate-of increase percentage to be applied to the target amount for these hospitals would be the FY 2026 percentage increase in the proposed 2023-based IPPS operating market basket. Furthermore, we are proposing that if more recent data become available for the FY 2026 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2026.

D. Rebasing and Revising the Capital Input Price Index (CIPI)

The CIPI was originally described in the FY 1993 IPPS final rule (57 FR 40016). There have been subsequent discussions of the CIPI presented in the IPPS proposed and final rules. The FY 2022 IPPS/LTCH PPS final rule (86 FR 45208 through 45213) described the most recent rebasing and revising of the CIPI to a 2018 base year, which reflected the capital cost structure of IPPS hospitals available at that time.

Effective for FY 2026, we are proposing to rebase and revise the CIPI to a 2023 base year to reflect a more current structure of capital costs for IPPS hospitals. We invite public comments on our proposed methodology discussed in this section of this proposed rule, for deriving the proposed 2023-based CIPI. This proposed 2023-based CIPI was derived using data from the 2023 cost reports for IPPS hospitals, which includes providers whose cost reporting period began on or after October 1, 2022, and prior to September 30, 2023. We are also proposing to start with the same subset of Medicare cost reports from IPPS hospitals as previously described in section IV.B.1.a. of the preamble of this proposed rule. As with the 2018-based index, we are proposing to develop two sets of weights to derive the proposed 2023-based CIPI. The first set of weights identifies the proportion of hospital capital expenditures attributable to each expenditure category, while the second set of weights is a set of relative vintage weights for depreciation and interest. The set of vintage weights is used to identify the proportion of capital expenditures within a cost category that is attributable to each year over the useful life of the capital assets in that category. A more thorough discussion of vintage weights is provided later in this section.

Using 2023 Medicare cost reports (CMS Form 2552–10, OMB Control number 0938–0050), we are able to obtain capital costs for the following categories: Depreciation, Interest, Lease, and Other. Specifically, we are proposing to determine what proportion of total capital costs that each category represents using the data reported by IPPS hospitals on Worksheet A–7, Part III. We are proposing that Depreciation costs are equal to the sum of Worksheet A–7, Part III, column 9, lines 1 and 2. We are proposing that Interest costs are equal to the sum of Worksheet A–7, Part III, column 11, lines 1 and 2. We are proposing that Lease costs are equal to the sum of Worksheet A–7, Part III, column 10, lines 1 and 2. We are proposing that Other costs are equal to the sum of Worksheet A–7, Part III, columns 12 through 14, lines 1 and 2. We are proposing that Total Capital costs are equal to the sum of Worksheet A–7, Part III, column 15, lines 1 and 2. We are proposing to derive cost weights for each IPPS hospital for each CIPI cost category by calculating the ratio of the costs reported for each cost category (for example, Depreciation) to Total Capital costs. Finally, we are proposing to apply a set of simultaneous trims based on these derived cost weights to remove outliers. Specifically, we are proposing to only include cost reports for providers where their Depreciation cost weight is between 25 percent and 90 percent; Interest cost weight is between 0 and 75 percent, Lease cost weight is between 0 and 50 percent and Total Capital costs are greater than zero and less than Total Facility Costs reported on Worksheet B, Part I, column 26, line 202. The trimming process is done simultaneously on each cost category so that if a cost weight is outside the specific range for one or more of the cost weight criteria mentioned, the provider is excluded from the sample. We note that these proposed trimming methods are the same types of edits performed for the 2018-based CIPI. We then are proposing to sum the costs for each cost category (Depreciation, Interest, Lease, and Other) and divide each sum by the sum of Total Capital costs for this same set of IPPS hospitals. The ratio of the total costs for each category to the sum of Total Capital costs represents the cost weight for each of the Depreciation, Interest, Lease and Other cost categories. This is the same methodology as was used for the 2018-based CIPI. As shown in the left column of Table IV–08, in 2023 depreciation expenses accounted for 67.2 percent of total capital costs, interest expenses accounted for 15.2 percent, leasing expenses accounted for 11.6 percent, and other capital expenses accounted for 6.0 percent.

We also are proposing to allocate lease costs across each of the remaining capital cost categories as was done in the 2018-based CIPI. We are proposing to proportionally distribute leasing costs among the cost categories of Depreciation, Interest, and Other, reflecting the assumption that the underlying cost structure of leases is similar to that of capital costs in general. As was done for the 2018-based CIPI, we are proposing to assume that 10 percent of the lease costs as a proportion of total capital costs represents overhead and to assign those costs to the Other capital cost category accordingly. Therefore, we are assuming that approximately 1.2 percent (11.6 percent $\times$ 0.1) of total capital costs represent lease costs attributable to overhead, and we are proposing to add this 1.2 percent to the 6.0 percent Other cost category weight. We are then proposing to distribute the remaining lease costs (10.4 percent, or 11.6 percent $-$ 1.2 percent) proportionally across the three cost categories (Depreciation, Interest, and Other) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other cost categories (excluding lease expenses). For example, the Other cost category represented 6.7 percent of all three cost categories (Depreciation, Interest, and Other) prior to any lease expenses being allocated. This 6.7 percent is applied to the 10.4 percent of remaining lease expenses so that another 0.7 percent of lease expenses as a percent of total capital costs is allocated to the Other cost category. Therefore, the resulting proposed Other cost weight is 7.8 percent (calculated using unrounded numbers, which is approximately equal to 6.0 percent + 1.2 percent + 0.7 percent). This is the same methodology used for the 2018-based CIPI. The resulting cost weights of the proposed allocation of lease expenses are shown in the right column of Table IV–08.

TABLE IV–08—PROPOSED ALLOCATION OF LEASE EXPENSES FOR THE PROPOSED 2023-BASED CIPI

Cost categories	Proposed cost shares obtained from medicare cost reports (percent of total capital costs)	Proposed cost shares after allocation of lease expenses (percent of total capital costs)
Depreciation	67.2	75.1
Interest	15.2	17.0
Lease	11.6	
Other	6.0	7.8

Note: Detail may not add to 100 percent due to rounding.

Finally, we are proposing to further divide the Depreciation and Interest cost categories. We are proposing to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also are proposing to separate the Interest cost category into the following two categories: (1) Government/Nonprofit; and (2) For-profit. These are the same categories used for the 2018-based CIPI.

To disaggregate the depreciation cost weight, we needed to determine the percent of total depreciation costs for IPPS hospitals (after the allocation of lease costs) that are attributable to building and fixed equipment, which we hereafter refer to as the ''fixed percentage.'' After applying the trim requiring that the Depreciation cost weight is between 25 percent and 90 percent as described previously, for the providers remaining, we calculate the fixed percentage as the ratio of the sum of building and fixed equipment depreciation (Worksheet A–7, Part III, column 9, line 1) to the sum of total depreciation (sum of Worksheet A–7, Part III column 9, lines 1 and 2). Based on the 2023 IPPS Medicare cost reports, we have determined that depreciation costs for building and fixed equipment account for approximately 52 percent of total depreciation costs, while depreciation costs for movable equipment account for approximately 48 percent of total depreciation costs. This is the same methodology used for the 2018-based CIPI. As was done for the 2018-based CIPI, we are proposing to apply this fixed percentage to the depreciation cost weight (after leasing costs are included) to derive a Depreciation cost weight attributable to Building and Fixed Equipment and a Depreciation cost weight attributable to Movable Equipment.

To disaggregate the Interest cost weight, we needed to determine the percent of total interest costs for IPPS hospitals that are attributable to government and nonprofit facilities, which we hereafter refer to as the ''nonprofit percentage,'' because interest price pressures tend to differ between nonprofit and for-profit facilities. After applying the trim requiring that the Interest cost weight is between 0 percent and 75 percent as described previously, for the providers remaining, we calculate the nonprofit percentage as the ratio of the sum of interest costs (Worksheet A–7, Part III, column 11, lines 1 and 2) for government and nonprofit facilities to the sum of total interest costs for all facilities. This is the same methodology used for the 2018-based CIPI. The nonprofit percentage determined using this method is 91 percent. Table IV–09 provides a comparison of the 2018-based CIPI cost weights and the proposed 2023-based CIPI cost weights. After the capital cost category weights were computed, it was necessary to select appropriate price proxies to reflect the rate-of-increase for each expenditure category. We are proposing to use the same price proxies as were used in the 2018-based CIPI, which are listed in Table IV–09. We also are proposing to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is the same general method that was used for the 2018-based CIPI (with a proposed change to the data source used to derive the vintage weights) and is described later in this section of this proposed rule.

For the Depreciation—Building and Fixed Equipment cost category, we are proposing to continue to use the BEA Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type) as the price proxy. This BEA index is intended to capture prices for construction of facilities such as hospitals, nursing homes, hospices, and rehabilitation centers. For the Depreciation—Movable Equipment cost category, we are proposing to continue to use the PPI Commodity for Machinery and Equipment (BLS series code WPU11) as the price proxy. This price index reflects price inflation associated with a variety of machinery and equipment that would be utilized by hospitals including but not limited to communication equipment, computers, and medical equipment. For the Nonprofit Interest cost category, we are proposing to continue to use the average yield on domestic municipal bonds (Bond Buyer 20-bond index) as the price proxy. For the For-profit Interest cost category, we are proposing to continue to use the iBoxx AAA Corporate Bond Yield index as the price proxy. For the Other capital cost category (including insurances, taxes, and other capital-related costs), we are proposing to continue to use the CPI for Rent of Primary Residence (All Urban Consumers) (BLS series code CUUS0000SEHA) as the price proxy. We believe that these price series continue to be the most appropriate proxies for IPPS capital costs that meet our selection criteria of relevance, timeliness, availability, and reliability.

TABLE IV–09—PROPOSED 2023-BASED CIPI COST WEIGHTS AND PRICE PROXIES COMPARED TO 2018-BASED CIPI COST WEIGHTS

Cost categories	2018 cost weights	Proposed 2023 cost weights	Proposed price proxy
Total	100.0	100.0	
Depreciation	76.8	75.1	
Building and Fixed Equipment	39.3	39.3	BEA's Chained Price Index for Private Fixed Investment in Structures, Nonresidential, Hospitals and Special Care.
Movable Equipment	37.5	35.9	PPI Commodity for Machinery and Equipment.
Interest	16.6	17.0	
Government/Nonprofit	14.9	15.4	Average Yield on Domestic Municipal Bonds (Bond Buyer 20-Bond Index).
For-Profit	1.7	1.6	Average Yield on iBoxx AAA Corporate Bonds.
Other	6.6	7.8	CPI for Rent of Primary Residence.

Note: The cost weights are calculated using three decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

Because capital is acquired and paid for over time, capital expenses in any given year are determined by both past and present purchases of physical and financial capital. The proposed vintage-weighted 2023-based CIPI is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest.

Vintage weights are an integral part of the CIPI. Capital costs are inherently complicated and are determined by complex capital purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual nonvintage price changes for capital are unstable due to the volatility of interest rate changes and, therefore, do not reflect the actual annual price changes for IPPS capital costs. The CIPI reflects the underlying stability of the capital acquisition process.

To calculate the vintage weights for depreciation and interest expenses, we first needed a time series of capital purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital purchases by hospitals for all of the components of capital purchases previously noted. For the 2018-based CIPI, we calculated capital purchases using data on total expenses from the American Hospital Association (AHA) for the years 1964 through 2018 and the method was described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45210). The data from AHA are no longer available beyond 2020 and, therefore, for the 2023-based CIPI, we are proposing to use an alternative data source for deriving the capital purchases needed to calculate the vintage weights. Specifically, we are proposing to obtain a time series of building and fixed equipment acquisitions (that is, purchases) and movable equipment acquisitions using two different data sources. For the years 1996 through 2023, we are proposing to use data from Worksheet A–7 on the Medicare cost report as reported by IPPS hospitals (with the exception of 2002 through 2004 due to the temporary discontinuation of Worksheet A–7 from the Medicare cost report in those years). For the years 1977 through 1995 we are proposing to use the growth rates in the building and fixed equipment and movable equipment acquisitions derived using our previous method used for the 2018-based CIPI (based on AHA data) to extrapolate the levels from the Medicare cost report back in time. Below we provide the proposed steps for calculating capital acquisitions (that is, capital purchases) used to derive the vintage weights for the proposed 2023-based CIPI.

Step 1—We obtain data from Worksheet A–7 of the Medicare cost reports and apply basic trims. Specifically, for 1996 through 2010 we use the CMS Form 2552–96, OMB Control number 0938–0050 and for 2010 through 2023 we use the CMS Form 2552–10, OMB Control number 0938–0050 (where 2010 data were collected using both forms). Specific cost report references in this discussion are based on the CMS Form 2552–10, OMB Control number 0938–0050. For each of the years 1996 through 2001 and 2005 through 2023, we propose to apply a set of general trims based on data obtained from Worksheet A–7 requiring that total capital costs (sum of Worksheet A–7, part III, column 15, lines 1 and 2) are greater than zero; beginning values of building and fixed equipment (sum of Worksheet A–7, part I, column 1, lines 2 through 5) and movable equipment (sum of Worksheet A–7, part I, column 1, lines 6 and 7) are greater than zero; ending asset values of building and fixed equipment and movable equipment are greater than zero; building and fixed equipment depreciation is greater than zero; movable equipment depreciation is greater than zero; building and fixed equipment acquisitions are greater than zero; movable equipment acquisitions are greater than zero as well as total facility costs (Worksheet B, part I, column 26, line 202) are greater than zero.

In addition to these basic edits, we also propose to remove outliers in the data by trimming separately the top and bottom 1 percent building and fixed equipment useful lives and top and bottom 1 percent movable equipment useful lives. We first calculate the building and fixed equipment useful life and movable equipment useful life for each hospital for the years 1996 through 2001 and 2005 through 2023. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We propose to calculate the building and fixed equipment useful life as the ending value of fixed assets (sum of Worksheet

A–7, part I, column 6, lines 2 through 5, less sum of Worksheet A–7, part I, column 7, lines 2 through 5) divided by fixed asset depreciation (Worksheet A–7, part III, column 9, line 1). We propose to calculate the movable equipment useful life as the ending value of movable assets (sum of Worksheet A–7, part I, column 6, lines 6 through 7, less sum of Worksheet A–7, part I, column 7, lines 6 through 7) divided by movable depreciation (Worksheet A–7, part III, column 9, line 2). For the remaining hospitals (after applying the top and bottom 1 percent trim on useful lives), we obtain a time series of building and fixed equipment acquisitions (sum of Worksheet A–7, part I, columns 2 and 3, lines 2 through 5) and a time series of movable equipment acquisitions (sum of Worksheet A–7, part I, columns 2 and 3, lines 6 through 7).

Step 2—Due to the temporary discontinuation of Worksheet A–7 from the Medicare cost reports for the years 2002 through 2004, we need to derive the building and fixed equipment acquisitions and movable equipment acquisitions using a slightly different methodology. First, for each of the years 1996 through 2001 and 2005 through 2023 we calculate the annual ratio of the sum of building and fixed equipment acquisitions from Worksheet A–7 to the sum of building and fixed equipment ending asset values from Worksheet G. We next estimate these fixed ratios for 2002 through 2004 (when Worksheet A–7 data are not available) by straight-line interpolating the ratios between 2001 and 2005. Finally, we multiply these fixed ratios for 2002 through 2004 by the total ending building and fixed equipment asset values (as reported on Worksheet G). This results in an estimate of building and fixed equipment acquisitions for the years 2002 through 2004. We use this same methodology to derive movable equipment acquisitions using the movable equipment data. We note that the total ending asset values from Worksheet G are calculated after the application of a set of general trims (similar to those in Step 1) requiring total capital costs to be greater than zero and ending asset values of building and fixed equipment and movable equipment (as reported on Worksheet G) to be greater than zero.

Step 3—As done with prior vintage weights (including those used in the 2018-based CIPI), we propose to use a time series of capital acquisitions of more than 50 years in the derivation of the vintage weights. Since we only have Medicare cost report data back to 1996, we are proposing to derive capital acquisitions for the prior period based on the capital acquisitions used to derive the vintage weights for the 2018-based CIPI based on AHA data. Specifically, beginning with the 1996 acquisition level derived in Step 1 (first year of data available from the Medicare cost reports) we propose to apply the growth rate of acquisitions derived using the prior method going back to 1977. We do this separately for both building and fixed equipment acquisitions and movable equipment acquisitions.

As done in prior CIPI rebasings (including the 2018-based CIPI), in order to derive the proposed vintage weights, we need to calculate the average useful lives for building and fixed equipment and movable equipment based on the most recent Medicare cost report data. As previously described in Step 1, we propose to calculate the average building and fixed equipment useful life using 2023 Medicare cost report data as the ending asset value of building and fixed equipment (sum of Worksheet A–7, part I, column 6, lines 2 through 5, less sum of Worksheet A–7, part I, column 7, lines 2 through 5) divided by building and fixed equipment depreciation (Worksheet A–7, part III, column 9, line 1). We propose to calculate the average movable equipment useful life using 2023 Medicare cost report data as the ending asset value of movable equipment (sum of Worksheet A–7, part I, column 6, lines 6 through 7, less sum of Worksheet A–7, part I, column 7, lines 6 through 7) divided by movable equipment depreciation (Worksheet A–7, part III, column 9, line 2). Using this proposed method, we determined the average expected life of building and fixed equipment to be equal to 28 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe that vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note that the 2018-based CIPI was based on an expected average life of building and fixed equipment of 27 years and an expected average life of movable equipment of 12 years.

For the building and fixed equipment and movable equipment vintage weights, we are proposing to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount (as calculated in Steps 1 through 3) by the associated price proxy as provided earlier in this proposed rule. For the interest vintage weights, we are proposing to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital purchases time series specific to each asset type, we are proposing to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 28 years, and in the case of movable equipment, 12 years). For each asset type, we are proposing to use the time series of annual capital purchases amounts available from 1977 to 2023. These data allow us to derive twenty 28-year periods of capital purchases for building and fixed equipment and interest, and thirty-five 12-year periods of capital purchases for movable equipment. For each 28-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we are proposing to calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the entire 28-year or 12-year period. This calculation was done for each year in the 28-year or 12-year period and for each of the periods for which we have data. We then calculated the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data. This is the same methodology used for the 2018-based CIPI but using 27 years and 12 years and reflecting data through 2018.

The vintage weights for the proposed 2023-based CIPI and the 2018-based CIPI are presented in Table IV–10. While we are proposing an alternative methodology for calculating the vintage weights due to the discontinuation of AHA data, Table IV–10 shows this change had limited impact on the results. We note that using the proposed 2023-based vintage weights instead of the 2018-based vintage weights has a minimal impact on the overall CIPI update (averaging 0.0 percent over FY 2021 through FY 2026).

TABLE IV–10—PROPOSED 2023-BASED CIPI AND 2018-BASED CIPI VINTAGE WEIGHTS

Year [1]	Building and fixed equipment		Movable equipment		Interest	
	2018-based 27 years	Proposed 2023-based 28 years	2018-based 12 years	Proposed 2023-based 12 years	2018-based 27 years	Proposed 2023-based 28 years
1	0.026	0.024	0.064	0.066	0.015	0.014
2	0.028	0.025	0.069	0.069	0.016	0.016
3	0.029	0.026	0.072	0.072	0.018	0.017
4	0.031	0.027	0.075	0.075	0.019	0.018
5	0.032	0.028	0.078	0.079	0.021	0.020
6	0.032	0.029	0.082	0.082	0.022	0.021
7	0.033	0.030	0.086	0.085	0.023	0.022
8	0.034	0.030	0.088	0.089	0.026	0.024
9	0.036	0.031	0.091	0.092	0.028	0.025
10	0.036	0.031	0.095	0.094	0.029	0.026
11	0.036	0.032	0.099	0.097	0.029	0.028
12	0.036	0.033	0.101	0.100	0.031	0.030
13	0.037	0.034	.....	.....	0.033	0.031
14	0.038	0.035	.....	.....	0.036	0.033
15	0.039	0.036	.....	.....	0.039	0.035
16	0.040	0.037	.....	.....	0.041	0.037
17	0.041	0.038	.....	.....	0.044	0.039
18	0.042	0.039	.....	.....	0.046	0.041
19	0.041	0.039	.....	.....	0.047	0.043
20	0.041	0.040	.....	.....	0.049	0.045
21	0.042	0.041	.....	.....	0.052	0.047
22	0.042	0.042	.....	.....	0.053	0.049
23	0.042	0.043	.....	.....	0.055	0.051
24	0.042	0.044	.....	.....	0.055	0.053
25	0.041	0.046	.....	.....	0.057	0.056
26	0.041	0.047	.....	.....	0.058	0.058
27	0.041	0.047	.....	.....	0.059	0.060
28	.....	0.047	.....	.....	.....	0.062
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

[1] Vintage weight in the last year (for example, year 28 for the proposed 2023-based CIPI) is applied to the most recent data point and prior vintage weights are applied going back in time. For example, year 28 vintage weight would be applied to the 2026q3 fixed price proxy level, year 27 vintage weight would be applied to the 2025q3 fixed price proxy level, etc.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table IV–10 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found under the following CMS website link: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information* in the zip file titled ''Weight Calculations as described in the IPPS FY 2010 Proposed Rule.''

Table IV–11 in this section of this proposed rule compares both the historical and forecasted percent changes in the 2018-based CIPI and the proposed 2023-based CIPI. Over the most recent historical period, the proposed 2023-based CIPI increases at a slightly lower rate, on average, than the 2018-based CIPI primarily due to rebasing the CIPI from 2018 to 2023 and updating the base year cost weights.

TABLE IV–11—COMPARISON OF 2018-BASED AND PROPOSED 2023-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2021 THROUGH FY 2028

Fiscal year	CIPI, 2018-based	Proposed CIPI, 2023-based
Historical Data:		
FY 2021	1.0	0.8
FY 2022	2.0	1.8
FY 2023	3.0	2.8
FY 2024	2.8	2.7
Average FYs 2021–2024	2.2	2.0
Forecast:		
FY 2025	2.7	2.6
FY 2026	2.7	2.6
FY 2027	2.6	2.5
FY 2028	2.5	2.4

TABLE IV–11—COMPARISON OF 2018-BASED AND PROPOSED 2023-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2021 THROUGH FY 2028—Continued

Fiscal year	CIPI, 2018-based	Proposed CIPI, 2023-based
Average FYs 2025–2028	2.6	2.5

Source: IHS Global, Inc., 4th quarter 2024 forecast.

IHS Global, Inc. forecasts a 2.6 percent increase in the proposed 2023-based CIPI for FY 2026, as shown in Table IV–11. The underlying vintage-weighted price increases for depreciation (including building and fixed equipment and movable equipment) and interest (including government/nonprofit and for-profit) based on the proposed 2023-based CIPI are included in Table IV–12.

TABLE IV–12—PROPOSED 2023-BASED CAPITAL INPUT PRICE INDEX PERCENT CHANGES, TOTAL AND DEPRECIATION AND INTEREST COMPONENTS—FYS 2021 THROUGH 2028

Fiscal year	Total	Depreciation	Interest
Historical Data:			
FY 2021	0.8	1.8	−3.7
FY 2022	1.8	2.7	−2.8
FY 2023	2.8	3.3	−1.5
FY 2024	2.7	3.3	−1.1
Forecast:			
FY 2025	2.6	3.2	−0.8
FY 2026	2.6	3.2	−0.8
FY 2027	2.5	3.1	−1.0
FY 2028	2.4	3.0	−1.2

Source: IHS Global, Inc., 4th quarter 2024 forecast.

The FY 2026 percentage increase based on the proposed 2023-based CIPI is 0.1 percentage point lower than the increase based on the 2018-based CIPI when rounded, as shown in Table IV–11. Rebasing the CIPI from 2018 to 2023 and updating the base year cost weights lowered the FY 2026 update by approximately 0.1 percentage point, which was partially offset by the incorporation of the 2023-based vintage weights.

V. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2026 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals [211] that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the more commonly used method, is based on the hospital's disproportionate patient percentage (DPP), described below, under which the DSH payment adjustment is based a complex statutory formula which includes the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's DPP.

A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

DSH eligibility	Qualifying criteria
Statutory Formula	A hospital that has a disproportionate patient percentage equal to or exceeding 15 percent may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.

[211] See section 1886(d)(1)(B) of the Act for the definition of a ''subsection (d) hospital''.

DSH eligibility	Qualifying criteria
''Pickle Method''	A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. We refer to these provisions collectively as section 3133 of the Affordable Care Act. 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. This provision applies equally to hospitals that qualify for DSH payments on the basis of the hospital's DPP under section 1886(d)(5)(F)(i)(I) of the Act and those hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

Since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible for DSH payments under section 1886(d)(5)(F) of the Act receive 2 separately calculated payments:

Medicare DSH Payment: An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act.

Medicare DSH Uncompensated Care Payment: An uncompensated care payment determined as the product of 3 factors, as discussed in this section.

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress.[212] We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospitals an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. In other words, the first factor of the uncompensated care payment calculation is 75 percent of the payments that would otherwise be made as Medicare DSH payments under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, 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). As discussed in a later section, we note that the second factor is computed based on estimates of the total U.S population.

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data), including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.'' In brief, the uncompensated care payment for an individual hospital is determined as the product of the following 3 factors:

Factor 1: 75% of the total amount of DSH payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

Factor 2: 1 minus the percent change in the percent of individuals who are uninsured.

Factor 3: The hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that receive DSH payments, expressed as a percentage.

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies

[212] *https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/.*

for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act for FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under the regulations at 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or of the periods selected to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

The payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the empirically justified Medicare DSH payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to ''such subsection (d) hospitals'' the uncompensated care payment. Section 1886(r)(2)'s reference to ''such subsection (d) hospitals'' refers to hospitals that receive empirically justified Medicare DSH payments under section 1886(r)(1) for the applicable fiscal year.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we explained that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status (that is, eligibility to receive empirically justified Medicare DSH payments) for the applicable fiscal year (using the most recent data that are available). For this proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note that FY 2021 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing this proposed rule.[213] If more recent data on DSH eligibility becomes available before the final rule, we would use such data in the final rule.

Our final determinations of a hospital's eligibility for uncompensated care and empirically justified Medicare DSH payments will be based on the hospital's actual DSH status at cost report settlement for FY 2026.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemakings for subsequent fiscal years, we have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act. Eligible hospitals include the following:

- Subsection (d) Puerto Rico hospitals that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623 and 79 FR 50006).
- Sole community hospitals (SCHs) that are paid under the IPPS Federal rate receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the fiscal year (based on the best available data at that time) subject to settlement through the cost report. If they receive interim empirically justified Medicare DSH payments in a fiscal year, they will also be eligible to receive interim uncompensated care payments for that fiscal year on a per discharge basis. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).
- Medicare-dependent, small rural hospitals (MDHs) are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals. Recently enacted legislation has extended the MDH program through September 30, 2025. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program. We will continue to make a determination concerning an MDH's eligibility for interim empirically justified Medicare DSH and uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.
- IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model, will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments until the Model's final performance year, which ends on December 31, 2025. For further information regarding the BPCI Advanced model, we refer readers to the CMS website at *https://innovation.cms.gov/innovation-models/bpci-advanced*.
- Transforming Episode Accountability Model (TEAM) is a new episode-based payment model. Hospitals participating in TEAM would continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. The model's start date is January 1, 2026.

Ineligible hospitals include the following:

- Maryland hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1866(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland

[213] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

Total Cost of Care (TCOC) Model, which began on January 1, 2019. Under the Maryland TCOC Model, which concludes on December 31, 2026, Maryland hospitals are not paid under the IPPS and are ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

- SCHs that are paid under their hospital-specific rate are not eligible for Medicare DSH and uncompensated care payments (78 FR 50623 and 50624).
- Hospitals participating in the Rural Community Hospital Demonstration Program are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173).[214] The period of participation for the last hospital in the demonstration under this most recent legislative authorization will end on June 30, 2028. Under the payment methodology that applies during this most recent extension of the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are excluded from receiving interim and final uncompensated care payments. At the time of development of this proposed rule, we believe 16 hospitals may participate in the demonstration program at the start of FY 2026. We note that if at the time of developing the final rule there is a different number of hospitals projected to participate in the demonstration program during FY 2026, we would use updated information in the FY 2026 final rule.

C. Empirically Justified Medicare DSH Payments

As we have discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the Secretary to pay a designated percentage of these payments, without revising the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we did not believe that it was necessary to develop any new operational mechanisms for making such payments.

Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust subsection (d) hospitals' interim claim payments to an amount equal to 25 percent of what would have been paid if section 1886(r) of the Act did not apply. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments could be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule that are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html.*

D. Supplemental Payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income insured days as a proxy for uncompensated care costs for these hospitals and to prevent undue long-term financial disruption for these providers. The regulations located at 42 CFR 412.106(h) govern the supplemental payment. In brief, the supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g)(1). The base year amount is the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable fiscal year (that is, FY 2026 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a fiscal year is determined as the product of Factor 1 and Factor 2 for that year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

For FY 2026, we are not proposing any changes to the methodology for determining supplemental payments and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals consistent with the methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and § 412.106(h).

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the eligibility and payment processes for the supplemental payment are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH PPS final rule. We note that the MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

E. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of three factors, which are discussed in the next sections.

1. Proposed Calculation of Factor 1 for FY 2026

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. The regulations located at 42 CFR 412.106(g)(1)(i) govern the Factor 1 calculation. Under a prospective payment system, we would not know the precise aggregate Medicare DSH

[214] The Rural Community Hospital Demonstration Program was extended for a subsequent 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). The period of performance for this 5-year extension period ended on December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted on December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the demonstration program for an additional 5-year period.

payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, we would not know the precise aggregate empirically justified Medicare DSH payment amounts that would be paid for a fiscal year until cost report settlement for all IPPS hospitals is completed. Thus, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount. In brief, Factor 1 is the difference between the Secretary's estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year, in the absence of section 1886(r) of the Act; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act.

In this FY 2026 IPPS/LTCH PPS proposed rule consistent with the policy that has applied since the FY 2014 final rule (78 FR 50627 through 50631), we are determining Factor 1 from the most recently available estimates of the aggregate amount of Medicare DSH payments that would be made for FY 2026 in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments that would be made for FY 2026, both as calculated by CMS' Office of the Actuary (OACT). Consistent with the policy that has applied in previous years, these estimates will not be revised or updated subsequent to publication of our final projections in the FY 2026 IPPS/LTCH PPS final rule.

For this proposed rule, to calculate both estimates, we used the most recently available projections of Medicare DSH payments for the fiscal year, as calculated by OACT using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent DPPs and Medicare DSH payment adjustments provided in the IPPS Impact File. The projection of Medicare DSH payments for the fiscal year is also partially based on OACT's Part A benefits projection model, which projects, among other things, inpatient hospital spending. Projections of DSH payments additionally require projections of expected increases in utilization and case-mix. The assumptions that were used in making these inpatient hospital spending, utilization, and case-mix projections and the resulting estimates of DSH payments for FY 2023 through FY 2026 are discussed later in this section and in the table titled ''Factors Applied for FY 2023 through FY 2026 to Estimate Medicare DSH Expenditures Using FY 2022 Baseline.''

For purposes of calculating Factor 1 and modeling the impact of this FY 2026 IPPS/LTCH PPS proposed rule, we used OACT's January 2025 Medicare DSH estimates, which were based on data from the December 2024 update of the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2025 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the publication of the FY 2025 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are ineligible for empirically justified Medicare DSH payments and uncompensated care payments, they were excluded from the January 2025 Medicare DSH estimates. Because Maryland hospitals are not paid under the IPPS, they are also ineligible for empirically justified Medicare DSH payments and uncompensated care payments and were also excluded from OACT's January 2025 Medicare DSH estimates.

The 16 hospitals that CMS expects will participate in the Rural Community Hospital Demonstration Program in FY 2026 were also excluded from OACT's January 2025 Medicare DSH estimates because under the payment methodology that applies during the demonstration, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For this proposed rule, using the data sources previously discussed, OACT's January 2025 estimates of Medicare DSH payments for FY 2026 without regard to the application of section 1886(r)(1) of the Act is approximately $15.682 billion. Therefore, also based on OACT's January 2025 Medicare DSH estimates, the estimate of empirically justified Medicare DSH payments for FY 2026, with the application of section 1886(r)(1) of the Act, is approximately $3.92 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2026). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, in this proposed rule, we are determining that Factor 1 for FY 2026 would be $11.761 billion, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2026 ($15.682 billion minus $3.92 billion). We note that consistent with our 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 2026 IPPS/LTCH PPS final rule.

We note that the Factor 1 estimates for IPPS/LTCH PPS proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and Factor 1 estimates for IPPS/LTCH PPS final rules are generally consistent with those used for the Midsession Review of the President's Budget.[215] Consistent with historical practice, we expect the Midsession Review will have updated economic assumptions and actuarial analysis, which will be used for the development of Factor 1 estimates in the FY 2026 IPPS/LTCH PPS final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2024 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available on the CMS website at *https://www.cms.gov/oact/tr/2024*.[216] The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by OACT's actuaries in determining our estimate of Factor 1. In summary, we indicate the historical HCRIS data update OACT used to estimate Medicare DSH payments; we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with

[215] As we have in the past, for additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget*.

[216] We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program.

the associated rationale and assumptions. The discussion also includes descriptions of the ''Other'' and ''Discharges'' assumptions.

OACT's estimates for FY 2026 for this proposed rule began with a baseline of $13.018 billion in Medicare DSH expenditures for FY 2022. The following table shows the factors applied to update this baseline through the current estimate for FY 2026:

FACTORS APPLIED FOR FY 2023 THROUGH FY 2026 TO ESTIMATE MEDICARE DSH EXPENDITURES USING FY 2022 BASELINE

FY	IPPS hospital market basket update factor	Discharges	Case-mix	Other	Total	Estimated DSH payment (in billions) *
2023	1.043	0.994	0.990	1.0504	1.0784	14.038
2024	1.031	0.998	0.997	1.0310	1.0573	14.842
2025	1.029	0.991	1.005	0.9976	1.0228	15.180
2026 **	1.024	0.999	1.005	1.0048	1.0331	15.682

* Rounded.
** The FY 2026 figures reflect the proposed inpatient hospital market basket percentage increase and productivity adjustment and are based on the 4th quarter 2024 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this proposed rule.

In this table, the discharges column shows the changes in the number of Medicare FFS inpatient hospital discharges. The discharge figures for FY 2023 and FY 2024 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. The discharge figures for FY 2025 and FY 2026 are assumptions based on recent historical experience and assumptions related to how many beneficiaries will be enrolled in MA plans.

The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2023 and FY 2024 are based on actual claims data adjusted by a completion factor to account for incomplete claims data. The case-mix figures for FY 2025 and for FY 2026 are assumptions based on the 2012 ''Review of Assumptions and Methods of the Medicare Trustees' Financial Projections'' report by the 2010–2011 Medicare Technical Review Panel.[217]

The ''Other'' column reflects the change in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns. In addition, the ''Other'' column includes a factor for the estimated changes in Medicaid enrollment through FY 2023.

The following table shows the factors that are included in the ''IPPS Hospital Market Basket Update Factor'' column of the previous table:

FY	IPPS hospital market basket percentage increase	Productivity adjustment	Documentation and coding	Total update percentage
2023	4.1	0.3	0.5	4.3
2024	3.3	0.2	0.0	3.1
2025	3.4	0.5	0.0	2.9
2026	3.2	0.8	0.0	2.4

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year, except for the FY 2026 figures. The FY 2026 figures reflect the proposed inpatient hospital market basket percentage increase and productivity adjustment and are based on the 4th quarter 2024 IGI forecast, the most recent forecast available at the time of development of this proposed rule. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion of the inpatient hospital market basket update for FY 2026.

We are inviting public comments on our proposed Factor 1 for FY 2026.

IV. Proposed Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2026 (§ 412.106)

2. Calculation of Proposed Factor 2 for FY 2026

a. Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, 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).

We are continuing to use the methodology that was used in FY 2018 through FY 2025 to determine Factor 2 for FY 2026—to use the National Health Expenditure Accounts (NHEA) data to determine the percent change in the percent of individuals who are uninsured. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198) for a complete discussion of the NHEA and why we determined, and continue to believe, that it is the data source for the rate of uninsurance that, on balance, best meets all our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate.

[217] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf.*

In brief, the NHEA represents the government's official estimates of economic activity (spending) within the health sector. The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct-purchase and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

To compute Factor 2 for FY 2026, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. For a complete discussion of the approach OACT used to prepare the NHEA's estimate of the rate of uninsurance in 2013, including the data sources used, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58998–58999).

The next metrics needed to compute Factor 2 for FY 2026 are projections of the rate of uninsurance in both CY 2025 and CY 2026 for the total U.S. population. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2023 through 2032 and were published on June 12, 2024. Those projections used the latest NHEA historical data that were available at the time of their construction (that is, historical data through 2022). The NHEA projection methodology accounts for expected changes in enrollment across all of the categories of insurance coverage previously listed. For a complete discussion of how the NHEA data account for expected changes in enrollment across all the categories of insurance coverage previously listed, we refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 58999).

b. Proposed Factor 2 for FY 2026

Using these data sources and the previously described methodologies, at the time of developing this proposed rule, OACT has estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent, and that the uninsured rates for CYs 2025 and 2026 were 7.7 percent and 8.7 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this FY 2026 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance.[218]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we use a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, in order to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, in this FY 2026 IPPS/LTCH PPS proposed rule, we are continuing to apply the weighted average approach used in past fiscal years to estimate this proposed rule's rate of uninsurance for FY 2026.

OACT certified the estimate of the rate of uninsurance for FY 2026 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. We note that we may also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2026. The calculation of the proposed Factor 2 for FY 2026 is as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2025: 7.7 percent.
- Percent of individuals without insurance for CY 2026: 8.7 percent.
- Percent of individuals without insurance for FY 2026: (0.25 times 0.077) + (0.75 times 0.087) = 8.5 percent.
- FY 2026's proposed Factor 2 is calculated as 1 minus the percent change in the percent of individuals without insurance between CY 2013 and FY 2026.
- Proposed Factor 2 is as follows: $1-|((0.14-0.085)/0.14)| = 1-0.3929 = 0.6071$.

We are proposing that Factor 2 for FY 2026 would be 60.71 percent.

The proposed FY 2026 uncompensated care amount is equivalent to proposed Factor 1 multiplied by proposed Factor 2, which is $7,140,406,650.

We are inviting public comments on our proposed Factor 2 for FY 2026.

3. Calculation of Proposed Factor 3 for FY 2026

a. General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, 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. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary for us to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based

[218] *https://www.cms.gov/files/document/certification-rates-uninsured-2026-proposed-rule.pdf.*

on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. For a discussion of the methodology, we used to calculate Factor 3 for fiscal years 2014 through 2022, we refer readers to the FY 2024 IPPS/LTCH final rule (88 FR 59001 and 59002).

b. Background on the Methodology Used To Calculate Factor 3 for FY 2024 and Subsequent Years

Section 1886(r)(2)(C) of the Act governs the selection of the data to be used in calculating Factor 3 and allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50634 through 50647), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments for a fiscal year and for those hospitals that we do not estimate will qualify for Medicare DSH payments for that fiscal year but that may ultimately qualify for Medicare DSH payments for that fiscal year at the time of cost report settlement.

As described in the FY 2022 IPPS/LTCH PPS final rule, commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of historical data from Worksheet S–10 data of the Medicare cost report (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, we stated that we would consider using multiple years of data when the vast majority of providers had been audited for more than 1 fiscal year under the revised reporting instructions. Audited FY 2020 cost reports were available for the development of the FY 2024 IPPS/LTCH PPS proposed and final rules. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2020 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49036 through 49047), we finalized a policy of using a multi-year average of audited Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years. We explained our belief that this approach would be generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Under this policy, we used a 2-year average of audited FY 2018 and FY 2019 Worksheet S–10 data to calculate Factor 3 for FY 2023. We also indicated that we expected FY 2024 would be the first year that 3 years of audited data would be available at the time of rulemaking. For FY 2024 and subsequent fiscal years, we finalized a policy of using a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, if a hospital does not have data for all 3 years used in the Factor 3 calculation, we will determine Factor 3 based on an average of the hospital's available data. For IHS and Tribal hospitals and Puerto Rico hospitals, we use the same multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2024 and subsequent fiscal years as is used to determine Factor 3 for all other DSH-eligible hospitals (in other words, hospitals eligible to receive empirically justified Medicare DSH payments for a fiscal year) to determine Factor 3.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49033 through 49047), we also modified our policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent fiscal year to determine uncompensated care costs for the subsequent fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we finalized our proposal to use the hospital's most recent prior cost report, if that cost report spans the applicable period.[219]

(1) Scaling Factor

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) to address the effects of calculating Factor 3 using data from multiple fiscal years, in which we apply a scaling factor to the Factor 3 values calculated for all DSH-eligible hospitals so that total uncompensated care payments to hospitals that are projected to be DSH-eligible for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Pursuant to that policy, we divide 1 (the expected sum of all DSH-eligible hospitals' Factor 3 values) by the actual sum of all DSH-eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH-eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH-eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year.

(2) New Hospital Policy for Purposes of Factor 3

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69323), we continued our new hospital policy that was modified in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) and initially adopted in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370 through 42371) to determine Factor 3 for new hospitals. Consistent with our policy of using

[219] For example, in determining Factor 3 for FY 2023, we did not use the same cost report to determine a hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we used the cost report that spanned the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and used the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spanned some portion of FY 2018.

multiple years of cost reports to determine Factor 3, we defined new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Under this definition, the cut-off date for the new hospital policy is the beginning of the fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2026, the FY 2022 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CMS Certification Numbers (CCNs) established on or after October 1, 2022, would be subject to the new hospital policy for FY 2026.

Under our modified new hospital policy, if a new hospital has a preliminary projection of being DSH-eligible based on its most recent available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments because we would have no uncompensated care data on which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement. In FY 2025, while we continued to determine the numerator of the Factor 3 calculation using the new hospital's uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the current fiscal year, we determined Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. In addition, we applied a scaling factor to the Factor 3 calculation for a new hospital.[220]

(3) Newly Merged Hospital Policy

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we continued our policy of treating hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021 and 50022), we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals.

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 690323 through 690324), we stated that we would continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the methodology used to determine Factor 3 for new hospitals described in section IV.E.3. of the preamble of this proposed rule, we continued our policy for determining Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we apply a scaling factor, as discussed in section IV.E.3. of the preamble of this proposed rule, to the Factor 3 calculation for a newly merged hospital. In the FY 2025 IPPS/LTCH PPS final rule, we explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital would be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule.

(4) CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we continued the policy of trimming CCRs, which we adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49043), for FY 2025. Under this policy, we apply the following steps to determine the applicable CCR separately for each fiscal year that is included as part of the multi-year average used to determine Factor 3:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including hospitals that are not DSH-eligible), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including hospitals that are not DSH-eligible), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling'').

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in step 3.

After completing these steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

(5) Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant uncompensated

[220] In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we explained our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, to improve consistency and predictability across all hospitals.

care costs (UCC) that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for any fiscal year that is included as a part of the multi-year average are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year.[221]

However, we note that we have audited the Worksheet S–10 data that will be used in the Factor 3 calculation for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, as we explained in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), we determined it is unnecessary to apply the UCC trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In rare cases, hospitals that are not currently projected to be DSH-eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324 through 69325), we stated that in addition to the UCC trim methodology, we will continue to apply an alternative trim specific to certain hospitals that do not have audited Worksheet S–10 data for one or more of the fiscal years that are used in the Factor 3 calculation. For FY 2023 and subsequent fiscal years, in the rare case that a hospital's insured patients' charity care costs for a fiscal year are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we will not calculate a Factor 3 for the hospital at the time of proposed or final rulemaking. This trim will only impact hospitals that are not currently projected to be DSH-eligible; and therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for hospitals projected to be DSH-eligible. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we will apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69324), we also stated that we would continue to use a threshold of 3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continued to believe these thresholds are appropriate to address potentially aberrant data. We also continued to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our policy finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051). In addition, we continued our policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044) of applying the same threshold amounts originally calculated for the FY 2019 reports to identify potentially aberrant data for FY 2025 and subsequent fiscal years to facilitate transparency and predictability. If a hospital subject to this trim is determined to be DSH-eligible at cost report settlement, the MAC will calculate the hospital's Factor 3 using the same methodology used to calculate Factor 3 for new hospitals.

c. Methodology for Calculating Factor 3 for FY 2026

For FY 2026, consistent with § 412.106(g)(1)(iii)(C)(*11*), we are following the same methodology as applied in FY 2024 and described in the previous section of the preamble of this proposed rule to determine Factor 3 using the most recent 3 years of audited cost reports, from FY 2020, FY 2021, and FY 2022. Consistent with our approach for FY 2025, for FY 2026, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this proposed rule. For purposes of the FY 2026 IPPS/LTCH PPS proposed rule, we are using reports from the December 2024 HCRIS extract to calculate Factor 3. We intend to use the March 2025 update of HCRIS to calculate the final Factor 3 for the FY 2026 IPPS/LTCH PPS final rule.

Thus, for FY 2026, we will use 3 years of audited Worksheet S–10 Part 1 data to calculate Factor 3 for all eligible hospitals, including IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013, following the below steps. We note that we are clarifying in these steps our use of Worksheet S–10, Part I, rather than Worksheet S–10, Part II, to calculate Factor 3.

Step 1: Select the hospital's longest cost report for each of the most recent 3 years of fiscal year (FY) audited cost reports (FY 2020, FY 2021, and FY 2022). Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous fiscal year spanned the more recent fiscal year, the previous fiscal year cost report will be used in this step. In the rare case that using a previous fiscal year cost report results in a period without a report, we would use the prior year report, if that cost report spanned the applicable period.[222] In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost report that spans the relevant fiscal year.

Step 2: Annualize the UCC from Worksheet S–10, Part I, Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for all DSH-eligible hospitals using annualized uncompensated care costs (Worksheet S–10, Part I, Line 30) based on cost report data from the most recent 3 years

[221] For example, if a hospital's FY 2018 cost report is determined to include potentially aberrant data, data from its FY 2019 cost report would be used for the ratio calculation.

[222] For example, if a hospital does not have a FY 2020 cost report because the hospital's FY 2019 cost report spanned the FY 2020 time period, we will use the FY 2019 cost report that spanned the FY 2020 time period for this step. Using the same example, where the hospital's FY 2019 report is used for the FY 2020 time period, we will use the hospital's FY 2018 report if it spans some of the FY 2019 time period. We will not use the same cost report for both the FY 2020 and the FY 2019 time periods.

of audited cost reports (from Step 1, 2 or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply by a scaling factor, as discussed in the previous section of the preamble of this proposed rule.

As we explained previously in this section, for FY 2026, we are also applying the scaling factor, new hospital, newly merged hospital, CCR trim methodology, UCC trim, and alternative trim methodology policies discussed in the previous section of the preamble of this proposed rule. For a hospital that is subject to either of the trims for potentially aberrant data (the UCC trim and alternative trim methodology explained in the previous section of the preamble of this proposed rule) and is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment will be calculated only after the hospital's reporting of insured charity care costs on its FY 2026 Worksheet S–10 has been reviewed. Accordingly, the MAC will calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2026 cost report. Then we will calculate Factor 3 for the hospital using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator will reflect the uncompensated care costs reported on the hospital's FY 2026 cost report, while the denominator will reflect the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2022 cost reports of all DSH-eligible hospitals. In addition, we will apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital.

Under the CCR trim methodology, for purposes of this proposed rule, the statewide average CCR was applied to 8 hospitals' FY 2020 reports, of which 2 hospitals had FY 2020 Worksheet S–10 data. The statewide average CCR was applied to 10 hospitals' FY 2021 reports, of which 4 hospitals had FY 2021 Worksheet S–10 data. The statewide average CCR was applied to 8 hospitals' FY 2022 reports, of which 2 hospitals had FY 2022 Worksheet S–10 data.

For purposes of the FY 2026 IPPS/LTCH PPS final rule, consistent with our Factor 3 methodology since the FY 2014 IPPS/LTCH PPS final rule (78 FR 50642), we intend to use data from the March 2025 HCRIS extract for this calculation, which would be the latest quarterly HCRIS extract that is publicly available at the time of the development of the FY 2026 IPPS/LTCH PPS final rule.

Regarding requests from providers to amend and/or reopen previously audited Worksheet S–10 data for the most recent 3 cost reporting years that are used in the methodology for calculating Factor 3, we note that MACs follow normal timelines and procedures. For purposes of the Factor 3 calculation for the FY 2026 IPPS/LTCH PPS final rule, any amended reports and/or reopened reports would need to have completed the amended report and/or reopened report submission processes by the end of March 2025. In other words, if the amended report and/or reopened report is not available for the March HCRIS extract, then that amended and/or reopened report data would not be part of the FY 2026 IPPS/LTCH PPS final rule's Factor 3 calculation. We note that the March HCRIS data extract will be available during the comment period for this proposed rule if providers want to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

d. Per-Discharge Amount of Interim Uncompensated Care Payments for FY 2026

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per-discharge basis. Typically, we use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69328–69329), we finalized a policy to use a 3-year average of the most recent years of available historical discharge data to calculate a per-discharge payment amount that would be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2026 and subsequent fiscal years, codified at 42 CFR 412.106(i)(1). We are applying this policy for FY 2026. Interim uncompensated care payments made to a hospital during the fiscal year are reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the fiscal year.

As we explained in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69329 through 69330), we also finalized a voluntary process in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), through which a hospital may submit a request to its MAC for a lower per-discharge interim uncompensated care payment amount, including a reduction to zero, once before the beginning of the fiscal year and/or once during the fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment at cost report settlement if the per-discharge amount is not lowered (for example, recoupment of 10 percent or more of the hospital's total uncompensated care payment, or at least $100,000). For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per-discharge uncompensated care payment amount. As another example, a hospital might request that its per-discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 through 58834), the hospital's MAC will evaluate these requests and the supporting documentation before the beginning of the fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected discharges for the current fiscal year. If, following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per-discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per-discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the fiscal year. We are continuing to

apply this policy for FY 2026. We refer readers to the Addendum in the FY 2023 IPPS/LTCH final rule for a more detailed discussion of the steps for determining the operating and capital Federal payment rate and the outlier payment calculation (87 FR 49431 through 49432). No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per-discharge uncompensated care payment amount will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

e. Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this proposed rule, we will publish on the CMS website a table listing Factor 3 for hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2026 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We will also publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 8 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals have 60 days from the date of public display of the FY 2026 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with this proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process.[223] Comments raising issues or concerns that are specific to the information included in the table and supplemental data file should be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We will address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2026 IPPS/LTCH PPS final rule. All other comments submitted in response to our proposals for FY 2026 must be submitted in one of the three ways found in the **ADDRESSES** section of the proposed rule before the close of the comment period in order to be assured consideration. In addition, we note that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

VI. Other Proposed Decisions and Changes to the IPPS for Operating Costs

A. Proposed Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to (Fixed-Loss Outlier threshold for Nontransfer Cases adjusted for geographic variations in costs/Geometric Mean Length of Stay for the MS–DRG) * (Length of Stay for the Case plus 1 day).

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute at subparagraph 1886(d)(5)(J) of the Act directs CMS to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6))). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4

[223] For example, if the report does not reflect audit results due to MAC mishandling, or the most recent report differs from a previously accepted, amended report due to MAC mishandling.

days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018, as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment.

2. Proposed Changes for FY 2026

As discussed in the preamble of this proposed rule, based on our analysis of FY 2024 MedPAR claims data, CMS proposed to make changes to a number of MS–DRGs, effective for FY 2026. Specifically, we are proposing the following changes:

- Adding ICD–10–PCS codes describing restriction and replacement of the thoracic aorta, and bypass and occlusion of the subclavian and carotid arteries, to proposed new MS–DRG 209 (Complex Aortic Arch Procedures).
- Adding ICD–10–PCS codes describing restriction of the abdominal aorta and restriction of the iliac artery to proposed new MS–DRG 213 (Endovascular Abdominal Aorta with Iliac Branch Procedures).
- Reassigning ICD–10–PCS codes describing extirpation of matter from coronary arteries to proposed new MS–DRG 318 (Percutaneous Coronary Atherectomy without Intraluminal Device).
- Reassigning ICD–10–PCS codes describing extirpation of matter from coronary arteries and adding ICD–10–PCS codes describing dilation of coronary arteries and insertion of an intraluminal or other device to proposed new MS–DRGs 359 and 360 (Percutaneous Coronary Atherectomy with Intraluminal Device with MCC and without MCC, respectively).
- Adding ICD–10–CM diagnosis codes describing periprosthetic joint infection and ICD–10–PCS procedure codes describing hip or knee procedures to proposed new MS–DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively).
- Deleting MS–DRGs 294 and 295 (Deep Vein Thrombophlebitis with CC/MCC and without CC/MCC, respectively) and reassigning the ICD–10–CM codes to MS–DRGs 299, 300, and 301 (Peripheral Vascular Disorders with MCC, with CC, and without CC/MCC, respectively).
- Deleting MS–DRG 509 (Arthroscopy) and reassigning the ICD–10–PCS codes describing inspection of various anatomic sites to their respective clinically appropriate MS–DRGs.
- Adding ICD–10–CM diagnosis codes describing the insertion of a radioactive element into the brain to MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator).

When proposing changes to MS–DRGs that involve adding, deleting, and reassigning procedure or diagnosis codes between proposed new and revised MS–DRGs, we continue to believe it is necessary to evaluate the affected MS–DRGs to determine whether they should be subject to the postacute care transfer policy. Considering the proposed changes to the MS–DRGs for FY 2026, according to the regulations under § 412.4(d), we evaluated the proposed new MS–DRGs using the general postacute care transfer policy criteria and data from the FY 2024 MedPAR file. We continue to believe it is appropriate to assess new MS–DRGs and reassess revised MS DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS DRG. We evaluated any current MS–DRGs if we estimate that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs, or to a current MS–DRG from a proposed revised or deleted MS–DRG.

For existing MS–DRGs 321 and 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ arteries/intraluminal devices, and without MCC, respectively), we determined that more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs 359 and 360. We also determined that for MS–DRGs 463, 464, and 465 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC, with CC, and without MCC/CC, respectively), more than 5 percent of the current cases would shift from the current assigned MS–DRGs to proposed new MS–DRGs 403 and 404. We note that for all other proposed changes, the relative volume of cases shifting to or from current MS–DRGs does not exceed the 5 percent threshold.

If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6).

We note that proposed new MS–DRGs 403 and 404 would qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We therefore are proposing to add proposed new MS–DRGs 403 and 404 to the list of MS–DRGs that are subject to the postacute care transfer policy.

We note that MS–DRGs 463, 464 and 465 are currently subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy.

Using the December 2024 update of the FY 2024 MedPAR file, we have developed the following chart which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS–DRGs. For the FY 2026 final rule, we intend to update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2026

Proposed new or revised MS–DRG	MS–DRG title	Total cases	Postacute care transfer cases (55th percentile: 1,028)	Short-stay postacute care transfer cases	Percent of shortstay postacute care transfers to all cases (55th percentile: 9.654%)	FY 2025 postacute transfer policy status	Proposed postacute care transfer policy status
209	Complex Aortic Arch Procedures	334	*181	34	10.2%	New	No.
213	Endovascular Abdominal Aorta with Iliac Branch Procedures	1,163	*185	0	*0	New	No.
318	Percutaneous Coronary Atherectomy without Intraluminal Device.	915	*164	7	*0.8	New	No.
359	Percutaneous Coronary Atherectomy with Intraluminal Device with MCC.	3,027	*876	65	*2.2	New	No.
360	Percutaneous Coronary Atherectomy with Intraluminal Device without MCC.	3,934	*398	36	*0.9	New	No.
321	Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ arteries/intraluminal devices.	30,850	8710	798	*2.6	No	No.
322	Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC.	46,159	4254	0	*0	No	No.
403	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC.	1,250	1071	494	39.5	New	Yes.
404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC.	2,400	1995	682	28.4	New	Yes.
463	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC.	3,477	2865	1244	35.8	Yes	Yes.
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC.	4,959	3714	1124	22.7	Yes	Yes.
465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without CC/MCC.	1,357	*688	0	*0	Yes	Yes.**

*Indicates a current postacute 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 postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

During our annual review of proposed new or revised MS–DRGs and analysis of the December 2024 update of the FY 2024 MedPAR file, we reviewed the list of proposed revised or new MS–DRGs that qualify to be included on the list of MS–DRGs subject to the postacute care transfer policy for FY 2026 to determine if any of these MS–DRGs would also be subject to the special payment methodology policy for FY 2026.

Based on our analysis of the proposed changes to the MS–DRGs included in the proposed rule, we determined that proposed new and revised MS–DRGs 404 and 464 meet the criteria for the MS–DRG special payment methodology. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we are proposing that MS–DRGs 403, 404, 463, 464, and 465 would be subject to the MS–DRG special payment methodology, effective for FY 2026. For the FY 2026 final rule, we intend to update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS–DRGS SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2026

Proposed new or revised MS–DRG	MS–DRG title	Geometric mean length of stay	Average charges of 1-day discharges	50 Percent of average charges for all cases within MS–DRG	FY 2025 special payment policy status	Proposed special payment policy status
403	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC.	10.57	$0	$130,572	New	Yes.*
404	Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection without MCC.	5.58	87,126	72,946	New	Yes.
463	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with MCC.	10.58	58,384	114,609	No	Yes.*
464	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders with CC.	5.40	71,548	68,604	No	Yes.
465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders without MCC/CC.	1.97	69,981	44,134	No	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.

B. Proposed Changes in the Inpatient Hospital Update for FY 2026 (§ 412.64(d))

1. Proposed FY 2026 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2026, we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2025. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2026 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of 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) in accordance with section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

As published in the FY 2006 IPPS final rule (70 FR 47403), in accordance with section 404 of Public Law 108–173, CMS determined a new frequency for rebasing the hospital market basket of every 4 years. In compliance with section 404 of Public Law 108–173, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022. Consistent with our established frequency of rebasing the IPPS market basket every 4 years, in this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing to rebase and revise the IPPS market basket to a 2023 base year, effective beginning in FY 2026.

We are proposing to base the FY 2026 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2024, which is estimated to be 3.2 percent. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2026 market basket update in the final rule.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, calendar year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment, to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2026, we are proposing a productivity adjustment of 0.8 percent. Similar to the proposed market basket rate-of-increase, for this proposed rule, the estimate of the proposed FY 2026 productivity adjustment is based on IGI's fourth quarter 2024 forecast. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2026 productivity adjustment for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2026, as specified in the following table:

TABLE VI.B–01—PROPOSED FY 2026 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2026	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	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.8	−0.8

TABLE VI.B–01—PROPOSED FY 2026 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS—Continued

FY 2026	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 Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.4	0.0	−2.4
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.4	0.0	1.6	−0.8

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment.

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section V.F. of the preamble of this proposed rule, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program. We note that if the MDH program were to be extended by law into FY 2026, the proposed updates to the hospital-specific rates for SCHs as described in this section would also apply to the hospital-specific rates for MDHs for FY 2026.

For FY 2026, we are proposing the following updates to the hospital-specific rates applicable to SCHs: A proposed update of 2.4 percent for a hospital that submits quality data and is a meaningful EHR user (as defined in section 1886(n) of the Act); a proposed update of 0.0 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 1.6 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.8 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. As previously discussed, we are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the market basket update and the productivity adjustment in the final rule.

2. Proposed FY 2026 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2026, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to 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 Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket update with historical data through third quarter 2024, for this FY 2026 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing a market basket update of 3.2 percent less a productivity adjustment of 0.8 percentage point. Therefore, for FY 2026, depending on whether a Puerto

Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2026 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing a FY 2026 applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2026 estimate of the proposed market basket rate-of-increase of 3.2 percent less 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing a FY 2026 applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2026 estimate of the proposed market basket rate-of-increase of 3.2 percent, less an adjustment of 2.4 percentage points (the proposed market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and less 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2026 market basket update and the productivity adjustment for the FY 2026 IPPS/LTCH PPS final rule.

TABLE VI.B–02—PROPOSED FY 2026 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS UNDER THE IPPS

FY 2026	Hospital is a meaningful EHR user	Hospital is NOT a meaningful EHR user
Proposed Market Basket Rate-of-Increase	3.2	3.2
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.4
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.4	0.0

C. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at 42 CFR 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173) raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of the Balanced Budget Act of 1997 (Pub. L. 105–33) states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999 through 46000), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000, IPPS final rule (65 FR 47087), we indicated that we were revisiting that decision. Specifically, we stated that we would permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (42 CFR 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to 42 CFR 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- 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
- 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 per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at 42 CFR 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at 42 CFR 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations 42 CFR 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment

rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at 42 CFR 412.96(c)(1)(ii). The proposed national median CMI value for FY 2026 is based on the CMI values of all urban hospitals nationwide, and the proposed regional median CMI values for FY 2026 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in 42 CFR 413.75). These proposed values are based on discharges occurring during FY 2024 (October 1, 2023, through September 30, 2024), and include bills posted to CMS' records through December 2024. We believe that this is the best available data for use in calculating the proposed national and regional median CMI values and is consistent with our proposal to use of the FY 2024 MedPAR claims data for FY 2026 ratesetting.

In this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing that, in addition to meeting other criteria, 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, 2025, they must have a CMI value for FY 2024 that is at least—

- 1.7802 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in 42 CFR 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region are set forth in the following table. We intend to update the proposed CMI values in the FY 2026 IPPS/LTCH PPS final rule to reflect the updated FY 2024 MedPAR file, which will contain data from additional bills received through March 2025.

Region	Proposed case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.499
2. Middle Atlantic (PA, NJ, NY)	1.56165
3. East North Central (IL, IN, MI, OH, WI)	1.6175
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.73965
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.635
6. East South Central (AL, KY, MS, TN)	1.5901
7. West South Central (AR, LA, OK, TX)	1.78085
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.8092
9. Pacific (AK, CA, HI, OR, WA)	1.7793

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

2. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. For FY 2026, we are proposing to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2023 (that is, October 1, 2022, through September 30, 2023), which are the latest cost report data available at the time this proposed rule was developed. We believe that this is the best available data for use in calculating the proposed median number of discharges by region and is consistent with our data proposal to use cost report data from cost reporting periods beginning during FY 2023 for FY 2026 rate setting. Therefore, we are proposing that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2025, must have, as the number of discharges for its cost reporting period that began during FY 2023, 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. We refer readers to the proposed number of discharges as set forth in the following table. We intend to update these numbers in the FY 2026 final rule based on the latest available cost report data.

Region	Proposed number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,903
2. Middle Atlantic (PA, NJ, NY)	9,844
3. East North Central (IL, IN, MI, OH, WI)	7,762
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,614
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,919
6. East South Central (AL, KY, MS, TN)	8,315
7. West South Central (AR, LA, OK, TX)	5,911
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,048
9. Pacific (AK, CA, HI, OR, WA)	8,932

We note 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)

1. Background

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The low-volume hospital payment adjustment is implemented in the regulations at 42 CFR 412.101. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in addition to any payment calculated under section 1886 of the Act and is based on the per discharge amount paid to the qualifying hospital. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment. The payment adjustment for low-volume hospitals is not budget neutral.

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69348 through 69352), Section 306 of the Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS, that is the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12), through December 31, 2024. Section 3201 of the American Relief Act, 2025 (Pub. L. 118–158), further extended those temporary changes through March 31, 2025. Most recently, section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4), enacted on March 15, 2025, provides an extension of those temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals through September 30, 2025. Absent further Congressional action, beginning October 1, 2025, the low-volume hospital qualifying criteria and payment adjustment are set to 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 and discussed later in this section, will resume. We discuss the payment policies for FY 2026, in section V.D.3. of the preamble of this proposed rule.

TABLE V.D.–01—LOW-VOLUME HOSPITAL QUALIFYING CRITERIA AND PAYMENT ADJUSTMENT FOR FYS 2019 AND SUBSEQUENT FYS

Fiscal years	Road miles	Total discharges	Payment adjustment
2019 through 2025	>15	≤500	0.25.
		>500 <3,800	0.25 − [0.25/3300] × (number of total discharges − 500) = (95/330) − (number of total discharges/13,200).
2026 and subsequent years	>25	<200	0.25.

2. Extension of Temporary Changes to Low-Volume Hospital Payment Definition and Payment Adjustment Methodology and Conforming Changes to Regulations

As discussed previously, prior to the enactment of the American Relief Act, 2025, the temporary changes to the low-volume hospital qualifying criteria and payment adjustment provided by section 306 of CAA, 2024 were set to expire on January 1, 2025. Section 3201 of the American Relief Act, 2025 extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for the portion of FY 2025 beginning on January 1, 2025, and ending on March 31, 2025 (that is, for discharges occurring before April 1, 2025). We note that we address the extension provided by section 3201 of the American Relief Act, 2025, in Change Request 13949 (Transmittal 13035), issued January 6, 2025. For additional information, please refer to the transmittal *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13035otn.* Subsequently, section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 further extended the temporary changes to the low-volume hospital qualifying criteria and payment adjustment under the IPPS for the remainder of FY 2025 (that is, for discharges occurring before October 1, 2025). We note the extension provided by section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 will be addressed in forthcoming guidance.

Under section 1886(d)(12)(C)(i) of the Act, as amended by the Full-Year Continuing Appropriations and Extensions Act, 2025, for FYs 2019 through FY 2025, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. In accordance with the existing regulations at § 412.101(a), we define the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1). Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through 2025, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), we specified a continuous, linear sliding scale formula to determine the low volume payment adjustment, as reflected in the regulations at § 412.101(c)(3)(ii). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. For qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment is calculated using the formula at § 412.101(c)(3)(ii) (which

is shown in the Table V.D.–01). For this purpose, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges). The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low volume payment adjustment in the current year (§ 412.101(b)(2)(iii)). The low-volume hospital payment adjustment for FYs 2019 through 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024, is set forth in the current regulations at § 412.101(c)(3).

In this proposed rule, we propose to make conforming changes to the regulation text in § 412.101 to reflect the extensions of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals in accordance with provisions of the American Relief Act, 2025 and the Full-Year Continuing Appropriations and Extensions Act, 2025. Specifically, we propose to make conforming changes to paragraphs (b)(2)(iii) and (c)(3) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect through FY 2025 is the same low-volume hospital payment adjustment policy in effect for FYs 2019 through December 31, 2024 (as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399) and in the FY 2025 IPPS/LTCH final rule (89 FR 69348 through 69352)). In addition, in accordance with the provisions of the Full-Year Continuing Appropriations and Extensions Act, 2025, we propose to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for FY 2026 and subsequent fiscal years, the low-volume hospital payment adjustment policy will revert back to the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described in section V.D.3. of the preamble of this proposed rule. We further propose that if the temporary changes to the low-volume payment adjustment are extended through legislation beyond September 30, 2025, we would make the conforming changes to the regulations at § 412.101(b)(2)(i) and (iii) and (c)(1) and (3) to reflect any further extension.

3. Payment Adjustment for FY 2026 and Subsequent Fiscal Years

In accordance with section 1886(d)(12) of the Act, as amended by section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025, beginning with discharges occurring on or after October 1, 2025, the low-volume hospital definition and payment adjustment methodology will revert to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act and subsequent legislation. Specifically, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and for discharges occurring in FY 2026 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals.

Therefore, absent further Congressional action, effective FY 2026 and subsequent years, under current policy at § 412.101(b), to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year. For FY 2026 and subsequent years, the statute specifies that a low-volume hospital must have less than 800 discharges during the fiscal year. However, as required by section 1886(d)(12)(B)(i) of the Act, the Secretary has developed an empirically justifiable payment adjustment based on the relationship, for IPPS hospitals with less than 800 discharges, between the additional incremental costs (if any) that are associated with a particular number of discharges. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief for low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. (Under the policy we established in that same final rule, hospitals with between 200 and 799 discharges do not receive a low-volume hospital adjustment.)

As discussed previously, for FYs 2005 through 2010 and FY 2019 and subsequent years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges. The hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year (§ 412.101(b)(2)(i)). We use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. We note that, for FYs 2011 through 2018, we used the most recently available MedPAR data to determine the hospital's Medicare discharges because only Medicare discharges were used to determine if a hospital met the discharge criterion for those years.

In addition to the discharge criterion, a hospital must also meet the mileage criterion to qualify for the low-volume payment adjustment. As specified by section 1886(d)(12)(C)(i) of the Act, a low-volume hospital must be more than 25 road miles (or 15 road miles for FYs 2011 through 2025) from another subsection (d) hospital. Accordingly, for FY 2026 and subsequent fiscal years, in addition to the discharge criterion, the eligibility for the low-volume payment adjustment is also dependent upon the hospital meeting the mileage criterion at § 412.101(b)(2)(i), which specifies that a hospital must be located more than 25 road miles from the nearest subsection (d) hospital, consistent with section 1886(d)(12)(C)(i) of the Act. We define, at § 412.101(a), the term ''road miles'' to mean ''miles'' as defined at § 412.92(c)(1) (75 FR 50238 through 50275 and 50414). As previously noted, we propose to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that for FY 2026 and subsequent fiscal years, the low-volume hospital payment adjustment policy is the same as that in effect for FYs 2005 through 2010.

4. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment for FY 2026

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking, most recently in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69348 through 69352), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital

qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

In addition to the discharge criterion, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in section 1886(d)(12)(C)(i) of the Act, which is codified at § 412.101(b)(2), for the fiscal year. To meet the mileage criterion to qualify for the low-volume hospital payment adjustment for FY 2026, a hospital must be located more than 25 road miles from the nearest subsection (d) hospital. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospital(s), location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low-volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with this previously established process, for FY 2026, we are proposing that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, for FY 2026, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2025, in order for the 25-percent, low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2025. If a hospital's written request for low-volume hospital status for FY 2026 is received after September 1, 2025, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2026 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2025, may continue to receive a low-volume hospital payment adjustment for FY 2026 without reapplying if it meet both the discharge criterion and the mileage criterion applicable for FY 2026 (that is, the preexisting low-volume hospital qualifying criteria as implemented in FY 2005 and specified in the existing regulations at § 412.101(b)(2)(i), as discussed previously). In such a case, we propose that the hospital must send written verification that is received by its MAC no later than September 1, 2025, stating that it meets the mileage criterion for FY 2026, consistent with our process in previous years. If a hospital's request for low-volume hospital status for FY 2026 is received after September 1, 2025, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume add-on payment adjustment to determine the payment for the hospital's discharges for the applicable portion of FY 2026, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

E. Proposed Changes in the Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background for the MDH Program

Section 1886(d)(5)(G) of the Act provides special non-budget neutral payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). MDHs are paid for their hospital inpatient services based on the higher of the Federal rate or a blended rate based in part on the Federal rate and in part on the MDH's hospital specific rate. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).) Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4), enacted on March 15, 2025, extended the MDH program through September 30, 2025 (that is, for discharges occurring before October 1, 2025). Prior to enactment of the Full-Year Continuing Appropriations and Extensions Act, 2025, the MDH program was only to be in effect for FY 2025 discharges occurring before April 1, 2025. Under current law, the MDH program provisions at section 1886(d)(5)(G) of the Act will expire for

discharges on or after October 1, 2025. Beginning with discharges occurring on or after October 1, 2025, absent further Congressional action, all hospitals that previously qualified for MDH status will be paid based on the Federal rate.

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program had been extended by subsequent legislation as follows: section 606 of the American Taxpayer Relief Act (Pub. L. 112–240) extended the MDH program through FY 2013 (that is, for discharges occurring before October 1, 2013). Section 1106 of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) extended the MDH program through the first half of FY 2014 (that is, for discharges occurring before April 1, 2014). Section 106 of the Protecting Access to Medicare Act (Pub. L. 113–93) extended the MDH program through the first half of FY 2015 (that is, for discharges occurring before April 1, 2015). Section 205 of the MACRA (Pub. L. 114–10) extended the MDH program through FY 2017 (that is, for discharges occurring before October 1, 2017). Section 50205 of the Bipartisan Budget Act (Pub. L. 115–123) extended the MDH program through FY 2022 (that is for discharges occurring before October 1, 2022). Section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180) extended the MDH program through December 16, 2022. Section 102 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229) extended the MDH program through December 23, 2022. Section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328) extended the MDH program through FY 2024 (that is for discharges occurring before October 1, 2024). Section 307 of the CAA, 2024 (Pub. L. 118–42) extended the MDH program through December 31, 2024 (that is, for discharges occurring before January 1, 2025). Section 3202 of the American Relief Act, 2025 (Pub. L. 118–158) extended the MDH program through March 31, 2025 (that is, for discharges occurring before April 1, 2025). Lastly, under current law, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) extended the MDH program through September 30, 2025 (that is, for discharges occurring before October 1, 2025).

For additional information on the extensions of the MDH program after FY 2012, we refer readers to the following **Federal Register** documents: The FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53413 through 53414); the FY 2013 IPPS notice (78 FR 14689); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50647 through 50649); the FY 2014 interim final rule with comment period (79 FR 15025 through 15027); the FY 2014 notice (79 FR 34446 through 34449); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50022 through 50024); the August 2015 interim final rule with comment period (80 FR 49596); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57054 through 57057); the FY 2018 notice (83 FR 18303 through 18305); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41429); the FY 2024 IPPS/LTCH PPS final rule (88 FR 59045); and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69352).

2. Implementation of Legislative Extension of MDH Program

Prior to the enactment of Public Law 119–4, under section 3202 of Public Law 118–158, the MDH program authorized by section 1886(d)(5)(G) of the Act was set to expire on April 1, 2025. Section 2202 of Public Law 119–4 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act by striking ''April 1, 2025'' and inserting ''October 1, 2025''. Section 2202 of Public Law 119–4 also made conforming amendments to sections 1886(b)(3)(D)(i) and 1886(b)(3)(D)(iv) of the Act.

Therefore, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through September 30, 2025.

As a result of the extension of the MDH program through September 30, 2025, as provided by section 2202 of Public Law 119–4, a provider that was classified as an MDH as of March 31, 2025, will continue to be classified as an MDH as of April 1, 2025, with no need to reapply for MDH classification. We addressed the extension provided by section 3202 of the American Relief Act, 2025, in Change Request 13949 (Transmittal 13035), issued January 6, 2025. For additional information, please refer to the transmittal *https://www.cms.gov/medicare/regulations-guidance/transmittals/2025-transmittals/r13035otn*. We intend to address the extension provided by section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 in forthcoming guidance.

3. Expiration of the MDH Program

Because section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through September 30, 2025, only, beginning October 1, 2025, the MDH program will no longer be in effect. Since the MDH program is not authorized by statute beyond September 30, 2025, absent Congressional action, beginning October 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 Federal rate.

When the MDH program was set to expire at the end of FY 2012, in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405), we revised our sole community hospital (SCH) policies to allow MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. We codified these changes in the regulations at § 412.92(b)(2)(i) and (v). For additional information, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53404 through 53405 and 53674). We note that a MDH that classifies as a SCH in anticipation of the MDH program expiration would have to reapply for MDH classification in accordance with the regulations at 42 CFR 412.108(b) and meet the classification criteria at 42 CFR 412.108(a) in the event that the MDH program is further extended and the provider wishes to return to its classification as a MDH.

As noted, we are proposing to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through September 30, 2025. We are further proposing that if the MDH program were to be extended by law beyond September 30, 2025, similar to how it was extended by prior legislation as described previously, we would, depending on timing of such legislation in relation to the final rule, modify our proposed conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect any such further extension of the MDH program. These modifications to our proposed conforming changes would only be made if the MDH program were to be extended by statute beyond September 30, 2025.

F. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and

as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983, through September 30, 1984). The base year PRA is updated annually for inflation.

In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at non-provider sites, when applicable), and the hospital's Medicare share of total inpatient days. Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, in order to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes in the Balanced Budget Act of 1997 (Pub. L. 105–33). Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME cannot exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Calculating Full-Time Equivalent Counts and Caps for Cost Reporting Periods Other Than Twelve Months

CMS's full-time equivalent (FTE) counting regulations, as established in the September 29, 1989, **Federal Register** (54 FR 40291), specify that no individual should be counted as more than one FTE, and that FTE status is based on the total time necessary to fill a residency slot and the share of total time spent training at each training site (see 42 CFR 412.105(f)(1)(iii)(A) for IME and 42 CFR 413.78(b)(1) for DGME). The requirements for what constitutes full-time participation may vary from specialty to specialty, or among different programs in the same specialty. Additionally, full-time equivalency may be computed based on various increments, such as hours, days, weeks, or months, in order for a hospital to obtain the full-time equivalent which it is allowed to count.

Full-time equivalency for each resident is computed by determining the portion of total allowable training time that may be claimed by each hospital. In general, these data are sourced from a ''master'' rotation schedule for each approved residency program. Each rotation may consist of both allowable and non-allowable training time. For example, the time that a resident spends in a hospital's distinct-part unit is allowable to the hospital for purposes of DGME, but not for purposes of IME, while time spent in research activities at an offsite nonpatient care facility is not allowable for either DGME or IME. Additionally, a hospital cannot claim the time spent by residents training at another hospital. Consistent with the regulations at 42 CFR 413.75(d), hospitals that cross-train residents in the same program need to agree on the method of computing FTEs to ensure that no resident is counted as more than one FTE.

For purposes of completing the Medicare cost report (Worksheet E, Part A, for IME and Worksheet E–4 for DGME of Form CMS–2552–10), full-time equivalency is typically calculated on the basis of 365 days (or 366 days, in the case of a leap year) for DGME *versus* the actual number of days in the cost reporting period for IME. Thus, for a standard 12-month cost reporting period, there is no difference in the calculation of the DGME and IME FTE counts.

In the case of a cost reporting period other than 12 months in length, the statute for both DGME and IME instructs the Secretary to make ''appropriate modifications'' to ensure that the FTE counts are based on the equivalent of 12 months. Specifically, for DGME, section 1886(h)(4)(G)(ii) states that if any cost reporting period beginning on or after October 1, 1997, is not equal to 12 months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent resident counts pursuant to section 1886(h)(4)(G)(i) are based on the equivalent of full 12-month cost reporting periods. Similarly, for IME, section 1886(d)(5)(B)(vii) states that if any cost reporting period beginning on or after October 1, 1997, is not equal to 12 months, the Secretary shall make appropriate modifications to ensure that the average full-time equivalent residency count pursuant to section 1886(d)(5)(B)(vi)(II) is based on the equivalent of full 12-month cost reporting periods.

The procedures for determining the total DGME and IME FTE counts for a non-12-month cost reporting period reflect the underlying differences in the two payment methodologies. A hospital's DGME count represents the number of FTE residents working in the healthcare complex over the course of an entire cost reporting period, and the total DGME payment is based on the hospital's PRA, which reflects the average costs incurred per resident during a 12-month base period or equivalent (see discussion at 54 FR 40290). Accordingly, the DGME FTE count must be prorated to reflect the length of a short or long cost reporting period, as illustrated in the following section of this preamble. By contrast, the IME adjustment reflects the average intensity of teaching activity in a hospital at any given time, and the total IME payment is based on the hospital's DRG payments during a cost reporting period. Because the size of a hospital's DRG payments already reflects the amount of patient care furnished during a short or long cost reporting period, it is not necessary to prorate the IME FTE count in the same manner as the DGME FTE count.

Similarly, as explained below, proration must be applied to a hospital's

DGME FTE cap (but not the IME FTE cap) to account for a non-12-month cost reporting period, as well as to the prior- and penultimate-year DGME FTE counts (but not the IME FTE counts) for the purpose of calculating the three-year rolling average FTE count. We also note that, while these methodological distinctions become apparent in the context of calculating the counts and caps for a non-12-month cost reporting period, they are equally applicable in the case of a standard 12-month cost reporting period.

While CMS's FTE counting policy is long-established and widely used in existing cost reporting software and the Intern and Resident Information System (IRIS) software, we are taking the opportunity to restate and clarify our FTE counting policy in rulemaking. We are not proposing any changes to the FTE counting policy at this time.

a. Calculating FTE Counts

To determine the unweighted FTE count for DGME, *whether or not the cost reporting period is 12 months, or more or less,* the following steps should be used:

- For each resident and each of that resident's individual rotations, determine the ratio of total days allowable to the hospital in that rotation, to total days in that entire rotation, consistent with the regulations at 42 CFR 413.78.
- Multiply the ratio from Step 1 by the ratio of (total days in the entire rotation divided by 365) (or 366, in the case of a leap year).[224] This represents the portion of total FTE time for this rotation that may be claimed by the hospital for purposes of DGME payment, prorated for the length of the cost reporting period.
- Calculate the sum of the products from Step 2 for all residents and rotations in the hospital's programs to arrive at the hospital's total unweighted DGME FTE count for the cost reporting period.

Stated formulaically:

Unweighted DGME FTE count = Sum of [(Allowable days in a rotation/Total days in the rotation) × (Total days in the rotation/365)]

Note: This portion of the FTE calculation is not weighted for years outside of the Initial Residency Period, as the application of weighting factors is a separate step in the calculation of DGME payment on the cost report. See 42 CFR 413.79(a) for more information about the Initial Residency Period.

[224] 366 days should be used when the cost reporting period includes February 29.

Example: A resident worked in a rotation at Hospital A for 4 weeks (28 days) but spent 1 week (7 days) offsite engaged in non-patient care research.

- *Step 1:* Consistent with the DGME regulations, the total time allowable to Hospital A for this rotation is 21 days. The ratio is (21 days/28 days) = 0.75.
- *Step 2:* The portion of total FTE time for this rotation that Hospital A may claim for purposes of DGME payment is 0.75 × (28/365) = 0.06 FTE. (*Note:* In the case of a leap year, divide by 366 days.)
- *Step 3:* Repeat Steps 1 and 2 for all residents and rotations in the hospital's programs, and sum the results from Step 2 to arrive at Hospital A's total unweighted DGME FTE count for the cost reporting period.

As stated above, 365 or 366 days is used as the denominator in Step 2 of the calculation regardless of the actual number of days in the cost reporting period. Thus, in computing the DGME FTE count, the length of the cost reporting period can affect the full-time equivalency determined for a given number of residents training at the hospital. For example, there would be fewer total rotations in a 3-month cost reporting period than in a 12-month period, and thus a commensurately smaller DGME count calculated in accordance with the procedure outlined above.

Note that the hospital's updated PRA is always used and is not prorated, as it represents that hospital's average cost to train an FTE resident determined in a base period, and is not dependent upon the length of cost reporting periods subsequent to the PRA base period.

In this manner, the DGME FTE count continues to be based on the ''equivalent of 12 months,'' as required by section 1886(h)(4)(G)(ii) of the Act. This procedure is performed to determine the total unweighted DGME FTE count on Form CMS–2552–10, Worksheet E–4, line 6 and line 7, as well as for the weighted FTE counts on lines 8 through 11, lines 15 and 16, and lines 21 and 22. For lines that record weighted FTE counts, the appropriate weighting factors are applied consistent with the regulations at 42 CFR 413.79(a).

As mentioned above, the procedure for determining the 12-month equivalent IME FTE count, in accordance with section 1886(d)(5)(B)(vii) of the Act, is different in that the number of days used in the denominator of the calculation in Step 2 depends on the length of the cost reporting period. For 12-month cost reporting periods, a denominator of 365 days is used (or 366 days in the case of a leap year), while for cost reporting periods of different lengths, the denominator is equal to the actual number of days in the cost reporting period. The resulting FTE count represents the average number of residents in the hospital at any given time, and in turn is multiplied by the DRG payments in that same cost reporting period to obtain the hospital's total IME payment.

Accordingly, to determine the FTE count for IME, *whether or not the cost reporting period is 12 months, or more or less,* the following steps should be used:

- For each resident and each of that resident's individual rotations, determine the ratio of total days allowable to the hospital in that rotation, to total days in that entire rotation, consistent with the regulations at 42 CFR 412.105(f).
- Multiply the ratio from Step 1 by the ratio of (total days in the entire rotation divided by the *actual number of days in the cost reporting period*). This represents the portion of total FTE time for this rotation that may be claimed by the hospital for purposes of IME payment.
- Calculate the sum of the products from Step 2 for all residents and rotations in the hospital's programs to arrive at the hospital's total IME FTE count for the cost reporting period.

Stated formulaically:

IME FTE count = Sum of [(Allowable days in a rotation/Total days in the rotation) × (Total days in the rotation/Days in cost reporting period)]

Example 1: 12-Month Cost Reporting Period (365 Days)

A resident worked in a rotation at Hospital A for 4 weeks (28 days) but spent 1 week (7 days) offsite engaged in non-patient care research.

Step 1: Consistent with the IME regulations, the total time allowable to Hospital A for this rotation is 21 days. The ratio is (21 days/28 days) = 0.75.

Step 2: The portion of total FTE time for this rotation that Hospital A may claim for purposes of IME payment is 0.75 × (28/365) = 0.06 FTE. (*Note:* In the case of a leap year, divide by 366 days.)

Step 3: Repeat Steps 1 and 2 for all residents and rotations in the hospital's programs, and sum the results from Step 2 to arrive at Hospital A's total IME FTE count for the cost reporting period.

Example 2: 3-Month Cost Reporting Period (92 Days)

During a 92-day cost reporting period, a resident worked in a rotation at Hospital A for 4 weeks (28 days) but

spent 1 week (7 days) offsite engaged in non-patient care research.

Step 1: Consistent with the IME regulations, the total time allowable to Hospital A for this rotation is 21 days. The ratio is (21 days/28 days) = 0.75.

Step 2: The portion of total FTE time for this rotation that Hospital A may claim for purposes of IME payment is 0.75 × (28/92) = 0.23 FTE.

Step 3: Repeat Steps 1 and 2 for all residents and rotations in the hospital's programs, and sum the results from Step 2 to arrive at Hospital A's total IME FTE count for the 3-month cost reporting period.

Consistent with the regulations at 42 CFR 412.105(b), the bed count used in the denominator of the intern and resident to bed (IRB) ratio is determined by counting the number of available bed days during the cost reporting period and dividing that number by the number of days in the cost reporting period.

While the IME FTE count itself is not prorated, the final amount of a hospital's IME payment nonetheless will be commensurate with the cost reporting period by virtue of the total amount of its DRG payments, which will generally increase or decrease as a result of the length of the period. For example, if a cost reporting period is 12 months long, the DRG payments by which the IME adjustment factor is multiplied to derive the total IME payment will also reflect 12 months of patient care. By contrast, the DRG payments for the 3-month (or 92-day) cost reporting period in Example 2 would reflect just 3 months of patient care.

This procedure is performed to determine the total IME FTE count on Form CMS–2552–10, Worksheet E, Part A, lines 10 through 12, as well as the FTE counts on lines 16 and 17 and lines 24 and 25.

b. Calculating FTE Caps for Cost Reporting Periods Other Than Twelve Months

Just as the DGME FTE counts are prorated on the basis of a standard 365- or 366-day cost reporting period, a hospital's DGME FTE cap must similarly be prorated for cost reporting periods other than 12 months in length. To calculate the prorated cap, the hospital's regular 12-month DGME FTE cap is divided by 365 days (or 366 days, in the case of a leap year) and then multiplied by the actual number of days in the cost reporting period. For example, if a hospital has a regular DGME FTE cap of 270 FTEs, then the prorated DGME cap for a 3-month cost reporting period with 92 days would be: (270/365) × (92) = 68.05 FTEs. (If the hospital subsequently had a 9-month cost report with 273 days, the DGME FTE cap for the 9-month cost report would be calculated as follows: (270/365) × (273) = 201.95 FTEs. Note that 68.05 + 201.95 = 270, equivalent to the total DGME cap for 12 months (totals may be slightly off due to rounding)). Proration applies similarly to all lines on Worksheet E–4 that are associated with the FTE cap, including lines 1 through 5 and line 20.

For reasons similar to those explained above in the discussion of the FTE counts, it is not necessary to prorate the IME FTE caps for a non-12-month cost reporting period; the same IME FTE cap and any associated cap adjustments apply to a cost reporting period that is less than or more than 12 months.

c. Calculating the Three-Year Rolling Average for Cost Reporting Periods of Unequal Lengths

Sections 1886(d)(5)(B)(vi)(II) and 1886(h)(4)(G)(i) of the Act require that a hospital's FTE counts for IME and DGME payment, respectively, in the current cost reporting period be based on a three-year rolling average. That is, the FTE counts in the current cost reporting period, prior cost reporting period, and penultimate cost reporting period are summed, then divided by 3. These provisions phase in any reductions or increases in payment over a three-year period for hospitals that experience a change in the number of residents they train. The regulations are at 42 CFR 412.105(f)(1)(v) for IME and 42 CFR 413.79(d)(3) for DGME.

For reasons similar to those discussed above, no adjustments need to be made to the prior and penultimate years when calculating the rolling average IME count. However, if the current, prior and/or penultimate year cost reporting periods are of different lengths, adjustments must be made to the respective DGME FTE counts so that the rolling average is based on quantities that are comparable with one another. Accordingly, if the current cost reporting period is other than 12 months in length, the prior- and penultimate-year DGME FTE counts must be prorated, yielding 3 years of comparable FTE counts from which to calculate the rolling average:

For the prior year, take the FTE count that would be reported on Worksheet E–4, line 12, and divide by 365 (or 366, if the prior year cost reporting period includes February 29), and then multiply that quotient by the number of days in the current non-12-month cost reporting period. Report this prorated FTE count on Worksheet E–4, line 12, of the current year cost report.

For the penultimate year, take the FTE count that would be reported on Worksheet E–4, line 13, and divide by 365 (or 366, if the penultimate year cost reporting period includes February 29), and then multiply that quotient by the number of days in the current non-12-month cost reporting period. Report this prorated FTE count on Worksheet E–4, line 13, of the current year cost report.

Stated formulaically:

Prorated DGME FTE count = [(Total annual DGME FTE count/365 or 366) × (Number of days in current cost reporting period)]

For example, if the current year cost reporting period is 3 months (92 days), while the prior year cost reporting period was 12 months, and the hospital's total capped DGME FTE count in the prior year was 300, then the prorated FTE count for the prior year would be: [(300/365) × (92)] = 75.62. That is, a DGME FTE count of 300 in a 12-month cost reporting period would be the equivalent of 75.62 FTEs in the current year 3-month cost reporting period. On the current year cost report, the hospital would enter 75.62 on line 12 of Worksheet E–4 (prior year FTE count). If the total capped DGME FTE count in the penultimate cost reporting period was 302, and the penultimate year was also 12 months, then the prorated FTE count for the penultimate year would be: [(302/365) × (92)] = 76.12. On the current year cost report, the hospital would enter 76.12 on line 13 of Worksheet E–4 (penultimate year FTE count).

We note that in this scenario, if either the prior or penultimate year cost reporting period was also other than 12 months in length, then it would be necessary to adjust the calculation to account for that difference. For instance, suppose that the hospital's penultimate year cost reporting period was 9 months or 273 days long, and its capped DGME FTE count during that period (prorated on a 12-month basis as described earlier in this preamble) was 225. In this case, rather than dividing by 365 days, the hospital would divide the penultimate-year DGME FTE count by 273 days, as follows: [(225/273) × (92)] = 75.82 FTEs. Thus, the hospital would enter 75.82 on line 13 of Worksheet E–4 of the current year cost report.

Conversely, if the current year is a full cost reporting period, but the prior and/or penultimate cost reporting period was other than 12 months, then the prior and/or penultimate year DGME FTE counts (which have been prorated on a 12-month basis as described earlier

in this preamble) must be annualized to yield 12-month equivalents. This procedure avoids understatement (or overstatement) of the DGME FTE count in the current year and, similar to the proration of DGME counts in the preceding scenario, results in 3 years of comparable FTE counts from which to calculate the DGME rolling average:

For the prior year, take the FTE count that would be reported on Worksheet E–4, line 12, and divide by the number of days in the non-12-month cost reporting period, and then multiply that quotient by 365 (or 366, if the current cost reporting period includes February 29). Report this annualized FTE count on Worksheet E–4, line 12 of, the current year cost report.

For the penultimate year, take the FTE count that would be reported on Worksheet E–4, line 13, and divide by the number of days in the non-12-month cost reporting period, and then multiply that quotient by 365 (or 366, if the current cost reporting period includes February 29). Report this annualized FTE count on Worksheet E–4, line 13 of the current year cost report.

Stated formulaically:

Annualized DGME FTE count = [(Prorated DGME FTE count/Number of days in the non-12-month cost reporting period) × (365 or 366)]

For example, if the current year cost reporting period is 12 months (365 days), while the prior year cost reporting period was 3 months (92 days), and the prior-year capped DGME FTE count (prorated on a 12-month basis) was 75, then the annualized FTE count for the prior year would be: [(75/92) × (365)] = 297.55. On the current year cost report, the hospital would enter 297.55 on line 12 of Worksheet E–4 (prior year FTE count).

3. Notice of Closure of Teaching Hospitals and Opportunity To Apply for Available Slots

Section 5506 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, ''Affordable Care Act''), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Section 5506 of the Affordable Care Act instructs the Secretary to establish a process by regulation that redistributes slots from teaching hospitals that close to hospitals that meet the certain criteria, with priority given to certain hospitals including those located in the same Core Based Statistical Area (CBSA), in a contiguous CBSA or in the same state as the closed hospital.

Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the full-time equivalent (FTE) resident caps in teaching hospitals that closed on or after a date that is 2 years before the date of enactment (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72264), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain additional modifications to § 413.79 in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010 (75 FR 72215).

a. Notice of Closure of Wahiawa General Hospital Located in Wahiawa, HI, and the Application Process—Round 24

CMS has learned of the closure of Wahiawa General Hospital, located in Wahiawa, HI (CCN 120004). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round (''Round 24'') of the application and selection process. This round will be the 24th round (''Round 24'') of the application and selection process. The table in this section of this proposed rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 24 application process under section 5506 of the Affordable Care Act.

TABLE V.F.–01—WAHIAWA GENERAL HOSPITAL FTE RESIDENT CAPS

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including ± MMA Sec. 422 adjustments [1])	Direct GME FTE resident cap (including ± MMA Sec. 422 adjustments)
120004	Wahiawa General Hospital.	Wahiawa, HI	46520	April 2, 2024	11.67 + 5.49 sec. 422 increase = 17.16 [2]	12.11 + 2.20 sec. 422 increase = 14.31.[3]

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
[2] Wahiawa General Hospital's 1996 IME FTE resident cap is 11.67. Under section 422 of the MMA, the hospital received an increase of 5.49 to its IME FTE resident cap: 11.67 + 5.49 = 17.16.
[3] Wahiawa General Hospital's 1996 direct GME FTE resident cap is 12.11. Under section 422 of the MMA, the hospital received an increase of 2.20 to its direct GME FTE resident cap: 12.11 + 2.20 = 14.31.

b. Notice of Closure of Carney Hospital Located in Boston, MA and the Application Process—Round 25

CMS has learned of the closure of Carney Hospital, located in Boston, MA (CCN 220017). Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round (''Round 25'') of the application and selection process. This round will be the 25th round (''Round 25'') of the application and selection process. The table in this section of this proposed rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 25 application process under section 5506 of the Affordable Care Act.

TABLE V.F.–02—CARNEY HOSPITAL FTE RESIDENT CAPS

CCN	Provider name	City and state	CBSA code	Terminating date	IME FTE resident cap (including ± MMA Sec. 422[1] and ACA Sec. 5503[2] adjustments)	Direct GME FTE resident cap (including ± MMA Sec. 422 and ACA Sec. 5503 adjustments)
220017	Carney Hospital.	Boston, MA	14454	August 31, 2024.	73.00 − 9.78 sec. 422 reduction − 0.07 sec. 5503 reduction = 63.15[3].	73.00 − 10.16 sec. 422 reduction − 1.70 sec. 5503 reduction = 61.14.[4]

[1] Section 422 of the MMA, Public Law 108–173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
[2] Section 5503 of the Affordable Care Act of 2010, Public Law 111–148 and Public Law 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.
[3] Carney Hospital's 1996 IME FTE resident cap is 73.00. Under section 422 of the MMA, the hospital received a reduction of 9.78 to its IME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 0.07 to its IME FTE resident cap: 73.00 − 9.78 − 0.07 = 63.15.
[4] Carney Hospital's 1996 direct GME FTE resident cap is 73.00. Under section 422 of the MMA, the hospital received a reduction of 10.16 to its direct GME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 1.70 to its direct GME FTE resident cap: 73.00 − 10.16 − 1.70 = 61.14.

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the previously noted hospitals' FTE resident caps must submit applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), with application submissions for Round 24 and 25 due no later than July 10, 2025. The section 5506 application can be accessed at: *https://mearis.cms.gov/public/home*.

CMS will only accept Round 24 and 25 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the ''Resources'' section for guidance regarding the application submission process at: *https://mearis.cms.gov/public/resources*.
- Technical support is available under ''Useful Links'' at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources*.

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the application deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/direct-graduate-medical-education-dgme*. Hospitals should access this website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

G. Reasonable Cost Payment for Nursing and Allied Health Education Programs (§ 413.85 and § 413.87)

1. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. The costs of these activities are excluded from the definition of ''inpatient hospital operating costs'' and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis).

Under the existing regulations at 42 CFR 413.85, approved nursing and allied health (NAH) education programs must meet State licensure requirements or be accredited by a recognized national professional organization. Additionally, an approved NAH education program must be operated by a provider. The most recent substantive rulemakings on these regulations were in the January 12, 2001, final rule (66 FR 3358 through 3374), and in the August 1, 2003, final rule (68 FR 45423 and 45434). The regulations regarding Medicare Advantage (MA) add-on payments for NAH education programs are at 42 CFR 413.87.

2. Medicare Advantage Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now called Medicare Advantage (MA))[225] enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs may receive additional payments to account for MA enrollees. Section 541 of the BBRA limits total spending under the provision for MA enrollees to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool''.) Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for Medicare+Choice (now MA) utilization be reduced to the extent that these additional payments are made for nursing and allied health education programs. This provision was effective for portions of cost reporting periods occurring in a calendar year, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for Medicare+Choice (now MA) nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital's specific Medicare+Choice (now MA) utilization. Section 512 of the BIPA revised this

[225] The M+C program in Part C of Medicare was renamed the Medicare Advantage (MA) Program under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), which was enacted in December 2003.

payment formula to specifically account for each hospital's Medicare+Choice (now MA) utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year, beginning with CY 2001.

The regulations at 42 CFR 413.87 implement both statutory provisions. We first implemented the BBRA NAH Medicare+Choice (now MA) provision in the August 1, 2000, IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039), and subsequently implemented the BIPA provision in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910). In those rules, we outlined the qualifying conditions for a hospital to receive the NAH Medicare+Choice (now MA) payment, how we would calculate the NAH Medicare+Choice (now MA) payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same variables, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH pass-through payment/ Hospital Part A Inpatient Days) * (Hospital MA Inpatient Days)) divided by
((National NAH pass-through payment/ National Part A Inpatient Days) * (National MA Inpatient Days))) * Current Year Payment Pool.

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary shall estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under section 1886(h)(3)(D) of the Act to total direct GME payments estimated for the same portions of periods under section 1886(h)(3) of the Act.

Accordingly, we stated in the August 1, 2000, IFC (65 FR 47038) that each year, we would determine and publish in a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year 2 years prior to the current calendar year. We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year.

To calculate the pool, in accordance with section 1886(l) of the Act, we stated that we would ''estimate'' a total amount for each calendar year, not to exceed $60 million (65 FR 47038). To calculate the proportional reduction to Medicare+Choice (now MA) direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME payments are based on the best available cost report data from the HCRIS (for example, for CY 2000, the projections are based on the best available cost report data from FY 1998 HCRIS), and these payment amounts are increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI–U) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000, IFC, we described our policy regarding the timing and source of the national data components for the NAH Medicare+Choice (now MA) add-on payment and the percent reduction to the direct GME Medicare+Choice payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000, IFC states that we would publish the NAH Medicare+Choice (now MA) rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and CY 2021, we proposed and finalized the NAH MA add-on rates in the FY 2023 IPPS/LTCH PPS proposed and final rules. We stated that for CYs 2022 and after, we would similarly propose and finalize the respective NAH MA rates and direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073, August 10, 2022).

In this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing the rates for CY 2024. Consistent with the use of HCRIS data for past calendar years, we are proposing to use data from cost reports ending in FY 2022 HCRIS (the fiscal year that is 2 years prior to CY 2024) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days.

For this proposed rule, we accessed the FY 2022 HCRIS data from the fourth quarterly HCRIS update of 2024. However, to calculate the ''pool'' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar year, which in this proposed rule is CY 2024, based on the ''best available cost report data from the HCRIS'' (65 FR 47038). Next, consistent with the method we described previously in the August 1, 2000, IFC, we increase these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index-Urban (CPI–U) increases for Part A direct GME). For CY 2024, the direct GME projections are based on the fourth quarterly update of CY 2022 HCRIS, adjusted for the CPI–U and for increasing MA enrollment.

For CY 2024, the proposed national rates and percentages, and their data sources, are set forth in this table. We intend to update these numbers in the FY 2026 final rule based on the latest available cost report data.

Proposed CY 2024 NAH MA rates	Proposed CY 2024	Source
NAH Pass-Through	$281,853,426	Cost reports ending in FY 2022 HCRIS.
Part A Inpatient Days	75,303,913	Cost reports ending in FY 2022 HCRIS.
MA Inpatient Days	16,305,155	Cost reports ending in FY 2022 HCRIS.
Part A Direct GME	$3,085,013,941	CY 2022 HCRIS + CPI–U + MA enrollment.

Proposed CY 2024 NAH MA rates	Proposed CY 2024	Source
MA Direct GME	$2,565,628,319	CY 2022 HCRIS + CPI–U + MA enrollment.
Pool (not to exceed $60 million)	$60,000,000	((MA DGME/Part A DGME) * (NAH Pass-through)).
Percent Reduction to MA DGME Payments	2.34%	Pool/MA direct GME.

3. Proposed Regulatory Changes Regarding the Calculation of Net Cost of NAH Education Programs (42 CFR 413.85(d)(2)(i) and (ii))

In the January 12, 2001, final rule (66 FR 3358), we codified the payment regulations regarding NAH education program costs at 42 CFR 413.85. With regard to determining the net costs which are allowed for ''pass-through'' payment, 42 CFR 413.85(d)(2)(i) states that the net cost of approved educational activities is determined by deducting the revenues that a provider receives from tuition and student fees from the provider's total allowable educational costs that are directly related to approved educational activities. Section 413.85(d)(2)(ii) further states that a provider's total allowable educational costs are those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24. These costs do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support. Worksheet A of the Medicare cost report captures the direct costs associated with a hospital's various cost centers, including its NAH education programs. The direct costs associated with operating a hospital's approved NAH education programs are reported on Worksheet A, line 20 (nursing programs) and line 23 (paramedical/allied health education programs). The instructions to these lines state—

Lines 20 and 23—If you have an approved nursing or allied health education program that meets the criteria of 42 CFR 413.85(e), classroom and clinical portions of the costs may be allowable as pass-through costs as defined in 42 CFR 413.85(d)(2). . . . (CMS Pub. 15–2, section 4013)

In addition to direct costs, hospitals also incur indirect or overhead costs associated with their operations. Overhead costs are assigned to the general service cost centers on lines 1 through 23 of Worksheet A, which are a hospital's non-patient care/non-revenue producing cost centers, and which include the Administrative & General (A&G) cost center on line 5. The general cost report instructions for Worksheet A state—

Lines 1 through 23—These lines are for the general service cost centers. These costs are expenses incurred in operating the facility as a whole *that are not directly associated with furnishing patient care* such as, but not limited to mortgage, rent, plant operations, administrative salaries, utilities, telephone charges, computer hardware and software costs, etc. General service cost centers furnish services to both general service areas and to other cost centers in the provider (emphasis added).

Because the costs of operating a hospital's NAH education programs are not directly associated with furnishing patient care, these cost centers are also included among the general service cost centers on Worksheet A. As noted in the cost report instructions cited previously, general service cost centers may furnish services to other general service areas. Thus, for example, a hospital's Administrative and General cost center may furnish services to its Nursing and Allied Health Education cost centers.

The regulations and cost report instructions require that, prior to allocating overhead costs to the revenue producing cost centers, a provider must make appropriate reclassifications and adjustments to its direct costs. Worksheet A–6 is used to reclassify costs between cost centers on the cost report, while Worksheet A–8 is used to adjust both a provider's revenue producing and non-revenue producing cost centers, and remove non-allowable costs. The cost report instructions for Worksheet A–8 state, in relevant part—

Types of adjustments entered on this worksheet include (1) those needed to adjust expenses to reflect actual expenses incurred; (2) *those items which constitute recovery of expenses through sales, charges, fees, etc.;* (3) those items needed to adjust expenses in accordance with the Medicare principles of reimbursement; and (4) those items which are provided for separately in the cost apportionment process (emphasis added). (CMS Pub. 15–2, section 4016.)

Adjustments, including the recovery of expenses through various forms of revenue, occur prior to cost finding, which is the process by which indirect costs (that is, the costs of the general service cost centers) are allocated to other cost centers (both other general service cost centers and revenue producing cost centers). Worksheets B, Part I, and B–1 have been designed to accommodate the stepdown method of cost finding described at 42 CFR 413.24(d)(1). Certain other cost adjustments, referred to as post-stepdown adjustments, occur after the allocation of indirect and overhead costs and are reported separately on Worksheet B–2.

On November 17, 2017, CMS issued Transmittal 12, which contained updates to the hospital cost report instructions at CMS–2552–10, Pub. 15–2, chapter 40. It added the following instructions to line 19 of Worksheet A–8:

Line 19—For each NAHE program on Worksheet A, line 20, and its subscripts, and Worksheet A, line 23, and its subscripts, enter the revenue adjustments (for tuition, fees, books, etc.) to be applied against total allowable costs that are directly related to the approved NAHE activities. Subscript this line to separately report the revenue offset for each NAHE program reported on line 20 and line 23. (See CMS Pub. 15–1, chapter 4, § 414, and 42 CFR 413.85(d)(2)(i).)

Transmittal 12 also added to Worksheet B–2 specific instructions for post-stepdown adjustments for certain costs associated with NAHE non-provider-operated programs under 42 CFR 413.85(g)(2), with the following note:

Note: Do not use this worksheet to reduce the total allowable costs that are directly related to the NAHE programs by the revenue received from tuition and student fees. Use Worksheet A–8 to offset NAHE program costs by tuition and student fees (42 CFR 413.85(d)(2)(i)). Do not use a post step-down adjustment.

By issuing these cost report clarifications in Transmittal 12, CMS was clarifying the rules regarding ensuring the appropriate order of operations for allocations and post-stepdown adjustments of overhead to the NAH education pass-through cost centers. Specifically, Transmittal 12 made it clear that adjustments to the direct costs of NAH education programs as a result of revenue received from tuition, student fees and other sources should occur on Worksheet A–8, prior to the allocation of overhead costs, and *not* as post-stepdown adjustments on Worksheet B–2.

On February 9, 2024, the U.S. District Court for the District of Columbia (D.C.) issued a decision involving five plaintiff hospitals (*Mercy Health—St. Vincent*

Medical Center LLC d/b/a Mercy St. Vincent Medical Center, et al., v. *Xavier Becerra,* Case No. 22–cv–3578 (TNM)). The providers disputed the order of operations for determining ''net costs'' under 42 CFR 413.85(d)(2)(i). The providers disagreed with the instructions in Transmittal 12, and argued that the offsets for revenue from tuition and student fees should be made after indirect costs are allocated, using Worksheet B–2, which follows the allocation of indirect costs on Worksheet B, Part I. According to the providers, the regulations require that indirect costs be included as part of a provider's total allowable educational costs before tuition and student fees are offset, and the change to the cost reporting instructions in 2017 was a change in policy that conflicts with the regulations.

The U.S. District Court for D.C. sided with the providers, arguing that the plain reading of the regulations text at 42 CFR 413.85(d)(2)(i) is consistent with the providers' interpretation of the order of operations, which is to allow direct and indirect costs to be summed, and tuition and fees to be subtracted from that sum. We disagree with the Court's ruling and assert that the cost report instructions at PRM 15–2 sec. 4016 are clear that revenue that is a recovery of expenses should be offset via Worksheet A–8, prior to the allocation of indirect costs, and that these instructions are consistent with the regulations and Medicare cost reporting policy broadly.

Nevertheless, in order to further clarify the regulations, we are proposing to change the regulations text at 42 CFR 413.85(d)(2)(i) to state that the net cost of approved educational activities is determined as follows:

- Determine allowable direct costs incurred by the provider for trainee stipends and compensation of teachers employed by the provider.
- Subtract from allowable direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale.
- Add indirect costs of the activities as determined under the Medicare cost-finding principles in 42 CFR 413.24, but limited to indirect costs that the provider itself incurs as a consequence of operating the approved educational activities.

We note that as a result of this proposal, we would be modifying and moving the first sentence of existing 42 CFR 413.85(d)(2)(ii), which defines a provider's total allowable educational costs as those costs incurred by the provider for trainee stipends, compensation of teachers, and other costs of the activities as determined under the Medicare cost-finding principles in § 413.24, up to proposed 42 CFR 413.85(d)(2)(i). However, we are not proposing to revise the portion of existing regulations text at 42 CFR 413.85(d)(2)(ii) which states that the direct and indirect allowable costs of educational activities do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

The effective date of this proposed regulatory change would be cost reporting periods beginning on or after October 1, 2025.

We understand that it is not uncommon for a provider's total revenues from tuition, student fees and other sources to exceed the provider's allowable direct costs of its nursing and allied health education programs. If the default method of cost allocation is used, the adjustments occurring on Worksheet A–8 would reduce the overhead costs apportioned to the nursing program or allied health education program cost centers. This is because the default statistical basis for allocating administrative and general costs to other cost centers is accumulated cost, which in this case would be zero. However, to mitigate this reduction of indirect costs, providers that directly incur legitimate overhead costs as a result of the operation of their NAH education programs have options under current regulations to seek permission from their MAC to employ a different allocation method that is more suited to the types of costs they incur. Exercising these options is at the request of the provider, and will not occur unless the provider seeks permission from its MAC to change its allocation method.

If a provider wishes to change its statistical allocation basis for a particular cost center and/or the order in which the cost centers are allocated, the provider must make a written request to its MAC in accordance with PRM 15–1, chapter 23, section 2313. Specific to the operation of NAH education programs, a provider may elect to subscript its A&G cost center (line 5 of Worksheet A) for overhead costs directly related to NAH programs and use a statistic other than accumulated costs, which specifically relates to the NAH cost being allocated. For example, after subscripting the A&G cost center, a provider can use clinical rotation hours spent in each routine or ancillary area, to compute a ratio to total clinical rotation hours for each program. Then, to apportion staff's salaries among more than one NAH cost center, a provider can use a ratio of the number of students enrolled in a program to total number of students. For instance, a clinical coordinator's salary, whose job is to schedule and manage the clinical rotations of multiple NAHE programs, can be included in a subscripted A&G cost center and allocated to multiple NAH programs based on the ratio of the number of students in each NAH program to total number of students in all of the hospital's NAH programs. Providers would thus be able to appropriately differentiate the A&G costs to be allocated to NAH programs from those that should not be allocated toward operation of those programs because the statistical basis for this subscripted cost center would be more specific to services rendered. As a result, the amount of overhead costs that ultimately flow to the NAH cost centers would be more accurate, albeit less than what would be allocated if tuition and student fees were subtracted as a post-stepdown adjustment, as argued by the providers in *Mercy Health;* however, as discussed above, the providers' desired method is not consistent with CMS's existing policy or existing cost report instructions.

The proposed order of operations to offset revenue from direct costs on Worksheet A–8 also is consistent with CMS policy that A&G costs allocated to the NAH cost centers must be *directly related* to the operation of specific approved programs under 42 CFR 413.85(f) and (g). In the January 12, 2001, final rule (66 FR 3367), we clarified the meaning of the term ''tuition'' and specified a formula for determining the net costs to indicate that ''total costs'' includes only direct and indirect costs incurred by a provider that are *directly attributable* to the operation of an approved educational activity. We explained that *these costs do not include usual patient care costs that would be incurred in the absence of the educational activity,* such as the salary costs for nursing supervisors who oversee the floor nurses and student nurses. Moreover, these costs do *not* include *costs incurred by a related organization.* We understand that a significant portion of indirect costs that certain plaintiffs in the litigation allocated to their nursing and allied health cost centers included costs incurred by a related organization (such as a home office), in violation of the regulation at 42 CFR 413.85(d)(2)(ii),

as well as A&G costs not directly attributable to the operation of the NAH programs. Those A&G costs not directly incurred as a result of operating the NAH education programs are to be paid under the IPPS, not ''passed through'' the IPPS (or other applicable hospital payment system). For instance, costs which benefit the hospital as a whole, such as Infection Control, Admissions, Patient Registration, Telecommunications, etc., would generally be incurred in the absence of a provider's NAH programs; therefore, these types of costs are not to be allocated to the NAH program cost centers. Consequently, it is the provider's responsibility to request permission from its MAC to use an allocation method for overhead costs that accurately and appropriately reflects overhead costs incurred by the provider as a direct result of operating NAH education programs.

In summary, we are proposing to amend the regulations at 42 CFR 413.85(d)(2)(i) and (ii) as specified previously.

H. Proposed Payment Adjustment for Certain Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 in order to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when, among other criteria, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat the disease or condition (21 CFR 312.305).[226]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial (85 FR 58844).

For FY 2026, we are proposing to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018, calculated using the same methodology, as modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59062), that we are proposing to use to adjust the case count for purposes of the relative weight calculations, including our proposed modifications to that methodology for FY 2026, as described in section II.D. of the preamble of this proposed rule.

As discussed in the FY 2024 IPPS/LTCH PPS final rule, the MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2023 MedPAR data and for subsequent years, this field identifies whether or not the claim includes condition code 90. The MedPAR files now also include information for claims with the payer-only condition code ''ZC'', which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*). We refer the readers to section II.D. of this proposed rule for further discussion of our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 and our methodology used to adjust the case count for purposes of the relative weight calculations, as modified in the FY 2024 IPPS/LTCH PPS final rule, and as further proposed to be modified for FY 2026 to identify other claims for which the immunotherapy product was not purchased in the usual manner, such as obtained at no cost.

In the FY 2025 IPPS/LTCH PPS final rule, we summarized a comment requesting that CMS establish a mechanism for hospitals to report when a product is not purchased in the usual manner, such as obtained at no cost, for reasons other than participation in a clinical trial or expanded access use (89 FR 69112). We indicated we may consider this request in future

[226] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

rulemaking. We agree that the same adjustment that applies to expanded access use of immunotherapy and applicable clinical trial cases should apply to other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and therefore are proposing that, beginning in FY 2026, the payment adjustment would also be applied in calculating the payment for such cases. We intend to issue billing instructions in separate guidance that would allow a provider to indicate, for that case, that the immunotherapy product was not purchased in the usual manner so that MACs would apply the same adjustment to the payment amount that is applied for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018. We are also proposing to modify our regulations at 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments) to codify this proposed payment adjustment for other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost. Specifically, we are proposing to modify the section heading and paragraphs (b) and (c) at 42 CFR 412.85 to include other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, and to make additional technical revisions to paragraph (c). We are also proposing to modify paragraph (f) at 42 CFR 412.312 to include cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost.

We also refer readers to section II.D. of the preamble of this proposed rule for further discussion of our proposed changes to our methodology for calculating the relative weight for MS–DRG 018 to identify other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost and to adjust the case count for purposes of the relative weight calculations.

Using the same methodology that we are proposing to use to adjust the case count for purposes of the relative weight calculations, including our proposed modifications as discussed in section II.D. of the preamble of this proposed rule, we are proposing to calculate the adjustment to the payment amount for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost as follows:

- Calculate the average cost for cases assigned to MS–DRG 018 that (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'', (b) contain condition code ''90'', or (c) contain standardized drug charges below the median standardized drug charge of clinical trial cases in MS–DRG 018.
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy, applicable clinical trial cases, and other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

We refer the readers to section II.D. of the preamble of this proposed rule for further discussion of our methodology.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for this proposed rule we are proposing to calculate this adjustor based on the December 2024 update of the FY 2024 MedPAR file for purposes of establishing the FY 2026 payment amount. Specifically, in accordance with proposed revised 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), we propose to multiply the FY 2026 relative weight for MS–DRG 018 by a proposed adjustor of 0.23 as part of the calculation of the payment for claims determined to be applicable clinical trial claims, expanded access use immunotherapy claims, or other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We also propose to update the value of the adjustor based on more recent data for the final rule.

K. Hospital Readmissions Reduction Program Updates and Changes

1. Regulatory Background

Section 1886(q) of the Act sets forth the requirements of the Hospital Readmissions Reduction Program effective for discharges from applicable hospitals beginning on or after October 1, 2012. Under the Hospital Readmissions Reduction Program, payments to applicable hospitals must be reduced to account for certain excess readmissions. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a general overview of the Hospital Readmissions Reduction Program. We also refer readers to 42 CFR 412.152 through 412.154 for codified Hospital Readmissions Reduction Program requirements.

2. Hospital Readmissions Reduction Program Measures

a. Proposal To Integrate Medicare Advantage (MA) Beneficiaries Into the Cohorts of the Hospital Readmissions Reduction Program Measure Set Beginning With the FY 2027 Program Year

(1) Background

In this proposed rule, we propose to adopt substantive updates to the Hospital 30-Day, All-Cause, Risk-Standardized Readmission Rate (RSRR) Following Acute Myocardial Infarction (AMI) Hospitalization; Hospital 30-Day, All-Cause, RSRR Following Heart Failure (HF) Hospitalization; Hospital 30-Day, All-Cause, RSRR Following Pneumonia (PN) Hospitalization; Hospital-Level, 30-Day, All-Cause, RSRR Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization; Hospital 30-Day, All-Cause, RSRR Following Total Hip Arthroplasty (THA) and Total Knee Arthroplasty (TKA) Hospitalization; and Hospital 30-Day, All-Cause, RSRR Following Coronary Artery Bypass Graft (CABG) Surgery measures, hereinafter referred to as the Hospital Readmissions Reduction Program measure set, beginning with the FY 2027 Program Year. The proposed updates to the Hospital Readmissions Reduction Program measure set would include integrating MA beneficiaries into each measure's cohorts and reducing the applicable period from a three-year period to a two-year period. In addition, we propose to make a non-substantive modification; we would update the risk adjustment model to use individual International Classification of Diseases (ICD)-10 codes instead of Hierarchical Condition Categories (HCCs). For the purposes of describing the substantive change of the Hospital Readmissions Reduction Program measure set, we note that ''cohort'' is defined as the hospitalizations, or ''index admissions,'' that are included when calculating each measure. This cohort is the set of hospitalizations that meet all the inclusion and exclusion criteria. For measure cohort details of the most recent versions of the Hospital Readmissions Reduction Program measure set, we refer readers to the

measure methodology report and measure risk adjustment statistical model on our website at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

Including MA beneficiaries in hospital outcome measures would help ensure that hospital quality would be measured across all Medicare beneficiaries and not just the Fee-For-Service (FFS) population. In 2024, 50 percent of eligible Medicare beneficiaries—or 34.3 million people—were covered by MA plans.[227] It is projected that nearly two-thirds of all Medicare enrollees will be enrolled in MA plans by 2030.[228] Consequently, using FFS-only beneficiaries may exclude a large segment of the focus population for quality measurement.

Additionally, studies comparing readmission rates between MA and FFS-only have shown mixed results. While several studies report lower readmissions for MA enrollees,[229] [230] others have found no difference or even higher risk-adjusted readmission rates for certain conditions.[231] [232] Due to these differing research study conclusions, adding the MA cohort to the Hospital Readmissions Reduction Program measures would allow for a more robust and holistic view of quality of care provided to all Medicare beneficiaries.[233] Most importantly, the FFS and MA data in our hospital outcome measures would empower patients and caregivers to make informed decisions about their healthcare by giving them additional comparative data on hospitals.

(2) Overview of Measure Updates

We refer readers to the CMS Measures Inventory Tool and Hospital Readmissions Reduction Program readmission measures specification manuals for more information on the Hospital Readmissions Reduction Program measure set, including background on each measure and a complete summary of measure specifications.[234] [235]

We propose to adopt updates to the Hospital Readmissions Reduction Program measure set in the Hospital Readmissions Reduction Program beginning with the FY 2027 program year. The newly refined versions of the Hospital Readmissions Reduction Program measure set would expand the measures' inclusion criteria to include MA beneficiaries. Currently, the measure denominator for the Hospital Readmissions Reduction Program measure set includes beneficiaries ''Enrolled in Medicare FFS Part A and Part B for the first 12 months prior to the date of admission and enrolled in Part A during the index admission.'' [236] We propose to modify the measure cohort to ''Enrolled in Medicare FFS and/or MA for the 12 months prior to the date of admission; and enrolled in FFS or MA during the index admission.'' [237] The addition of MA data to the measure doubles the cohort size and more accurately reflects the quality of care for both FFS and MA beneficiaries.

We are also providing a non-substantive update which would re-specify the risk model for each measure to primarily use individual ICD–10 codes, leveraging the specificity of individual ICD–10 coding in place of the previously used HCCs. This technical update would improve the performance of the risk adjustment models for condition- and procedure-specific mortality and complication measures.[238] We refer readers to the CMS Measures Management System for more on the list of ICD–10 codes used in the risk adjustment model, available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/2024-MUC-List-materials*.

(3) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the PRMR Process

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69457 through 69458) for details on the Pre-Rulemaking Measure Review (PRMR) process, including the voting procedures that the PRMR process uses to reach consensus on measure recommendations. The PRMR Hospital Committee, comprised of the PRMR Hospital Advisory Group and PRMR Hospital Recommendation Group, reviewed the proposed updated versions of the Hospital Readmissions Reduction Program measure set. Consensus is reached when there is 75 percent or higher agreement among members of a committee.[239] The PRMR Hospital Recommendation Group reviewed the proposed updated Hospital Readmissions Reduction Program measure set specifications (MUC2024–030, MUC2024–032, MUC2024–040, MUC2024–041, MUC2024–045, MUC2024–046) during a meeting on January 16, 2025, to vote on a recommendation about use of these measures for the Hospital Readmissions Reduction Program.[240]

The PRMR Hospital Recommendation Group reached consensus for each of the measures. For each measure, they voted to recommend the addition of MA data to each measure, with conditions.[241]

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital 30-Day, All-Cause, RSRR Following AMI Hospitalization measure were: 18 members of the group recommended adopting the updates without

[227] Centers for Medicaid & Medicare Services. Medicare Enrollment for September 2024 (Accessed on February 5, 2025). Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard*.

[228] Hale, J., Hong, N., Hopkins, B., et al. (2024) Health Insurance Coverage Projections for the US Population and Sources of Coverage, by Age, 2024–34. Health Affairs. 43(7); 922–932. *https://doi.org/10.1377/hlthaff.2024.00460*.

[229] Jacobs, P.D., Basu, J. Medicare Advantage and Post discharge Quality: Evidence From Hospital Readmissions. American Journal of Managed Care, 2020;26(12):524–529. Available at: *https://www.ajmc.com/view/medicare-advantage-and-postdischarge-quality-evidence-from-hospital-readmissions*.

[230] Huckfeldt, P.J., Escarce, J.J., Rabideau, B., et al. Less Intense Postacute Care, Better Outcomes for Enrollees in Medicare Advantage Than Those in Fee-For-Service. Health Affairs. 2017;26(1):91–100. *https://doi.org/10.1377/hlthaff.2016.1027*.

[231] Yayac, M.F., Harrer, S.L., Janiec, D.A., et al. Costs and Outcomes of Medicare Advantage and Traditional Medicare Beneficiaries After Total Hip and Knee Arthroplasty. Journal of American Academy of Orthopedic Surgeons. 2020;28(20):e910–e916. *https://doi.org/10.5435/JAAOS-D-19-00609*.

[232] Henke, R.M., Karaca, Z., Gibson, T.B., et al. Medicare Advantage and Traditional Medicare Hospitalization Intensity and Readmissions. Medical Care Research and Review. 2018;75(4):434–453. *https://doi.org/10.1177%2F1077558717692103*.

[233] Panagiotou, O.A., Kumar, A., Gutman, R., et al. Hospital Readmission Rates in Medicare Advantage and Traditional Medicare: A Retrospective Population-Based Analysis. Annals of Internal Medicine. 2019;171(2):99–106. *https://doi.org/10.7326/M18-1795*.

[234] CMS Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#*.

[235] CMS Quality Net. Available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

[236] CMS Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#*.

[237] 2024 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/2024/2024-11/2024-measures-under-consideration-list-now-available*.

[238] Krumholz, H.M., Coppi, A.C., Warner, F., et al. Comparative effectiveness of new approaches to improve mortality risk models from Medicare claims data. JAMA Network Open. 2019;2(7):e197314–e197314 Available at: *https://pmc.ncbi.nlm.nih.gov/articles/PMC6647547/*.

[239] Battelle—Partnership for Quality Measurement. (February 2025). Guidebook of Policies and Procedures for Pre-Rulemaking Measure Review (PRMR) and Measure Set Review (MSR). Available at: *https://p4qm.org/sites/default/files/2024-12/Final-Draft-Multi-Stakeholder-Group-Guidebook-of-Policies-and-Procedures.pdf*.

[240] Battelle—Partnership for Quality Measurement. (February 2025). PRMR 2024 MUC Recommendations Spreadsheet Final. Available at: *https://p4qm.org/PRMR/Resources*.

[241] Battelle—Partnership for Quality Measurement. (February 2025). PRMR 2024 MUC Recommendations Spreadsheet Final. Available at: *https://p4qm.org/media/3891*.

conditions; 9 members recommended adoption with conditions; and 0 members voted not to recommend the updates for adoption. Taken together, 100 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital 30-Day, All-Cause, RSRR Following AMI Hospitalization measure.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital 30-Day, All-Cause, RSRR Following HF Hospitalization measure were: 17 members of the group recommended adopting the updates without conditions; 10 members recommended adoption with conditions; and 0 members voted not to recommend the updates for adoption. Taken together, 100 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital 30-Day, All-Cause, RSRR Following HF Hospitalization measure.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital-Level, 30-Day, All-Cause, RSRR Following COPD Hospitalization measure were: 18 members of the group recommended adopting the updates without conditions; 9 members recommended adoption with conditions; and 0 members voted not to recommend the updates for adoption. Taken together, 100 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital-Level, 30-Day, All-Cause, RSRR Following COPD Hospitalization measure.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital 30-Day, All-Cause, RSRR Following THA and/or TKA Hospitalization measure were: 19 members of the group recommended adopting the updates without conditions; 7 members recommended adoption with conditions; and 1 member voted not to recommend the updates for adoption. Taken together, 96 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital 30-Day, All-Cause, RSRR Following THA and/or TKA Hospitalization measure.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital 30-Day, All-Cause, RSRR Following PN Hospitalization measure were: 17 members of the group recommended adopting the updates without conditions; 10 members recommended adoption with conditions; and 0 members voted not to recommend the updates for adoption. Taken together, 100 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital 30-Day, All-Cause, RSRR Following PN Hospitalization measure.

The voting results of the PRMR Hospital Recommendation Group for the proposed updates to the Hospital 30-Day, All-Cause, RSRR Following CABG Surgery measure were: 19 members of the group recommended adopting the updates without conditions; 8 members recommended adoption with conditions; and 0 members voted not to recommend the updates for adoption. Taken together, 100 percent of the votes were between ''recommend'' and ''recommend with conditions.'' Thus, the committee reached consensus and recommended with conditions the updates to the Hospital 30-Day, All-Cause, RSRR Following CABG Surgery measure.

The measure set was discussed as a group during the Hospital Recommendation Group meeting, with committee members providing recommendations that spanned across measures. The conditions submitted included: revising the inclusion criteria to include care provided in ambulatory settings; stratification of measure data by MA and FFS; consideration of a shorter 7- or 14-day readmission time period; and conducting additional testing to evaluate whether the measure is topped out for all subgroups reporting.

After taking these conditions into account, we propose to adopt the updated Hospital Readmissions Reduction Program measure set in the Hospital Readmissions Reduction Program. We note that the conditions were not specific to the addition of MA data into the measures but addressed the measures in totality. Therefore, we will review the applicability of stratifying the measures by MA or FFS data and provide that information through the confidential feedback reports for hospitals. We will also evaluate the readmission metrics to a shorter 7- or 14-day readmission time period and review the criteria to include care provided in ambulatory settings and its applicability to each measure. We continue to review each measure's topped out status through our internal measure evaluation reports.

(b) Measure Endorsement

We refer readers to FY 2025 IPPS/LTCH PPS final rule (89 FR 69457 through 69458) for details on the endorsement and maintenance (E&M) process including the procedures the CBE's E&M Committees use to evaluate measures and whether they meet endorsement criteria. The currently implemented version of these measures in the Hospital Readmissions Reduction Program were previously evaluated and endorsed by the CBE.[242] The proposed updated measures that include MA beneficiaries in the patient cohorts will each be considered for future endorsement.

(4) Data Submission and Reporting

The proposed updated Hospital Readmissions Reduction Program measure set would use index admission diagnoses and in-hospital comorbidity data from Medicare FFS Part A, MA claims/encounters, or both. Additional comorbidities prior to the index admission are assessed using Part A and Part B Medicare claims, MA encounters in the 12 months prior to index (initial) admission. A patient's Medicare FFS or MA enrollment status would be obtained from the Medicare enrollment data which contains beneficiary demographic, benefit/coverage, and vital status information. We propose to use claims and encounter data with admission dates beginning from July 1, 2023, through June 30, 2025, which is associated with the FY 2027 program year. By using CMS administrative data, hospitals would not be required to submit additional data for calculating the measures. If these measure updates are finalized, we would continue to publicly report readmission rates by posting the readmission measure results for the applicable conditions for a fiscal year for each applicable hospital on the Compare tool or successor website(s), currently available at *https://www.medicare.gov/care-compare/*, and on the Provider Data Catalog, available

[242] Hospital 30-Day, All-Cause, RSRR Following PN Hospitalization (CBE #0506), Hospital 30-Day, All-Cause, RSRR Following HF Hospitalization (CBE #0330), Hospital 30-Day, All-Cause, RSRR Following THA and/or TKA Hospitalization (CBE #1551), Hospital 30-Day, All-Cause, RSRR Following CABG Surgery (CBE #2515), Hospital-Level, 30-Day, All-Cause, RSRR Following COPD Hospitalization (CBE #1891), and Hospital 30-Day, All-Cause, RSRR Following AMI Hospitalization (CBE #0505) can all be found at *https://cmit.cms.gov/cmit/#/MeasureInventory*.

at *https://data.cms.gov/provider-data/*, as codified at § 412.154(f).

We invite public comment on this proposal.

b. Technical Updates to the Specifications of the Hospital Readmissions Reduction Program Measures Beginning With the FY 2027 Program Year

During the COVID–19 public health emergency (PHE), in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45256 through 45258), we updated the Hospital 30-Day All-Cause RSRR Following AMI Hospitalization; Hospital 30-Day, All-Cause, RSRR Following CABG Surgery; Hospital-Level, 30-Day, All-Cause, RSRR Following COPD Hospitalization; Hospital 30-Day, All-Cause, RSRR Following HF Hospitalization; and Hospital 30-Day, All-Cause, RSRR Following THA and/or TKA Hospitalization measures to exclude patients diagnosed with COVID–19, including a primary or secondary diagnosis present on admission (POA) of COVID–19, from both index admissions and readmissions (86 FR 45257 through 45258). In the FY 2023 IPPS/LTCH PPS final rule, we provided an update regarding the technical specifications for the Hospital 30-Day, All-Cause, RSRR Following PN Hospitalization measure to exclude patients with either principal or secondary diagnosis POA of COVID–19 from both index admissions and readmissions (87 FR 49083 through 49086). Additionally, in the FY 2023 IPPS/LTCH PPS final rule, we modified the technical measure specifications of each of the six readmission measures to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission beginning with the FY 2023 program year (87 FR 49086 through 49088).

We stated that we were making these updates pursuant to the technical updates policy we finalized in the FY 2015 IPPS/LTCH final rule. Under this policy, we finalized a subregulatory process to incorporate technical measure specification updates into the measure specifications we had previously adopted for the Hospital Readmissions Reduction Program (79 FR 50039). We reiterated this policy in the FY 2020 IPPS/LTCH final rule, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385 through 42387).

We are providing notice in this proposed rule that we intend to remove the COVID–19 exclusion from the readmission measures beginning with the FY 2027 program year. This technical update will modify these readmission measures to remove the exclusion of COVID–19 diagnosed patients from the index admissions and readmissions, including the removal of the exclusion of certain ICD–10 Codes that represented patients with a secondary diagnosis of COVID–19, and the history of COVID–19 risk variable.

The exclusion began as a response to the COVID–19 PHE which expired May 11, 2023. We believe that hospitals have had adequate time to adjust to the presence of COVID–19 as an ongoing virus. Using data from the last four years, July 2020–June 2024, our internal analysis showed a decline over time of the number of patients excluded from the various measure cohorts. Therefore, we believe that removing the exclusion of COVID–19 patients will ensure that these readmission measures continue to account for readmissions as intended and meet the goals of the Hospital Readmissions Reduction Program.

Additional resources about current measure technical specifications and the methodology for the Hospital Technical specification of the current readmission measures are provided at our website in the Measure Methodology Reports (available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*). Hospital Readmissions Reduction Program resources are located at the Resources web page of the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/hrrp/resources*). An updated measure methodology report will be made available in May 2026.

3. Additional Policies for the Hospital Readmissions Reduction Program

a. Proposal To Modify the Applicable Period for the Hospital Readmissions Reduction Program Measures Set

We propose to modify the definition of ''applicable period'' as specified at § 412.152. Currently, the ''applicable period'' is the 3-year period from which data are being collected to calculate excess readmission ratios (ERRs) and payment adjustment factors for the fiscal year; this includes aggregate payments for excess readmissions and aggregate payments for all discharges used in the calculation of the payment adjustment. In the FY 2013 IPPS/LTCH PPS final rule, we noted that the 3-year period provided an increase the number of cases per hospital used for measure calculation, which improved the precision of each hospital's readmission estimate (77 FR 53379 through 53382). The ''applicable period for dual eligibility'' is the same as the ''applicable period'' that we otherwise adopted for purposes of the Hospital Readmissions Reduction Program.

However, we now propose to reduce the applicable period from 3 to 2 years. The proposed update would allow for more recent data when assessing performance. With the proposed inclusion of MA patients in the cohort, we assessed whether the reliability of the measures could reach a satisfactory level when the applicable period is shortened. In testing, all measures showed better between-hospital variance using the 2-year FFS and MA combined cohort as compared to the current measure specifications of a 3-year applicable period and the FFS-only cohort.

Beginning in FY 2027, we propose that the ''applicable period'' for the Hospital Readmissions Reduction Program would be the 2-year period beginning 1 year advanced from the previous program fiscal year's start of the ''applicable period.'' For example, for the FY 2027 program determination, claims/encounter data with admission dates beginning from July 1, 2023, through June 30, 2025, would be used.

Under this proposed policy, for all subsequent years, we would advance this 2-year period by 1 year unless otherwise specified by the Secretary, which we would revise through notice and comment rulemaking. Similarly, the ''applicable period for dual eligibility'' would continue to correspond to the ''applicable period'' for the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary.

We invite public comment on this proposal.

b. Proposal To Identify Aggregate Payments for Each Condition/Procedure and All Discharges for FY 2027 and Subsequent Years

When calculating the numerator (aggregate payments for excess readmissions), we determine the base operating DRG payment amount for an individual hospital for the applicable period for each condition/procedure using Medicare FFS inpatient claims from the MedPAR file with discharge dates that are within the applicable period. Under our established methodology, we use the update of the MedPAR file for each Federal fiscal year, which is updated 6 months after the end of each Federal fiscal year

within the applicable period, as our data source.

In identifying discharges for the applicable conditions/procedures to calculate the aggregate payments for excess readmissions, we apply the same exclusions to the claims in the MedPAR file as are applied in the measure methodology for each of the applicable conditions/procedures. For example, for the FY 2025 applicable period, this included the discharge diagnoses for each applicable condition/procedure based on the list of specific ICD–10–CM and ICD–10–PCS code sets, as applicable, for that condition/procedure, as specified in the 2024 version of the measure methodology reports.

In this proposed rule, we propose to include payment data for Medicare FFS and MA beneficiaries that meet the criteria as previously described for each applicable condition/procedure to calculate the aggregate payments for excess readmissions. We will rely on the MedPAR and/or the latest available data source that would provide the most up-to-date comprehensive information on payment information for Medicare FFS and MA beneficiaries. This proposal results from our proposal to include MA beneficiaries in the Hospital Readmissions Reduction Program measure set cohorts.

We note that § 412.152 defines the terms ''aggregate payments for excess readmissions'' and ''excess readmissions ratio'' (ERR) broadly enough to allow us to include MA beneficiaries in the calculation without requiring us to revise the regulatory definition.

(1) Analysis of Proposed Changes Impact on Aggregate Payments

To assess the expected impact on hospital payment adjustments resulting from the changes to the readmission measures, the ''applicable period'', and calculations for aggregate payments for excess readmissions, we estimated hospitals' payment adjustment factors using the proposed measures updates to include MA data, the proposed two-year applicable period, and the proposed updates to the calculations for aggregate payments for each condition/procedure to include MA data. Later in this section we show the estimated total Medicare savings under the current payment adjustment factor calculations and the proposed payment adjustment factor calculations which would use a two-year applicable period and include MA data in the ERR calculations and calculations for aggregate payments for each condition/procedure. Based on our analysis, the estimated average change in Medicare savings per hospital from the proposed updates was $15,579, with 1,424 hospitals having a greater penalty amount and 1,547 hospitals having the same or lower penalty amount.

TABLE VI.K–01—ESTIMATED TOTAL MEDICARE SAVINGS OF PROPOSED ADDITION OF MA COHORT TO HOSPITAL READMISSIONS REDUCTION PROGRAM MEASURE SET

	Current methodology	Proposed updates	Difference between proposed updates and current methodology	Percentage difference between proposed updates and current methodology
Estimated total Medicare savings	$316,131,336	$357,264,092	$41,132,756	13
Number of penalized hospitals	2,342	2,417	75	3

Our analysis also assesses the impact of the proposed updates to the number of eligible hospitals, number and percentage of penalized hospitals, and penalties as a share of payments overall and by hospital characteristics. The first and fifth columns in the below table indicates the total number of hospitals eligible for a penalty under the Hospital Readmissions Reduction Program. In FY 2025, approximately 3,000 subsection (d) hospitals were included in the Hospital Readmissions Reduction Program. Poorly performing hospitals included in the program may receive a penalty if they are non-Maryland subsection (d) hospitals with 25 or more eligible discharges for at least one measure during the applicable period. The second and sixth columns in the table indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals). The third and seventh columns in the table indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. The fourth and eighth columns in the table estimate the financial impact on hospitals by hospital characteristic, referred to as the penalty as a share of payments. The penalty as a share of payments is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals. For example, under the current methodology, the penalty as a share of payments for urban hospitals is 0.42 percent, and with the proposed updates, the penalty as a share of payments for urban hospitals is 0.46 percent. This means that total penalties for all urban hospitals is 0.42 percent of total payments for urban hospitals under the current methodology and 0.46 percent with the proposed updates. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

TABLE VI.K–02—COMPARISON OF PROPOSED UPDATES TO CURRENT METHODOLOGY IN HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

Hospital characteristic	Current methodology (FY 2025 results: FFS only and 3-year performance period)				Proposed updates (adding MA stays and 2-year performance period)			
	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized (%) [c]	Penalty as a share of payments (%) [d]	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized (%) [c]	Penalty as a share of payments (%) [d]
All Hospitals	2,828	2,342	82.81	0.42	2,868	2,417	84.27	0.46
By Geographic Location:								
Urban hospitals	2,164	1,836	84.84	0.42	2,201	1,901	86.37	0.46

TABLE VI.K–02—COMPARISON OF PROPOSED UPDATES TO CURRENT METHODOLOGY IN HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC—Continued

Hospital characteristic	Current methodology (FY 2025 results: FFS only and 3-year performance period)				Proposed updates (adding MA stays and 2-year performance period)			
	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized (%) [c]	Penalty as a share of payments (%) [d]	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized (%) [c]	Penalty as a share of payments (%) [d]
1–99 beds	505	336	66.53	0.39	518	353	68.15	0.46
100–199 beds	624	549	87.98	0.48	637	574	90.11	0.53
200–299 beds	397	368	92.70	0.48	406	374	92.12	0.56
300–399 beds	268	250	93.28	0.43	269	249	92.57	0.47
400–499 beds	123	112	91.06	0.46	123	121	98.37	0.47
500 or more beds	247	221	89.47	0.34	248	230	92.74	0.37
Rural hospitals	664	506	76.20	0.41	667	516	77.36	0.45
1–49 beds	312	203	65.06	0.31	315	213	67.62	0.36
50–99 beds	186	151	81.18	0.46	186	151	81.18	0.48
100–149 beds	92	82	89.13	0.39	92	84	91.30	0.46
150–199 beds	44	41	93.18	0.43	44	40	90.91	0.59
200 or more beds	30	29	96.67	0.40	30	28	93.33	0.35
By Teaching Status: [e]								
Non-teaching	1,634	1,280	78.34	0.45	1,651	1,308	79.22	0.50
Fewer than 100 residents	910	806	88.57	0.44	932	837	89.81	0.48
100 or more residents	284	256	90.14	0.36	285	272	95.44	0.39
By Ownership Type:								
Government	403	313	77.67	0.29	408	340	83.33	0.31
Proprietary	636	519	81.60	0.55	637	511	80.22	0.64
Voluntary	1,789	1,510	84.40	0.41	1,822	1,565	85.89	0.45
By Safety-net Status: [f]								
Safety-net hospitals	2,284	1,889	82.71	0.44	2,312	1,945	84.13	0.47
Non-safety-net hospitals	544	453	83.27	0.34	556	472	84.89	0.42
By Disproportionate Share Hospital (DSH) Patient Percentage: [g]								
0–24	1,058	828	78.26	0.48	1,079	880	81.56	0.53
25–49	1,469	1,273	86.66	0.39	1,478	1,279	86.54	0.42
50–64	177	147	83.05	0.36	181	150	82.87	0.49
65 and over	124	94	75.81	0.43	130	108	83.08	0.53
By Medicare Cost Report (MCR) Percentage: [h]								
0–24	1,183	995	84.11	0.33	1,224	1,041	85.05	0.40
25–49	1,572	1,296	82.44	0.48	1,569	1,325	84.45	0.50
50–64	62	43	69.35	0.75	61	39	63.93	0.75
65 and over	10	7	70.00	0.29	11	9	81.82	1.21
By Region:								
New England	122	106	86.89	0.64	123	115	93.50	0.60
Middle Atlantic	313	287	91.69	0.46	318	293	92.14	0.56
East North Central	444	379	85.36	0.43	446	387	86.77	0.49
West North Central	228	172	75.44	0.23	227	184	81.06	0.38
South Atlantic	483	421	87.16	0.46	489	439	89.78	0.47
East South Central	253	210	83.00	0.47	257	221	85.99	0.42
West South Central	425	342	80.47	0.39	425	315	74.12	0.38
Mountain	211	151	71.56	0.31	212	150	70.75	0.30
Pacific	349	274	78.51	0.34	371	313	84.37	0.42

Source: Proposed Updates results based on: preliminary MA–FFS readmission measure results that were available using data from January 1, 2022, through December 31, 2023, and include non-HRRP hospitals (such as CAHs) in the estimation of ERRs; MA–FFS DRG ratios and dual proportions from July 1, 2021, through June 30, 2023. The Current Methodology results are the actual FY 2025 results using data from July 1, 2020, through June 30, 2023. Both analyses use MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), to calculate the payment adjustment as a proportion of total base operating DRG payments. Both analyses use data from the FY 2025 proposed rule impact file for hospital characteristics data. The number of hospitals with each characteristic may not sum to the total number of hospitals due to some hospitals having missing characteristic data in the impact file. This table only includes results for hospitals who are eligible for a penalty under the program on the basis of having at least 25 eligible discharges for at least one measure. The average share of penalties as a percentage of all DRG payments is calculated as the sum of all Medicare savings for the group of hospitals divided by total base operating DRG payments for all hospitals in that group.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.

[e] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[g] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[h] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

We invite public comment on this proposal.

c. Proposal To Update and Codify the Extraordinary Circumstance Exception (ECE) Policy for the Hospital Readmissions Reduction Program

(1) Background

Under our current Extraordinary Circumstances Exception (ECE) regulations, we have granted exceptions to exclude data from Hospital Readmissions Reduction Program payment reduction calculations (FY 2016 IPPS/LTCH PPS final rule, 80 FR 49542 through 49543). An exception may be granted for extraordinary circumstances including, but not limited to, natural disasters or systemic problems with CMS data collection systems that directly affected the ability of facilities to submit data.[243] We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49542 through 49544); FY 2018 IPPS/LTCH PPS final rule (82 FR 38239 through 38240), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45260 through 45262) for further background and details of our ECE policy. We also refer readers to the QualityNet website for the specific requirements for submission of an ECE request in the Hospital Readmissions Reduction Program.[244] Hospitals can request a CMS Quality Program ECE for multiple programs based on the same extraordinary circumstance using one ECE request form, including the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital VBP Program, and the HAC Reduction Program.

Our ECE policy provides flexibility for Hospital Readmissions Reduction Program participants to ensure continuity of quality care delivery and measure reporting in the event of an extraordinary circumstance. For instance, we recognize that, in circumstances where an exclusion of data from the calculation of a hospital's payment reduction for the applicable period is not applicable, it is beneficial for a hospital to submit data for use in payment reduction calculations later than the Hospital Readmissions Reduction Program data submission deadline. Delayed data submission for use in payment reduction calculations authorized under the ECE policy would allow temporary relief for a hospital experiencing an extraordinary circumstance while preserving data reporting such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to update our regulations to specify that an ECE could take the form of an extension of time for a hospital to comply with a data reporting requirement if CMS determines that this type of relief would be appropriate under the circumstances.

(2) Proposals To Update and Codify the Extraordinary Circumstances Exception (ECE) Policy for the Hospital Readmissions Reduction Program

We propose to update and codify our ECE policy at 42 CFR 412.154(d) to include extensions of time as a form of relief and to further clarify the policy. Specifically, at proposed § 412.154(d)(1), we propose that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance—defined as an event beyond the control of a hospital (for example a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

We propose that the process for requesting or granting an ECE will remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[245] At proposed § 412.154(d)(2)(i), we propose that a hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Under this proposed policy, we clarify that CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred. At proposed § 412.154(d)(2)(ii), we propose that CMS notify the requestor with a decision, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision will specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

Additionally, at § 412.154(d)(3), we propose that CMS may grant an ECE to one or more hospitals that have not requested an ECE, if CMS determines that: a systemic problem with CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement; or that an extraordinary circumstance has affected an entire region or locale. As is the case under our current policy, any ECE granted will specify whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

This proposed ECE policy would provide further reporting flexibility for hospitals and clarify the ECE process for participants of the Hospital Readmissions Reduction Program. We refer readers to sections X.C.8, VI.L.5, VI.M.3.b, and X.D.4 in this proposed rule for similar proposals in the Hospital IQR Program, Hospital VBP Program, HAC Reduction Program, and PCHQR Program, respectively.

We invite public comment on our proposals.

L. Hospital Value-Based Purchasing (VBP) Program

1. Background

a. Overview

For background on the Hospital VBP Program, we refer readers to the CMS website at: *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-value-based-purchasing*. We also refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

b. FY 2026 Program Year Payment Details

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2026 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2026 is approximately $1.7 billion, based on the December 2024 update of the FY 2024 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). We note that these proxy adjustment factors will not be used to adjust hospital payments. These

[243] Centers for Medicare & Medicaid Services (CMS) Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form. (2025). QualityNet. Available at: *https://qualitynet.cms.gov/files/677e843f50ed8df7419f60e1?filename=HQR_ECE_Req_Form_CY_2025.pdf*.

[244] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hrrp/participation#tab2*.

[245] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hrrp/participation#tab2*.

proxy value-based incentive payment adjustment factors were calculated using the proposed FY 2026 Hospital VBP program methodology and historical baseline and performance periods for the FY 2025 Hospital VBP Program and the SEP–1 measure. These proxy factors were calculated using the December 2024 update to the FY 2024 MedPAR file. The slope of the linear exchange function used to calculate these proxy factors was 4.5245231964, and the estimated amount available for value-based incentive payments to hospitals for FY 2026 is approximately $1.7 billion. We intend to include an update to this table, as Table 16A, with the FY 2026 IPPS/LTCH PPS final rule, to reflect changes based on the March 2025 update to the FY 2024 MedPAR file. We will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2026 Hospital VBP Program. We expect that Table 16B will be posted on the CMS website in Fall 2025.

2. Hospital VBP Program Measures

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

(1) Background

We are proposing to adopt substantive measure updates to the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (hereinafter referred to as the COMP–HIP–KNEE measure), beginning with the FY 2033 program year. We are proposing these updates contingent on our adopting the same updates to the COMP–HIP–KNEE measure for use in the Hospital IQR Program beginning with the FY 2027 payment determination, which we discuss further in section X.C. of the preamble of this proposed rule.

We adopted the COMP–HIP–KNEE measure in the FY 2015 IPPS/LTCH PPS final rule beginning with the FY 2019 program year for use in the Hospital VBP Program (79 FR 50062 through 50063). We previously adopted substantive updates to the COMP–HIP–KNEE measure in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59067 through 59070) to include index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims which expanded the measure outcome to include 26 additional mechanical complications as identified from 10th revision of the International Classification of Diseases (ICD–10) codes. We continue to consider the clinical outcomes of the COMP–HIP–KNEE measure a high priority, providing important data on patient safety and adverse events, which is why we are proposing to adopt additional updates to the COMP–HIP–KNEE measure in the Hospital VBP Program under the Clinical Outcomes Domain beginning with the FY 2033 program year. In Table VI.L.-01, we illustrate the program years for which we have adopted the COMP–HIP–KNEE measure and the updates that we have adopted, as well as the proposed updates.

TABLE VI.L.–01—SUMMARY OF CURRENT AND PROPOSED REPORTING OF THE COMP–HIP–KNEE MEASURE IN THE HOSPITAL IQR AND VBP PROGRAMS

Payment year or program year impacted	Version of measure in use	
	Hospital IQR Program	Hospital VBP Program
FY 2026	Modification 1 (Additional outcomes added) [1]	Original.[2]
FY 2027	Modification 2 (Add MA patients, shorten performance period) [3]	Original.
FY 2028	Modification 2	Original.
FY 2029	Modification 2	Original.
FY 2030	N/A	Modification 1.
FY 2031	N/A	Modification 1.
FY 2032	N/A	Modification 1.
FY 2033 and Subsequent Years	N/A	Modification 2.

[1] Modification 1 was finalized in the FY 2024 IPPS/LTCH PPS final rule.
[2] Original version of the measure was finalized in the FY 2015 IPPS/LTCH PPS final rule.
[3] Modification 2 is being proposed in this section of the proposed rule.

(2) Overview of Measure Updates

The proposed substantive updates to the COMP–HIP–KNEE measure would expand the measure's inclusion criteria to (1) include Medicare Advantage (MA) patients and (2) shorten the performance period from 3 years to 2 years. The addition of MA data to the measure would approximately double the cohort size, demonstrate measure reliability, and more accurately reflect the quality of care for both FFS and MA beneficiaries. Additionally, the proposed update to reduce the performance period from 3 to 2 years would allow for more recent data for assessing performance. Being able to report measures with only 2 years of data with satisfactory reliability would provide more relevant and up to date quality information for actionable quality improvement insights.

With the inclusion of MA patients in the cohort, we assessed whether the reliability of the measure could reach a satisfactory level when the performance period is shortened. Signal-to-noise reliability testing was calculated for all hospitals in the testing sample (n=3,124) and hospitals with at least 25 cases (n=1,777), using 2 years of data for analysis (CY 2022/2023). For hospitals with at least 25 cases, the median reliability score was 0.784, ranging from 0.545 to 0.997. The 25th and 75th percentiles were 0.673 and 0.883, respectively. Therefore 75% of hospitals exceed a 0.6 reliability score, using the 2 year FFS and MA combined cohort, and we believe that this reliability score demonstrates that 2 years of data provide satisfactory reliability.

The proposed updated COMP–HIP–KNEE measure would use index admission diagnoses and procedure codes from Medicare FFS claims and MA encounter data to determine cohort inclusion criteria, complications outcomes, and present on admission (POA) comorbidities. We would assess additional comorbidities prior to the index (initial) admission using Part A inpatient, outpatient, and Part B office visit Medicare claims and MA encounters in the 12 months prior to index admission. We would obtain enrollment status from the Medicare Enrollment Database which contains beneficiary demographic, benefit/

coverage, and vital status information. We refer readers to section X.C. of the preamble of this proposed rule for more information on the proposed updates. As stated previously, these proposed updates in the Hospital VBP Program are contingent on our adopting them in the Hospital IQR Program.

(3) Pre-Rulemaking Process and Measure Endorsement

We listed this updated COMP–HIP–KNEE measure in the publicly available document entitled ''List of Measures Under Consideration for December 1, 2024'' (the ''MUC List'') with identification number MUC2024–042.[246] [247] [248] We refer readers to section X.C. of the preamble of this proposed rule for a discussion of the Pre-Rulemaking Measure Review (PRMR) meeting for this measure.

The CBE previously re-endorsed the original measure in July of 2021.[249] We submitted the measure with the proposed modifications (CBE #1550) for re-endorsement for the Fall 2024 cycle. The CBE's Endorsement & Maintenance Cost and Efficiency Committee convened in the Fall 2024 cycle to review the COMP–HIP–KNEE measure that was submitted to the CBE for re-endorsement. The E&M Cost and Efficiency Committee voted, and did not reach consensus on this measure on February 10, 2025.[250] Thus, the measure was not re-endorsed by the CBE.

The committee discussed concerns about the case mix of patients, noting the shift from inpatient to outpatient for these elective procedures and that healthier patients may be directed to ambulatory surgical centers, leaving acute care hospitals with higher-risk individuals, which could affect case mix and measure outcomes. Another concern discussed was the limited scope of the measure which only includes inpatient complications, and whether this limited scope provides utility and relevance for patients. Additional concerns discussed include the overall approach to adjusting low-volume provider performance to the average, and that scores for lower volume providers may be misleading to patients.

Regarding concerns on patient mix, we note that this measure focuses on higher-risk patients and is intentionally narrow to capture significant complications, such as sepsis, pulmonary embolism, or a second surgery which should be treated in the inpatient setting. We wish to emphasize that those having elective THA or TKA procedures within the inpatient setting must meet certain criteria, resulting in a smaller cohort of patients, and in communities where there are no ambulatory care centers the patient would be treated in the hospital outpatient department and would not be counted in this measure. Regarding comments about adjusting for low patient volume, the goal of this measure and adjusting for low volume is to make performance scores available for as many providers as possible while trying to avoid misclassification or profiling of providers. We further note that scores are not available for facilities with fewer than 25 cases, because the number of cases may be too small for meaningful results. We wish to emphasize that this measure has been an important patient safety measure that has provided meaningful quality and patient safety information for patients on the hospital inpatient setting for a substantial period of time. Further, we are committed to continually improving quality and patient safety for as many patients as possible within the inpatient setting.

Section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. We note that although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act generally requires measures specified by the Secretary in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(4) Data Source, Submission and Public Reporting

To continue to assess clinical outcomes, we are proposing to adopt these measure updates to the COMP–HIP–KNEE measure in the Hospital VBP Program under the Clinical Outcomes Domain beginning with the FY 2033 program year, contingent on our adoption of these changes in the Hospital IQR Program as described in section X.C. of the preamble of this proposed rule. If finalized, we would begin posting the updated measure data on the Compare tool beginning in July 2026, which would enable us to post data on the substantive updates to the measure for at least one year before the proposed adoption beginning with the April 1, 2029–March 31, 2031, performance period which is associated with the FY 2033 payment determination, as required by section 1886(o)(2)(C)(i) of the Act.[251] We are also proposing that the performance standards calculation methodology for the updated COMP–HIP–KNEE measure would be the same as that which we currently use for the measure. The performance standards for the updated measure for FY 2033 are not yet available.

We invite public comment on this proposal.

b. Technical Updates to the Specifications of the COMP–HIP–KNEE Measure To Update the Risk Adjustment Model Beginning With the FY 2027 Program Year

In addition to the updates discussed previously and further updates we discuss below, we provide notice of our intent to make a non-substantive modification, as permitted under § 412.164(c)(1), to the COMP–HIP–KNEE measure to update the risk adjustment model to use individual International Classification of Diseases (ICD)–10 codes instead of Hierarchical Condition Categories (HCCs). Under this technical updates policy, we use a

[246] Centers for Medicare & Medicaid Services. (2024) Overview of the List of Measures Under Consideration December 1, 2024. Available at: *https://mmshub.cms.gov/sites/default/files/2024-MUC-List-Overview.pdf*.

[247] Centers for Medicare and Medicaid Services. (2024) 2024 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/2024-MUC-List.xlsx*.

[248] We note that the measure denominator of the updated COMP–HIP–KNEE measure, as described in the MUC List, excludes patients with a principal diagnosis code of COVID–19 ICD–10 code (U07.1) or with a secondary diagnosis code of COVID–19 coded as present on admission (POA) on the index admission claim. As discussed further below, we are providing notice of our intent to remove this exclusion from the measure.

[249] Centers for Medicare & Medicaid Services. (2022) MAP 2021–2022 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Available at: *https://www.qualityforum.org/Publications/2022/03/MAP_2021-2022_Considerations_for_Implementing_Measures_Final_Report_-_Clinicians,_Hospitals,_and_PAC-LTC.aspx*.

[250] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Endorsement Summary Report. This report will be available through this link: *https://p4qm.org/projects/cost-and-efficiency*.

[251] We note that this performance period would only be 2 years instead of 3 if the proposed updates to the COMP–HIP–KNEE measure, which includes shortening of the performance period, are adopted.

subregulatory process to incorporate technical measure specification updates into the measure specifications we have adopted for the Hospital VBP Program (79 FR 50077 through 50079). We continue to believe that this policy, codified at 42 CFR 412.164(c)(1), is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on substantive updates, which so fundamentally change a measure that it is no longer the same measure that we originally adopted. The current risk adjustment strategy for this measure involves grouping ICD–10 diagnosis codes from CMS's HCC system into clinically relevant categories. We then evaluate the HCCs for statistical association with the measure's outcome.[252] However, research has indicated that using individual ICD codes in place of HCCs could significantly improve the model performance of the mortality measures.[253] To better leverage the data and analytical advances since the measure was initially developed, we created a new approach to use individual ICD–10 codes for risk adjustment instead of grouping them into categories. With this new approach, the discriminative performance of the risk adjustment model as measured by c-statistic was significantly better and the calibration performance also proved to be satisfactory.

c. Technical Updates to the Specifications of the Five Condition- and Procedure-Specific Mortality Measures and the COMP–HIP–KNEE Measure Beginning With the FY 2027 Program Year

During the COVID–19 public health emergency, in the FY 2022 IPPS/LTCH PPS final rule, we stated that we were updating the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization (MORT–30–AMI), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery (MORT–30–CABG), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization (MORT–30 COPD), Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization (MORT–30–HF), and Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (COMP–HIP–KNEE) measures to exclude admissions with either a principal or secondary diagnosis of COVID–19 present on admission from the measure denominators (86 FR 45279 through 45281). In the FY 2023 IPPS/LTCH PPS final rule, we also updated the technical specifications for the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization (MORT–30–PN) measure to exclude patients with either principal or secondary diagnoses of COVID–19 from the measure denominator (87 FR 49109 through 49110). Additionally, we further modified the technical measure specifications for all six measures in the Clinical Outcomes domain, the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, MORT–30–PN, and COMP–HIP–KNEE measures, in the FY 2023 IPPS/LTCH PPS final rule to include a covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission beginning with the FY 2023 program year (87 FR 49106 through 49109).

We stated that we were making these updates pursuant to the technical updates policy we finalized in the FY 2015 IPPS/LTCH PPS final rule. We refer readers to the previous section of the preamble of this proposed rule for more details on our subregulatory technical updates policy.

Accordingly, we are providing notice in this proposed rule that we intend to remove the COVID–19 exclusions from the five condition- and procedure-specific mortality measures and one procedure-specific complication measure beginning with the FY 2027 program year. This technical update will modify the technical specifications of the MORT–30–AMI, MORT–30–CABG, MORT–30–COPD, MORT–30–HF, and MORT–30–PN measures to include the ICD–10 codes that identify patients with a principal or secondary diagnosis of COVID–19 in the measure denominators. The technical update will also modify the technical specifications of the COMP–HIP–KNEE measure to include the ICD–10 codes that identify patients with a principal or secondary diagnosis of COVID–19 in both the measure numerator and denominator. Lastly, the technical update will remove the covariate adjustment for patient history of COVID–19 in the 12 months prior to the admission for all six measures in the Clinical Outcomes domain for the Hospital VBP Program beginning with the FY 2027 program year.

We believe that including COVID–19 patients in the measure specifications for the measures in the Clinical Outcomes domain beginning with the FY 2027 program year provides a more complete picture of the care quality provided in hospitals, which we believe meets the goals of the Hospital VBP Program. Technical specifications of the Hospital VBP Program mortality and complication measures are provided on our website under the Measure Methodology Reports section (available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology* and *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*). Additional resources about the measure technical specifications and methodology for the Hospital VBP Program are on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/hvbp*).

d. Summary of Previously Adopted Quality Measures for the Hospital VBP Program

We refer readers to the FY 2025 IPPS/LTCH PPS final rule for summaries of the previously adopted measures for the FY 2026 through FY 2030 program years (89 FR 69402). We are not proposing any changes to the measure set. Table VI.L.–02 summarizes the previously adopted Hospital VBP Program measure set for the FY 2026 program year.

[252] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[253] Krumholz, H.M., Coppi, A.C., Warner, F., Triche, E.W., Li, S.X., Mahajan, S., Li, Y., Bernheim, S.M., Grady, J., Dorsey, K., Lin, Z., & Normand, S.T. (2019). Comparative Effectiveness of New Approaches to Improve Mortality Risk Models From Medicare Claims Data. JAMA network open, 2(7), e197314. *https://doi.org/10.1001/jamanetworkopen.2019.7314*.

TABLE VI.L.–02—SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2026 PROGRAM YEAR

Measure short name	Domain/measure name	CBE No.
	Person and Community Engagement Domain	
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions).	0166 (0228)
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
SEP–1	Severe Sepsis and Septic Shock: Management Bundle	0500
	Clinical Outcomes Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
COMP–HIP–KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

Table VI.L.–03 summarizes the previously adopted Hospital VBP Program measures for the FY 2027 through FY 2031 program years.

TABLE VI.L.–03—SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2027 THROUGH FY 2031 PROGRAM YEARS

Measure short name	Domain/measure name	CBE No.
	Person and Community Engagement Domain	
HCAHPS *	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition and Responsiveness of Hospital Staff dimensions).	0166 (0228)
	Safety Domain	
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure.	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
SEP–1	Severe Sepsis and Septic Shock: Management Bundle	0500

TABLE VI.L.–03—SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2027 THROUGH FY 2031 PROGRAM YEARS—Continued

Measure short name	Domain/measure name	CBE No.
	Clinical Outcomes Domain	
MORT–30–AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization.	0230
MORT–30–HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization.	0229
MORT–30–PN	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization.	0468
MORT–30–COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization.	1893
MORT–30–CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery.	2558
COMP–HIP–KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA).	1550
	Efficiency and Cost Reduction Domain	
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

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

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

a. Background

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69403 through 69405) for previously adopted baseline and performance periods for the FY 2026 through FY 2030 program years. We also refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998) in which we finalized a schedule for all future baseline and performance periods.

b. Summary of Baseline and Performance Periods for the FY 2027 Through FY 2031 Program Years

Tables VI.L.–04, VI.L.–05, VI.L.–06, VI.L.–07, and VI.L.–08 summarize the baseline and performance periods that we have previously adopted.

TABLE VI.L.–04—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2027 PROGRAM YEAR

Measures	Baseline period	Performance period
	Person and Community Engagement Domain	
HCAHPS	January 1, 2023–December 31, 2023	January 1, 2025–December 31, 2025.
	Clinical Outcomes Domain	
Mortality measures (MORT–30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN).	July 1, 2017–June 30, 2020*	July 1, 2022–June 30, 2025.
COMP–HIP–KNEE	April 1, 2017–March 31, 2020*	April 1, 2022–March 31, 2025.
	Safety Domain	
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	January 1, 2023–December 31, 2023	January 1, 2025–December 31, 2025.
SEP–1	January 1, 2023–December 31, 2023	January 1, 2025–December 31, 2025.
	Efficiency and Cost Reduction Domain	
MSPB	January 1, 2023–December 31, 2023	January 1, 2025–December 31, 2025.

*These baseline periods are impacted by the extraordinary circumstance exception (ECE) granted by CMS on March 22, 2020, due to the COVID–19 public health emergency. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE VI.L.–05—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline period	Performance period
	Person and Community Engagement Domain	
HCAHPS	January 1, 2024–December 31, 2024	January 1, 2026–December 31, 2026.

TABLE VI.L.–05—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR—Continued

Measures	Baseline period	Performance period
Clinical Outcomes Domain		
Mortality measures (MORT–30–AMI, MORT–30–HF, MORT3–0–COPD, MORT–30–CABG, MORT–30–PN).	July 1, 2018–June 30, 2021 *	July 1, 2023–June 30, 2026.
COMP–HIP–KNEE	April 1, 2018–March 31, 2021 *	April 1, 2023–March 31, 2026.
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	January 1, 2024–December 31, 2024	January 1, 2026–December 31, 2026.
SEP–1	January 1, 2024–December 31, 2024	January 1, 2026–December 31, 2026.
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2024–December 31, 2024	January 1, 2026–December 31, 2026.

* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE VI.L.–06—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2029 PROGRAM YEAR

Measures	Baseline period	Performance period
Person and Community Engagement Domain		
HCAHPS	January 1, 2025–December 31, 2025	January 1, 2027–December 31, 2027.
Clinical Outcomes Domain		
Mortality measures (MOR–T30–AMI, MORT–30–HF, MORT–30–COPD, MORT–30–CABG, MORT–30–PN).	July 1, 2019–June 30, 2022 *	July 1, 2024–June 30, 2027.
COMP–HIP–KNEE	April 1, 2019–March 31, 2022 *	April 1, 2024–March 31, 2027.
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	January 1, 2025–December 31, 2025	January 1, 2027–December 31, 2027.
SEP–1	January 1, 2025–December 31, 2025	January 1, 2027–December 31, 2027.
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2025–December 31, 2025	January 1, 2027–December 31, 2027.

* These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE VI.L.–07—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2030 PROGRAM YEAR

Measures	Baseline period	Performance period
Person and Community Engagement Domain		
HCAHPS	January 1, 2026–December 31, 2026	January 1, 2028–December 31, 2028.
Clinical Outcomes Domain		
Mortality measures (MORT–30–AMI, MORT–30–HF, MORT3–0–COPD, MORT–30–CABG, MORT–30–PN).	July 1, 2020–June 30, 2023	July 1, 2025–June 30, 2028.
COMP–HIP–KNEE	April 1, 2020–March 31, 2023 *	April 1, 2025–March 31, 2028.
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	January 1, 2026–December 31, 2026	January 1, 2028–December 31, 2028.
SEP–1	January 1, 2026–December 31, 2026	January 1, 2028–December 31, 2028.

TABLE VI.L.–07—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2030 PROGRAM YEAR—Continued

Measures	Baseline period	Performance period
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2026–December 31, 2026	January 1, 2028–December 31, 2028.

*This baseline period is impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculation for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication measure. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE VI.L.–08—BASELINE AND PERFORMANCE PERIODS FOR THE FY 2031 PROGRAM YEAR

Measures	Baseline period	Performance period
Person and Community Engagement Domain		
HCAHPS	January 1, 2027–December 31, 2027	January 1, 2029–December 31, 2029.
Clinical Outcomes Domain		
Mortality measures (MORT–30–AMI, MORT–30–HF, MORT3–0–COPD, MORT–30–CABG, MORT–30–PN).	July 1, 2021–June 30, 2024	July 1, 2026–June 30, 2029.
COMP–HIP–KNEE	April 1, 2021–March 31, 2024	April 1, 2026–March 31, 2029.
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia).	January 1, 2027–December 31, 2027	January 1, 2029–December 31, 2029.
SEP–1	January 1, 2027–December 31, 2027	January 1, 2029–December 31, 2029.
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2027–December 31, 2027	January 1, 2029–December 31, 2029.

4. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59089) for previously established performance standards for the FY 2026 program year. We also refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69406 through 69407) for the previously established performance standards for the FY 2027 program year.

b. Technical Update to the Five National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) Measures

In this section, we provide information regarding upcoming changes to the standard population data that are used to calculate the standardized infection ratio (SIR) for the CDC's NHSN measures. These changes are occurring as part of routine measure maintenance.

CDC's NHSN measures are used to monitor hospital performance on prevention of HAIs. For each NHSN measure, CDC calculates the standardized infection ratio (SIR), which compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusting for several risk factors. The predicted number of infections is determined using the amount of exposure (for example, the number of central line days when predicting CLABSI events) for a given hospital according to the relevant observed risk factors and infection rates for the same combination of risk factors that occurred among a standard population during a specified period as reflected by the appropriate risk adjustment model (this is sometimes referred to as a ''baseline,'' [254] but referred to here as ''standard population data''). This set of rates forms standard population data that promotes timely comparisons to measure change in an outcome. Since 2016, CDC has been using data collected in CY 2015 to determine the standard population and, currently, the 2015 standard population is used to calculate the HAI measures in the Hospital VBP Program.[255] Prior to 2016, calculated SIRs had different standard population years for each infection type and facility type.[256]

During this update, HAI SIR calculations of infections reported beginning in CY 2025 will reflect the use of both the new 2022 standard population data and the 2015 standard population data.

Because the Hospital VBP Program calculates improvement points using comparisons between data collected from hospitals in a baseline period and data collected in a performance period, the Hospital VBP Program must treat CDC's baseline update differently than other quality programs. We have determined that we cannot equally compare CDC's new baseline data to the current baseline data to calculate improvement points. If we do not address the CDC's measure update, we will be unable to compare the baseline and performance periods for NHSN measures in the FY 2027 through FY 2028 program years. To address the

[254] ''Rebaseline'' is a term that CDC's NHSN staff use to describe the process of updating the national HAI baseline data and risk adjustment models developed using these data. As part of routine measure maintenance, CDC has updated the baseline to ensure the number of predicted infections used in SIR calculations reflects the current state of HAIs in the United States using CY 2022 data. The CDC released its initial announcement of this rebaseline in June 2023. Resources and training regarding the 2015 and 2022 standard population data can be found at: *https://www.cdc.gov/nhsn/nhsnrebaseline/index.html.*

[255] Centers for Disease Control and Prevention. CHARTING THE COURSE: 2022 HAI REBASELINE. Available at: *https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf.*

[256] Centers for Disease Control and Prevention. Paving the Path Forward: 2015 Rebaseline. Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

problem, we intend to use the 2015 baseline data to calculate performance standards and calculate and publicly report measure scores until the FY 2029 program year, as depicted in the table below. For the FY 2029 program year and subsequent years, the Hospital VBP Program will use the ''new standard population data'' (that is, CY 2022 data) to calculate performance standards and calculate and publicly report measure scores.

TABLE VI.L.–09—CDC'S BASELINE DATA IN THE HOSPITAL VBP PROGRAM

Measures	FY 2026 Program year *	FY 2027 Program year *	FY 2028 Program year *	FY 2029 Program year *
NHSN Measures Baseline Periods	2015 Baseline Data	2015 Baseline Data	2015 Baseline Data	2022 Baseline Data.
NHSN Measures Performance Period.	2015 Baseline Data	2015 Baseline Data	2015 Baseline Data	2022 Baseline Data.

* CDC will use current baseline data (CY 2015) to calculate measure data that we will translate into scores on the measures.
** CDC will use new baseline data (CY 2022) to calculate measure data that we will translate into scores on the measures.

c. Previously and Newly Established Performance Standards for the FY 2027 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45294 through 45295), we established performance standards for the FY 2027 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). Additionally, in the FY 2025 IPPS/LTCH PPS final rule, we established the performance standards for the FY 2027 program year for the Safety domain measures (CAUTI, CLABSI, CDI, MRSA Bacteremia, Colon and Abdominal Hysterectomy SSI, and SEP–1) and the Person and Community Engagement Domain (the HCAHPS Survey Dimensions) (89 FR 69406 through 69407).

While we are making technical updates to the measures in the Clinical Outcomes domain beginning with the FY 2027 program year as discussed previously, the FY 2027 performance standards that we previously adopted for measures in this domain are unchanged because the applicable baseline period does not include COVID–19 impacted data after applying the national ECE. For the reader's reference, the performance standards for the measures in the Clinical Outcomes domain for the FY 2027 program year are set out in Table VI.L.–10.

TABLE VI.L.–10—PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain *		
MORT–30–AMI	0.877824	0.893133
MORT–30–HF	0.887571	0.913388
MORT–30–PN	0.844826	0.877204
MORT–30–COPD	0.917395	0.932640
MORT–30–CABG	0.971149	0.980752
COMP–HIP–KNEE **	0.023322	0.017018

* As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299), we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards due to the ECE granted by CMS on March 22, 2020.
** Lower values represent better performance.

d. Newly Established and Estimated Performance Standards for the FY 2028 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49118), we established performance standards for the FY 2028 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). However, given the technical update to the measures in the Clinical Outcomes domain beginning with the FY 2027 program year as discussed previously, we are establishing new performance standards for the measures in the Clinical Outcomes domain for the FY 2028 program year. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table VI.L.–11.

TABLE VI.L.–11.—NEWLY ESTABLISHED AND ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Safety Domain		
CAUTI* **	0.463	0.
CLABSI* **	0.549	0.
CDI* **	0.329	0.
MRSA Bacteremia* **	0.618	0.
Colon and Abdominal Hysterectomy SSI* **	0.74 0.899	0.
SEP–1***	0.632479	0.865693.
Clinical Outcomes Domain		
MORT–30–AMI♦	0.877260	0.893229.
MORT–30–HF♦	0.885427	0.910649.
MORT–30–PN♦	0.831776	0.866166.
MORT–30–COPD♦	0.913752	0.929652.
MORT–30–CABG♦	0.971052	0.980570.
COMP–HIP–KNEE*♦	0.029758	0.022002.
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

*Lower values represent better performance.

**We note that the numerical values for the performance standards for the HAI measures in this proposed rule represent estimates based on the most recently available data and have been rebaselined as discussed previously. We intend to update the numerical values in the FY 2026 IPPS/LTCH PPS final rule. These estimates are based on 10/01/2023–09/30/2024 data.

***We note that the numerical values for the performance standards for the SEP–1 measure in this proposed rule represent estimates based on the most recently available data. These estimates are based on 10/01/2023–09/30/2024 data.

♦As discussed in section VI.L.2.a. and b. of the preamble of this proposed rule, we are providing notice of a technical update for all measures in the Clinical Outcomes Domain. While these performance standards are unchanged at this time, we intend to update them in the FY 2026 IPPS/LTCH PPS final rule.

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507–69508) where we finalized the policy to modify the scoring of the HCAHPS Survey for the FY 2027 through FY 2029 program years while updates to the survey are publicly reported under the Hospital IQR Program. Scoring is modified to only score hospitals on the six unchanged Hospital VBP dimensions of the HCAHPS Survey until the updates to the HCAHPS Survey have been publicly reported for one year. The six unchanged dimensions of the HCAHPS Survey for the Hospital VBP Program are as follows:

- ''Communication with Nurses''.
- ''Communication with Doctors''.
- ''Communication about Medicines''.
- ''Discharge Information''.
- ''Cleanliness and Quietness''.
- ''Overall Rating.''

Scoring is modified such that for each of the six unchanged dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) will be calculated, the larger of which will be summed across these six dimensions to create a pre-normalized HCAHPS Base Score of 0–60 points (as compared to 0–80 points with the current eight dimensions). The pre-normalized HCAHPS Base Score will then be multiplied by 8/6 (1.3333333) and rounded according to standard rules (values of 0.5 and higher are rounded up, values below 0.5 are rounded down) to create the normalized HCAHPS Base Score. Each of the six unchanged dimensions will be of equal weight, so that, as currently scored, the normalized HCAHPS Base Score will range from 0 to 80 points. HCAHPS Consistency Points will be calculated in the same manner as the current method and will continue to range from 0 to 20 points. Like the Base Score, the Consistency Points Score will consider scores across the six unchanged dimensions of the Person and Community Engagement domain. The final element of the scoring formula, which will remain unchanged from the current formula, will be the sum of the HCAHPS Base Score and the HCAHPS Consistency Points Score for a total score that ranges from 0 to 100 points. The method for calculating the performance standards for the six dimensions will remain unchanged. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26512) for our methodology for calculating performance standards. The estimated performance standards for the six unchanged dimensions for the FY 2028 program year are set out in Table VI.L.–12.

TABLE VI.L.–12—ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN

HCAHPS survey dimension*	Floor (minimum)	Achievement threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	55.55	77.55	86.47
Communication with Doctors	55.53	77.66	86.34
Responsiveness of Hospital Staff**	X	X	X

TABLE VI.L.–12—ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN—Continued

HCAHPS survey dimension *	Floor (minimum)	Achievement threshold (50th percentile)	Benchmark (mean of top decile)
Communication about Medicines	38.47	58.25	69.90
Hospital Cleanliness & Quietness	40.97	63.69	77.70
Discharge Information	66.89	86.22	91.47
Care Transition **	X	X	X
Overall Rating of Hospital	35.06	69.07	84.04

* We note that the numerical values for the performance standards for the HCAHPS Survey in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2026 IPPS/LTCH PPS final rule. These estimates are based on 10/01/2023–09/30/2024 data.

** In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69507 and 69508), we finalized the policy to only score on the six unchanged dimensions of the original HCAHPS Survey for the FY 2028 program year while the updates to the survey are publicly reported on in the Hospital IQR Program for the statutorily required one year. Therefore, we are not reporting performance standards for the dimensions that are unscored.

e. Newly Established Performance Standards for Certain Measures for the FY 2029 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59091 through 59092), we established performance standards for the FY 2029 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). However, given the technical update to the measures in the Clinical Outcomes domain beginning with the FY 2027 program year as discussed previously, we are newly establishing the performance standards for the measures in the Clinical Outcomes domain for the FY 2029 program year to now include COVID–19 patients in the measure data. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table VI.L–13.

TABLE VI.L.13—NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain*		
MORT–30–AMI	0.874856	0.893101.
MORT–30–HF	0.880089	0.9072.
MORT–30–PN	0.814736	0.853996.
MORT–30–COPD	0.905916	0.924829.
MORT–30–CABG	0.971027	0.979822.
COMP–HIP–KNEE **	0.025024	0.018708.
Efficiency and Cost Reduction Domain		
MSPB **	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* As discussed in section VI.L.2.a. and b. of the preamble of this proposed rule, we are providing notice of a technical update for all measures in the Clinical Outcomes Domain. While these performance standards are unchanged at this time, we intend to update them in the FY 2026 IPPS/LTCH PPS final rule.

** Lower values represent better performance.

f. Newly Established Performance Standards for Certain Measures for the FY 2030 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69409 through 69410), we established performance standards for the FY 2030 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). However, given the technical update to the measures in the Clinical Outcomes domain beginning with the FY 2027 program year as discussed previously, we are newly establishing the performance standards for the measures in the Clinical Outcomes domain for the FY 2030 program year. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table VI.L.–14.

TABLE VI.L.—14 NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2030 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain*		
MORT–30–AMI	0.873975	0.89371.
MORT–30–HF	0.878881	0.90929.
MORT–30–PN	0.81782	0.858688.
MORT–30–COPD	0.903404	0.924332.
MORT–30–CABG	0.972219	0.9815.
COMP–HIP–KNEE**	0.028252	0.019993.
Efficiency and Cost Reduction Domain		
MSPB**	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

*As discussed in section VI.L.2.a. and b. of the preamble of this proposed rule, we are providing notice of a technical update for all measures in the Clinical Outcomes Domain. While these performance standards are unchanged at this time, we intend to update them in the FY 2026 IPPS/LTCH PPS final rule.

**Lower values represent better performance.

g. Newly Established Performance Standards for Certain Measures for the FY 2031 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN, MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB Hospital) for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26512), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2031 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table VI.L.–15.

TABLE VI.L.–15—NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2031 PROGRAM YEAR

Measure short name	Achievement threshold	Benchmark
Clinical Outcomes Domain*		
MORT–30–AMI	0.878523	0.896695.
MORT–30–HF	0.882749	0.912451.
MORT–30–PN	0.835165	0.873917
MORT–30–COPD	0.909324	0.929745.
MORT–30–CABG	0.975023	0.983685.
COMP–HIP–KNEE**	0.036439	0.02533.
Efficiency and Cost Reduction Domain		
MSPB**	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

*As discussed in section VI.L.2.a. and b. of the preamble of this proposed rule, we are providing notice of a technical update to remove the COVID–19 exclusion from the measure data for all measures in the Clinical Outcomes Domain. As a result, these performance standards have been calculated with the inclusion of COVID–19 data.

**Lower values represent better performance.

5. Proposals To Update the Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

(a) Background

Under our current Extraordinary Circumstances Exception (ECE) regulations, we have granted exceptions with respect to Hospital VBP Program requirements in the event of certain extraordinary circumstances beyond the control of the hospital. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45298 through 45299) and 42 CFR 412.165(c) for additional details related to the Hospital VBP Program ECE policy. We also refer readers to the QualityNet website for the specific requirements for submission of an ECE request in the Hospital VBP Program.[257]

Our ECE policies provide flexibility for Hospital VBP program participants to ensure continuity of quality care delivery and measure scoring in the event of an extraordinary circumstance. For instance, we recognize that, in circumstances where a full exception is not applicable, it is beneficial for a hospital to report data later than the reporting deadline. Delayed reporting authorized under our ECE policy allows temporary relief for a hospital

[257] *https://qualitynet.cms.gov/inpatient/hvbp/participation#tab6.*

experiencing an extraordinary circumstance while preserving the benefits of data reporting such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to update our regulations to specify that an ECE could take the form of an extension of time for a hospital to comply with a data reporting requirement if CMS determines that this type of relief would be appropriate under the circumstances.

(b) Proposal To Update the Extraordinary Circumstances Exception (ECE) Policy for the Hospital VBP Program

We propose to update the current ECE policy codified at 42 CFR 412.165(c) to include extensions of time as a form of relief and to further clarify the policy. Specifically, at proposed § 412.165(c)(1), we propose that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance—defined as an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

We propose that the process for requesting or granting an ECE would remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[258] At proposed § 412.165(c)(2)(i), we propose that a hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Our current policy allows a request within 90 days; however, this proposed change would align to CMS systems implementation requirements across all quality reporting programs. Under this proposed codified policy, we clarify that CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred. At proposed § 412.165(c)(2)(ii), we propose that CMS notify the requestor with a decision in writing. In the event that CMS grants an ECE to the hospital, the written decision will specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

Additionally, at § 412.165(c)(3), we note that CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines either of the following: a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement, or that an extraordinary circumstance has affected an entire region or locale. As is the case under our current policy, any ECE granted will specify whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

This proposed ECE policy would provide further reporting flexibility for hospitals and clarify the ECE process.

We invite public comment on our proposals.

6. Proposed Removal of the Health Equity Adjustment From the Hospital VBP Program

In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59092 through 59106), we adopted a Health Equity Adjustment (HEA) that, beginning with the FY 2026 program year, rewards top performing hospitals that serve higher proportions of patients with dual eligibility status. We codified the HEA at §§ 412.160 and 412.165(b) of our regulations. Section 1886(o)(5)(A) of the Act authorizes the Secretary to develop the methodology for assessing hospital performance based on performance standards established with respect to the measures selected for the Hospital VBP Program.

As discussed in the FY 2024 IPPS/LTCH PPS final rule, by providing the HEA to hospitals that serve higher proportions of patients with dual eligibility status and that perform well on quality measures, the HEA would appropriately recognize the resource intensity expended to achieve high performance on quality measures by hospitals that serve a high proportion of patients with dual eligibility status, while also mitigating the worse health outcomes experienced by dually eligible patients through incentivizing better care across all hospitals.

In this proposed rule, we are proposing to remove the HEA because simplifying the Hospital VBP Program's scoring methodology by removing the HEA will improve hospitals' understanding of the program and provide clearer incentives to hospitals as they seek to improve the quality of care for all patients. As noted in section I.G. of Appendix A of this proposed rule, in Table I.G.6.–01 and Table I.G.6.–02 the overall impact of the HEA on the overall payment adjustments is small. With the HEA, the average net percentage payment adjustment for FY 2026 is 0.170% and without the HEA, the average net percentage payment adjustment is 0.168%. Given this relatively small impact, and in light of the Administration's priority to streamline regulations and reduce burdens on those participating in the Medicare program, we are proposing to remove the HEA at this time. We refer readers to **SUPPLEMENTARY INFORMATION** section of this proposed rule for the Unleashing Prosperity Through Deregulation of the Medicare Program—Request for Information for more information.

We considered altering the structure of the adjustment methodology to simplify it, but that process will require time to develop and test a new adjustment and, if pursued, would be addressed in future rulemaking.

We do not anticipate any serious reliance interests as a result of this proposal since the HEA does not require any additional reporting burden.

We propose to codify this removal of the HEA by removing the definition of ''Health equity adjustment bonus points'' in § 412.160 of our regulations and revising § 412.165(b) to remove the calculation and addition of health equity adjustment bonus points from the Total Performance Score calculation beginning with the FY 2026 program year. We refer readers to Table I.G.6.–01 and Table I.G.6.–02 in K–CF, Section 6: Effects of Changes Under the FY 2026 Hospital Value-Based Purchasing (VBP) Program, which reflect an estimated impact analysis of base operating DRG payment amounts resulting from the FY 2026 Hospital VBP Program with and without the HEA, respectively.

We welcome public comment on these proposals.

M. Hospital-Acquired Condition Reduction Program Updates and Changes (HACRP)

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50709) for a general overview of the Hospital-Acquired Condition (HAC) Reduction Program and a detailed discussion of the statutory basis for the Program. We also refer readers to 42 CFR 412.170 through 412.172 for codified HAC Reduction Program requirements.

2. Measures for FY 2026 and Subsequent Years in the HAC Reduction Program

a. Current Measures

The previously finalized measures for the HAC Reduction Program for FY

[258] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

2026 and subsequent years are shown in table VI.M.–01. Technical specifications for the CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure can be found on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/psi/resources.* Technical specifications for the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) healthcare-associated infection (HAI) measures can be found at the CDC's NHSN website at: *https://www.cdc.gov/nhsn/acute-care-hospital/index.html* and on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/hai/resources.* These web pages provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

TABLE VI.M.–01—HAC REDUCTION PROGRAM MEASURES FOR FY 2026 AND SUBSEQUENT YEARS

Short name	Measure name	Consensus-based entity (CBE) No.
HAC Reduction Program Measures for FY 2026 and Subsequent Years		
CMS PSI 90	CMS Patient Safety and Adverse Events Composite	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure.	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure.	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.	1716

We are not proposing to add or remove any measures in this proposed rule. We refer readers to section I.G.9. of Appendix A of this proposed rule for an updated estimate of the impact of the Program policies on the proportion of hospitals in the worst performing quartile of Total HAC Scores for the FY 2026 HAC Reduction Program.

b. Technical Update to CDC's National Healthcare Safety Network Healthcare-Associated Infection Measures for the HAC Reduction Program

In this section, we provide information regarding upcoming changes to the standard population data that are used to calculate the standardized infection ratio (SIR) for the CDC's NHSN measures. These changes are occurring as part of routine measure maintenance.

CDC's NHSN measures are used to monitor hospital performance on prevention of healthcare-associated infections (HAIs). For each NHSN measure, CDC calculates the SIR, which compares a hospital's observed number of HAIs to the number of infections predicted for the hospital, adjusting for several risk factors. The predicted number of infections is determined using the amount of exposure (for example, the number of central line days when predicting CLABSI events) for a given hospital according to the relevant observed risk factors and infection rates for the same combination of risk factors that occurred among a standard population during a specified period as reflected by the appropriate risk adjustment model (this is sometimes referred to as a ''baseline,'' [259] but referred to here as ''standard population data''). This set of rates forms standard population data that promotes timely comparisons to measure change in an outcome. Since 2016, CDC has been using data collected in CY 2015 to determine the standard population and, currently, the 2015 standard population is used to calculate the HAI measures in the HAC Reduction Program.[260] Prior to 2016, calculated SIRs had different standard population years for each infection type and facility type.[261]

During this update, HAI SIR calculations of infections reported beginning in CY 2025 will reflect the use of both the new 2022 standard population data and the 2015 standard population data. We anticipate that the new 2022 standard population data will affect the HAC Reduction Program beginning with the FY 2028 program year when both years of the 2-year applicable period (also referred to as the ''performance period'' of the measures), CY 2025 and CY 2026, will use the 2022 update to the standard population for the CDC's NHSN measures.

Under the HAC Reduction Program, confidential reports are made available to hospitals with respect to HACs of the hospital during the applicable period (78 FR 50708 through 50709). In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484 through 41489), we clarified the Scoring Calculations Review and Correction Period (83 FR 41484) for the HAC Reduction Program, which provides hospitals with detailed HAC Reduction Program data and results in confidential Hospital-Specific Reports (HSRs). We give hospitals 30 days to review their HAC Reduction Program data, submit questions about the calculation of their results, and request corrections prior to such information being made public.[262] The HAI measures using the 2022 update to the standard population in the FY 2028 HAC Reduction Program dataset would be publicly reported on the Provider Data Catalog in early 2028.

For the HAI measure information publicly reported on the Compare tool

[259] ''Rebaseline'' is a term that CDC's NHSN staff use to describe the process of updating the national HAI baseline data and risk adjustment models developed using these data. As part of routine measure maintenance, CDC has updated the baseline to ensure the number of predicted infections used in SIR calculations reflects the current state of HAIs in the United States using CY 2022 data. The CDC released its initial announcement of this rebaseline in June 2023. Resources and training regarding the 2015 and 2022 standard population data can be found at: *https://www.cdc.gov/nhsn/nhsnrebaseline/index.html.*

[260] Centers for Disease Control and Prevention. CHARTING THE COURSE: 2022 HAI REBASELINE. Available at: *https://www.cdc.gov/nhsn/pdfs/rebaseline/22-Rebaseline-FAQs-Final-Version.pdf.*

[261] Centers for Disease Control and Prevention. Paving the Path Forward: 2015 Rebaseline. Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

[262] For more information on the Scoring Calculations Review and Correction Period, see: *https://qualitynet.cms.gov/inpatient/hac/payment#tab2.*

on *Medicare.gov,* it will continue to display on a quarterly basis calculated from a rolling four quarters of data. The HAI measures using the 2022 update to the standard population data will begin to be publicly reported on the Compare tool in fall 2026 using four quarters of CY 2025 data.

TABLE VI.M.–02—CDC BASELINE DATA ON THE COMPARE TOOL

Performance period for CDC NHSN HAI measures	Standard population data year	Public reporting
October 1, 2024, to September 30, 2025	2015	Summer 2026.
January 1, 2025, to December 31, 2025	2022	Fall 2026.

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38324), our current policy has been to report data as soon as it is feasible on CMS websites such as the Compare tool and the Provider Data Catalog, after a 30-day preview period.[263] Table VI.M.–03 summarizes the HAI performance periods, the standard population data year, HAC Reduction Program year, and public reporting timeframe for the CDC's NHSN measures.

TABLE VI.M.–03—CDC BASELINE DATA IN THE HAC REDUCTION PROGRAM

HAC Reduction Program year	Performance period for CDC NHSN HAI measures	Standard population data year	Public reporting
FY 2025	January 1, 2022, to December 31, 2023	2015	Early 2025.
FY 2026	January 1, 2023, to December 31, 2024	2015	Early 2026.
FY 2027	January 1, 2024, to December 31, 2025	2015	Early 2027.
FY 2028	January 1, 2025, to December 31, 2026	2022	Early 2028.

We refer readers to section VI.L.4.b of this proposed rule, where we are proposing updates to the standard population data for the CDC's NHSN HAI measures in the Hospital Value-Based Purchasing (VBP) Program.

While we are not required to solicit comments on technical updates, we invite public comment on this technical update.

3. Proposal To Codify the Extraordinary Circumstances Exception Policy for the HAC Reduction Program

a. Background

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45309 through 45310), we clarified that an Extraordinary Circumstances Exception (ECE) granted under the HAC Reduction Program may allow an exception from quality data reporting requirements and may grant a request to exclude any data submitted (whether submitted for claims purposes or to the CDC's NHSN) from the calculation of a hospital's measure results or Total HAC Score for the applicable period or both, depending on the exact circumstances under which the request was made. We intend to provide relief for a hospital whose ability to accurately collect quality measure data and to report those data in a timely manner has been negatively impacted as a direct result of experiencing a significant disaster or other extraordinary circumstance beyond the control of a hospital (80 FR 49579 through 49581) or both. An exception may be granted for extraordinary circumstances including, but not limited to, natural disasters or systemic problems with data collection systems.[264] We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49579 through 49581), FY 2018 IPPS/LTCH PPS final rule (82 FR 38276 through 38278), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45308 through 45310) for further background and details of our ECE policy. We also refer readers to the QualityNet website for the specific requirements for submission of an ECE request in the HAC Reduction Program.[265] Hospitals can request a CMS Quality Program ECE for multiple programs based on the same extraordinary circumstance using one ECE request form, including the Hospital IQR Program, the Hospital VBP Program, and the Hospital Readmissions Reduction Program.

Our ECE policy provides flexibility for HAC Reduction Program participants to ensure continuity of quality care delivery and measure reporting in the event of an extraordinary circumstance. For instance, we recognize that, in circumstances where an exclusion of any data submitted from the calculation of a hospital's measure results or Total HAC Score for the applicable period is not applicable, it may be beneficial for a hospital to report data later than the reporting deadline. Delayed reporting authorized under the ECE policy would allow temporary relief for a hospital experiencing an extraordinary circumstance, while preserving data reporting benefits such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to specify that an ECE could take the form of an extension of time for a hospital to comply with a data reporting requirement if CMS determines that this type of relief would be appropriate under the circumstances.

b. Proposals To Codify the Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

We propose to codify the ECE policy at 42 CFR 412.172(c) and include extensions of time as a form of relief. Specifically, at proposed § 412.172(c)(1), we propose that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary

[263] For more information on the Care Compare Preview period, see: *https://qualitynet.cms.gov/inpatient/public-reporting/public-reporting/hospital-compare-preview.*

[264] Centers for Medicare & Medicaid Services (CMS) Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form. (2025). QualityNet. Available at: *https://qualitynet.cms.gov/files/677e843f50ed8df7419f60e1?filename=HQR_ECE_Req_Form_CY_2025.pdf.*

[265] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hac/participation#tab2.*

circumstance—defined as an event beyond the control of a hospital (for example a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

We propose that the process for requesting or granting an ECE would remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[266] At proposed § 412.172(c)(2)(i), we propose that a hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Under this proposed policy, we clarify that CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred. At proposed § 412.172(c)(2)(ii), we propose that CMS notify the requestor with a decision in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision will specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

Additionally, at § 412.172(c)(3), we note that CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that: a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement, or that an extraordinary circumstance has affected an entire region or locale. Any ECE granted will specify whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

The ECE policy is intended to provide hospitals with further reporting flexibility and clarity regarding expectations when submitting ECE requests for participants of the HAC Reduction Program. We refer readers to sections X.C.8, VI.L.5, VI.K.3.c., and X.D.4. of the preamble of this proposed rule for similar proposals in the Hospital IQR Program, Hospital VBP Program, Hospital Readmissions Reduction Program, and PCHQR Program, respectively.

We invite public comment on our proposals.

[266] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

N. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which also reauthorized the RCHD for five years. Below we summarize the status of the demonstration program and the current methodologies for implementation and calculating budget neutrality, and propose the amount to be subtracted from the national IPPS payment rates to account for the costs of the demonstration in FY 2026. The amount would include the reconciled amount of demonstration costs for FY 2020 in the FY 2026 IPPS/LTCH final rule. We expect all finalized cost reports for FY 2020 to be available when the FY 2026 IPPS/LTCH final rule is published.

Last year we published a new solicitation (89 FR 105049) to select 10 additional qualifying hospitals to participate in the Rural Community Hospital Demonstration. We only accepted applications to this solicitation from hospitals in the 20 least densely populated States, according to data for 2020 from the U.S. Census Bureau. These States are: Alaska, Arizona, Arkansas, Colorado, Idaho, Iowa, Kansas, Maine, Mississippi, Montana, Nebraska, Nevada, New Mexico, North Dakota, Oklahoma, Oregon, South Dakota, Utah, Vermont, and Wyoming. We did not accept applications from hospitals located in other States or in the U.S. territories. Applications were due March 1, 2025; we will be selecting hospitals on a rolling basis beginning May 1, 2025. Given the upcoming statutory termination of the model, we are aligning performance dates for the selected hospitals with the last performance day for the currently authorized extension; therefore, although previous agreements ran for 5-year periods, agreements for hospitals selected under CMS–5051–N2 will run only until June 30, 2028.

2. Background

Section 410A(a) of the MMA (Pub. L. 108–173) required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Our policy for implementing the 5-year extension period authorized by the CAA, 2021 (Pub. L. 116–260) follows upon the previous extensions under the Affordable Care Act (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255). Section 410A of the MMA (Pub. L. 108–173) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148) required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. In addition, the Affordable Care Act (Pub. L. 111–148) limited the number of hospitals participating to no more than 30. Section 15003 of the Cures Act (Pub. L. 114–255) required a 10-year extension period in place of the 5-year extension period under the Affordable Care Act (Pub. L. 111–148), thereby extending the demonstration for another 5 years. Section 128 of CAA, 2021 (Pub. L. 116–260), in turn, revised the statute to indicate a 15-year extension period, instead of the 10-year extension period mandated by the Cures Act (Pub. L. 114–255). Please refer to the FY 2023 IPPS proposed and final rules (87 FR 28454 through 28458 and 87 FR 49138 through 49142, respectively) for an account of hospitals entering into and withdrawing from the demonstration with these re-authorizations. There are currently 20 hospitals participating in the demonstration.

2. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of the MMA (Pub. L. 108–173) requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, made it unlikely that increased Medicare outlays would produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (We applied a different methodology for FY 2017, with the demonstration expected to end prior to the Cures Act extension.) As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

We resumed this methodology of offsetting demonstration costs against the national payment rates in the IPPS final rules from FY 2018 through FY 2025. Please see the FY 2025 IPPS final rule for an account of how we applied the budget neutrality requirement for these fiscal years (89 FR 69412 through 69413).

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Updated factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year.

We note that we have calculated this difference for FYs 2005 through 2018 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by CAA, 2021

For the most-recently enacted extension period, under the CAA, 2021, we have continued upon the general budget neutrality methodology used in previous years, as described previously in the citations to earlier IPPS final rules. In this proposed rule, we outline the methodology to be used for determining the offset to the national IPPS payment rates for FY 2026.

(1) Methodology for Estimating Demonstration Costs for FY 2026

Consistent with the general methodology from previous years, we are estimating the costs of the demonstration for the upcoming fiscal year, and proposing to incorporate this estimate into the budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2026. We are conducting this estimate for FY 2026 based on the 20 currently participating hospitals. The methodology for calculating this amount for FY 2026 proceeds according to the following steps:

Step 1: For each of these 20 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. The ''as submitted'' cost report, submitted by each of the 20 hospitals, with a report end date in CY2023 is used. We sum these hospital -specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 20 hospitals eligible to participate during FY 2026.

Then, we multiply the total general amount by the FYs 2024, 2025, and 2026 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (We are using the proposed market basket percentage increase for FY 2026, which can be found at section VI.B.1. of the preamble to this proposed rule). The result for the 20 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2026.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2024 through 2026 to the applicable estimated reasonable cost amount (previously described) to model the estimated FY 2026 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise have been paid in FY 2026 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration had not been implemented. We sum these hospital-

specific amounts, and, in turn, multiply this sum by the FYs 2024, 2025, and 2026 IPPS applicable percentage increases. (For FY 2026, we are using the proposed applicable percentage increase, per section VI.B.1. of the preamble of this proposed rule). This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 20 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2026.

For this proposed rule, the resulting amount is $47,527,557, which, if finalized, would be incorporated into the budget neutrality offset adjustment for FY 2026. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. If updated data become available prior to the final rule, we will use them as appropriate to estimate the costs for the demonstration program for FY 2026 in accordance with our methodology for determining the budget neutrality estimate. We will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration. We are proposing to include estimated costs of the demonstration for FY 2026 for all participating hospitals, to include those participating as a result of the current solicitation, in the budget neutrality offset adjustment in the FY 2027 IPPS proposed and final rules.

(2) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2018 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

At this time, for the FY 2026 proposed rule, not all of the finalized cost reports are available for the 20 hospitals that completed cost report periods beginning in FY 2020 under the demonstration payment methodology. We expect all of these finalized cost reports to be available by the time of the final rule, and thus we are proposing to include the difference between the actual cost of the demonstration for FY 2020 as determined from finalized cost reports within the budget neutrality offset amount in the FY 2026 final rule.

(3) Total Proposed Budget Neutrality Offset Amount for FY 2026

For this FY 2026 IPPS/LTCH PPS proposed rule, the proposed budget neutrality offset amount for FY 2026 is the amount determined under section X.2.c.(2). of the preamble of this proposed rule, representing the difference applicable to FY 2026 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 20 hospitals eligible to participate in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $47,527,557.

However, we note, that the overall amount might change if there are any revisions prior to the final rule to the data used to formulate this estimate. We also expect to revise the budget neutrality offset amount upon calculating the actual costs of the demonstration for FY 2020, after receiving all of the finalized cost reports for that fiscal year.

VII. Proposed Changes to the IPPS for Capital-Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) × (DRG Weight) × (Geographic Adjustment Factor (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond

the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Proposed Annual Update for FY 2026

The proposed annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2026 is discussed in section III. of the Addendum to this FY 2026 IPPS/LTCH PPS proposed rule.

We also note that in section II.D. of the preamble of this proposed rule, we discuss our proposed revision to the adjustment to the payment amount for certain clinical trial or expanded access use immunotherapy cases to include other cases where the immunotherapy product is not purchased in the usual manner (such as provided at no cost) that will group to MS–DRG 018 for both operating IPPS payments and capital IPPS payments. We refer readers to section II.D. of this preamble for additional details on the proposed payment adjustment for these cases.

VIII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed Rate-of-Increase in Payments to Excluded Hospitals for FY 2026

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (formerly classified as ''Subclause II LTCs'') also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs.

Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating market basket to a 2018 base year, and finalized the use of the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years. As discussed in section IV. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing to rebase and revise the IPPS operating basket to a 2023 base year. Therefore, we are proposing to use the percentage increase in the proposed 2023-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2026 and subsequent fiscal years. Accordingly, for FY 2026, the rate-of-increase percentage to be applied to the target amount for these hospitals would be the FY 2026 percentage increase in the proposed 2023-based IPPS operating market basket.

For the FY 2026 IPPS/LTCH PPS proposed rule, based on IGI's 2024 fourth quarter forecast, we estimate that the proposed 2023-based IPPS operating market basket percentage increase for FY 2026 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the FY 2026 rate-of-increase percentage that will be applied to the FY 2025 target amounts in order to calculate the FY 2026 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data become available for the FY 2026 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2026.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for

cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). (For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322).) Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of total Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2026, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2026, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is estimated to be the proposed percentage increase in the proposed 2023-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2026 is 3.2 percent, which is based on IGI's fourth quarter 2024 forecast. Furthermore, we are proposing that if more recent data become available for the FY 2026 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2026.

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this proposed rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a State in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the proposed rule as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section of the proposed rule as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022.

As described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three States—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2025 IPPS/LTCH PPS final rule. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the

budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five have elected to participate in the extension period. The selected CAHs are located in two States—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, five CAHs are participants in the telehealth intervention, three CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2025IPPS/LTCH PPS final rule (89 FR 69416 through 69419), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. CMS Intervention Payment and Payment Waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site for Medicare telehealth services. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS reimburses the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS does not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies that the payment for a telehealth service furnished by a distant site practitioner is the same as it would be if the service had been furnished in-person. CMS modifies the payment amount specified for telehealth services under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(i)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a) and 485.645(a)(2) and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives section 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule, because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy that in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We explained our belief that this policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we finalized a policy in the FY 2023 IPPS/LTCH PPS final rule that we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

e. Policies for Implementing the 5-Year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the

demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

f. Total Budget Neutrality Offset Amount for FY 2026

At this time, for the FY 2026 IPPS/LTCH PPS proposed rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

Therefore, we do not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2026. This policy would have no impact for any national payment system for FY 2026.

IX. Proposed Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2026

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days.

Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002, **Federal Register** (67 FR 55954), we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA. For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this proposed rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002, final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002, final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002, final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002, final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1,

2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to (82 FR 38299).)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extends the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b–1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3021 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002, final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2026

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–

DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2026, there would be 774 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 standard, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities (45 CFR 160.103) must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this proposed rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare Administrative Contractors (MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic

information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Proposed Changes to the MS–LTC–DRGs for FY 2026

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2025, through September 30, 2026 (FY 2026), consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2026 are the same as the MS–DRGs being proposed for use under the IPPS for FY 2026. In addition, because the proposed MS–LTC–DRGs for FY 2026 are the same as the proposed MS–DRGs for FY 2026, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 43, as discussed in section II.E. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2026.

3. Proposed Development of the FY 2026 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002, LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs. We also made a modification in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). We also adopted, beginning in FY 2023, a 10-percent cap policy on the reduction in a MS–LTC–DRG's relative weight in a given year. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550)). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). For details on our adoption of the 10-percent cap policy, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49152 through 49154).)

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our proposed methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our proposed methodology). For FY 2026, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2026 MS–LTC–DRG relative weights.

b. Development of the MS–LTC–DRG Relative Weights for FY 2026

In this section, we present our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2026. We first list and provide a brief description of our proposed steps for determining the FY 2026 MS–LTC–DRG relative weights. Later in this section, we discuss in greater detail each step. We note that, as we did in FY 2025, we are proposing to use our historical relative weight methodology as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a ten percent cap as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162).

- *Step 1—Prepare data for MS–LTC–DRG relative weight calculation.* In this

step, we select and group the applicable claims data used in the development of the proposed MS–LTC–DRG relative weights.

• *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we trim the applicable claims data to remove cases with a length of stay of 7 days or less.

• *Step 3—Establish low-volume MS–LTC–DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with fewer than 25 cases).

• *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases.

• *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases.

• *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital-specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights.

• *Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity.

• *Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight.

• *Step 9—Budget neutralize the uncapped relative weights.* In this step, to ensure budget neutrality in the annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS–LTC–DRG classifications and relative weights.

• *Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.

• *Step 11—Budget neutralize the application of the 10-percent cap policy.* In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

We next describe each of the 11 proposed steps for calculating the proposed FY 2026 MS–LTC–DRG relative weights in greater detail.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

For this FY 2026 IPPS/LTCH PPS proposed rule, we obtained total charges from FY 2024 Medicare LTCH claims data from the December 2024 update of the FY 2024 MedPAR file and used proposed Version 43 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we are proposing that if better data become available, we would use those data and the finalized Version 43 of the GROUPER in establishing the FY 2026 MS–LTC–DRG relative weights in the final rule.

To calculate the FY 2026 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. Therefore, nearly all LTCH PPS cases in FY 2024 were subject to the dual rate LTCH PPS payment structure. However, a small number of FY 2024 LTCH PPS cases (those with admission dates on or before May 11, 2023) were subject to the CARES Act waiver and were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Therefore, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2026 (including MS–LTC–DRG relative weights), we are proposing to identify FY 2024 cases that meet the statutory patient criteria depending on date of admission as follows. First, we propose to use LTCH PPS cases in the FY 2024 MedPAR file with an admission date after May 11, 2023, that met the criteria for exclusion from the site neutral payment rate under § 412.522(b) and were paid the LTCH PPS standard Federal rate in FY 2024 (based on the claim payment amount). Second, we propose to also use LTCH PPS cases in the FY 2024 MedPAR file with an admission date on or before May 11, 2023, that would have met the criteria for exclusion from the site neutral payment rate if the CARES Act waiver had not been in effect. For these cases we relied on our historical process for identifying cases that would have met the criteria for exclusion from the site neutral payment rate rather than how those cases were paid in FY 2024. This process is explained in full detail in the FY 2024 IPPS/LTCH PPS final rule (89 FR 69425).

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In summary, in general, we identified the claims data used in the development of the FY 2026 MS–LTC–DRG relative weights in this proposed rule by trimming claims data that were paid the site neutral payment rate or would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all-inclusive rate providers reported in the December 2024 update of the FY 2024 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the December 2024 update of the FY 2024 MedPAR file, but had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy.

We used the remaining data (that is, the applicable LTCH data) in the subsequent proposed steps to calculate the proposed MS–LTC–DRG relative weights for FY 2026.

Step 2—Remove cases with a length of stay of 7 days or less.

The next step in our proposed calculation of the proposed FY 2026 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH

stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the proposed FY 2026 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, consistent with our existing relative weight methodology, in determining the proposed FY 2026 MS–LTC–DRG relative weights, we are proposing to remove LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish low-volume MS–LTC–DRG quintiles.

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, we are proposing to continue to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)).

In this proposed rule, based on the best available data (that is, the December 2024 update of the FY 2024 MedPAR file), we identified 239 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5. The quintiles each contained at least 47 MS–LTC–DRGs (239/5 = 47 with a remainder of 4). We are proposing to employ our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG. In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles results in nonmonotonicity within a base-DRG, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our proposed methodology.

To determine the FY 2026 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our proposed methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

For this proposed rule, we are providing the list of the composition of the proposed low-volume quintiles for low-volume MS–LTC–DRGs in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

Step 4—Remove statistical outliers.

The next step in our proposed calculation of the proposed FY 2026 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, we are proposing to continue to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater than or equal to 8 days. In this proposed rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).

As the next step in the proposed calculation of the proposed FY 2026 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, we are proposing to make this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the proposed FY 2026 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we propose to continue to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative value methodology.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing to continue to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2026. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, we propose to calculate the proposed FY 2026 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Therefore, in accordance with our established methodology, for FY 2026, we are proposing to continue to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our proposed methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each proposed MS–LTC–DRG, we calculated the FY 2026 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, it's case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the

payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the proposed FY 2026 MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the proposed FY 2026 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website.

Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the December 2024 update of the FY 2024 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of the preamble of this proposed rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, we are proposing to crosswalk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of the preamble of this proposed rule).

Of the 774 proposed MS–LTC–DRGs for FY 2026, we identified 419 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 419 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this proposed rule, such that we identified 391 MS–LTC–DRGs that for which, we are proposing to assign a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $419 - 11 - 2 - 15 = 391$). We are proposing to assign relative weights to each of the 391 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 355 ($774 - 419 = 355$) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2024 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 355 MS–LTC–DRGs to which we cross-walked each of the 391 ''no-volume'' MS–LTC–DRGs.) Then, in general, we are proposing to assign the 391 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the December 2024 update of the FY 2024 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2026, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the proposed relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2026. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and, therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2026. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this proposed rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2026 in a supplemental data file for public use posted via the internet on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the proposed relative weights for the FY 2026 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2024 MedPAR file that we are using for this proposed rule for proposed MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that proposed MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we are proposing to assign the same

relative weight (and average length of stay) of proposed MS–LTC–DRG 064 of 1.1689 for FY 2026 to proposed MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, we are proposing to use the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2026, consistent with our historical relative weight methodology, we are proposing to establish a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas and Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas and Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are proposing to establish a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are proposing to establish a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedures with Principal Diagnosis of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Intellectual Disability); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol, Drug Abuse or Dependence, Left AMA); MS–LTC–DRG 895 (Alcohol, Drug Abuse or Dependence with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol, Drug Abuse or Dependence without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are proposing to establish a relative weight of 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2026, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Budget neutralize the uncapped relative weights.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882)).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, we are proposing to continue to apply budget neutrality adjustments in determining the proposed FY 2026 MS–LTC–DRG relative weights so that our proposed update of the MS–LTC–DRG classifications and relative weights for FY 2026 are made in a budget neutral manner. For FY 2026, we are proposing to apply two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the proposed update of the MS–LTC–DRG classifications and relative weights prior to the application of the ten-percent cap. In steps 10 and 11, we describe the application of the 10-percent cap policy (step 10) and the determination of the proposed budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this proposed rule, to ensure budget neutrality for the proposed update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we are proposing to continue to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2026, we calculated and applied a proposed normalization factor to the recalibrated relative weights (the result of Steps 1 through 8 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the proposed normalization factor for FY 2026, we propose to use the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2024 MedPAR file) and group them using the proposed FY 2026 GROUPER (that is, Version 43 for FY 2026) and the proposed recalibrated FY 2026 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 8 discussed previously) to calculate the average case-mix index; (1.b.) group the

same applicable LTCH cases (as are used in Step 1.a.) using the FY 2025 GROUPER (Version 42) and FY 2025 MS–LTC–DRG relative weights in Table 11 of the FY 2025 IPPS/LTCH PPS final rule and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2025 (determined in Step 1.b.) by the average case-mix index for FY 2026 (determined in Step 1.a.). As a result, in determining the proposed MS–LTC–DRG relative weights for FY 2026, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the proposed normalization factor of 1.24603 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a proposed budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration. That is, for this proposed rule, for FY 2026, we propose to determine the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2026 and proposed GROUPER Version 43; (2.b.) simulate estimated total FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2025 GROUPER (Version 42) and the FY 2025 MS–LTC–DRG relative weights in Table 11 of the FY 2025 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the proposed FY 2026 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a proposed budget neutrality factor of 1.0112216 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.

To mitigate the financial impacts of significant year-to-year reductions in MS–LTC–DRGs relative weights, beginning in FY 2023, we adopted a policy that applies a budget neutral 10-percent cap on annual relative weight decreases for MS–LTC–DRGs with at least 25 applicable LTCH cases (§ 412.515(b)). Under this policy, in cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year. We refer readers to section VIII.B.3.b. of the preamble of the FY 2023 IPPS/LTCH PPS final rule with comment period for a detailed discussion on the adoption of the 10-percent cap policy (87 FR 49152 through 49154).

Applying the 10-percent cap to MS–LTC–DRGs with 25 or more cases results in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. For this proposed rule, in cases where the relative weight for a MS–LTC–DRG with 25 or more applicable LTCH cases would decrease by more than 10-percent in FY 2026 relative to FY 2025, we are proposing to limit the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the proposed low-volume MS–LTC–DRGs identified in Step 3 or the proposed no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each proposed FY 2026 MS–LTC–DRG with 25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2026 relative weight (after application of the proposed normalization and proposed budget neutrality factors determined in Step 9), to its FY 2025 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2026 relative weight would otherwise have declined more than 10 percent, we established a proposed capped FY 2026 MS–LTC–DRG relative weight that is equal to 90 percent of that MS–LTC–DRG's FY 2025 relative weight (that is, we set the proposed FY 2026 relative weight equal to the FY 2025 weight × 0.90).

In section II.E. of the preamble of this proposed rule, we discuss our proposed changes to the MS–DRGs, and by extension the MS–LTC–DRGs, for FY 2026. As discussed previously, under our current policy, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs. We are not proposing any changes to this policy for FY 2026, and as such any proposed new or renumbered MS–LTC–DRGs for FY 2026 would not be eligible for the 10-percent cap.

Step 11—Budget neutralize application of the 10-percent cap policy.

Under the requirement at existing § 412.517(b) that aggregate LTCH PPS payments will be unaffected by annual changes to the MS–LTC–DRG classifications and relative weights, consistent with our established methodology, we are proposing to continue to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we are proposing to determine the proposed budget neutrality adjustment factor for the 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed capped relative weights for FY 2026 (determined in Step 10) and proposed GROUPER Version 43; (b) simulate estimated total FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2026 (determined in Step 9) and proposed GROUPER Version 43; and (c) calculate the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the proposed FY 2026 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a proposed budget neutrality factor of 0.9984259 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this proposed rule and is available via the internet on the CMS website, 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 SSO cases under § 412.529(a)) for FY 2026. We also are making available on the 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.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2026

1. Overview of Development of the Proposed LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we are proposing to use to update the LTCH PPS standard Federal payment rate for FY 2026, that is, effective for LTCH discharges occurring on or after October 1, 2025, through September 30, 2026. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002, LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003 through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2026 IPPS/LTCH PPS proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2026.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2026 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed annual update to the LTCH PPS standard Federal payment rate for FY 2026 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2026 as required by the statute (as discussed in section IX.C.2.c. of the preamble of this proposed rule). We are proposing to make an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2026 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this proposed rule).

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

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Proposed Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2026

As previously noted, we adopted the 2022-based LTCH market basket for use under the LTCH PPS beginning in FY 2025. The 2022-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of LTCHs. For additional details on the development of the 2022-based LTCH market basket, we refer readers to the FY 2025 IPPS/LTCH final rule (89 FR 69435 through 69455). We continue to believe that the 2022-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2025 IPPS/LTCH PPS final rule. Therefore, in this proposed rule, we are proposing to use the 2022-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2026.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in section 1886(b)(3)(B)(xi)(II) of the Act. Section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure

referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. Section 1886(m)(3)(A)(ii) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Proposed Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, requires that a 2.0 percentage points reduction be applied to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP under 42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section X.E. of the preamble of this proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2026

Consistent with our historical practice, we estimate the market basket percentage increase and the productivity adjustment based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's fourth quarter 2024 forecast, the proposed FY 2026 market basket percentage increase for the LTCH PPS using the 2022-based LTCH market basket is 3.4 percent. The proposed productivity adjustment for FY 2026 based on IGI's fourth quarter 2024 forecast is 0.8 percentage point.

For FY 2026, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we are proposing to reduce the FY 2026 market basket percentage increase by the FY 2026 productivity adjustment. To determine the proposed market basket update for LTCHs for FY 2026 we subtracted the proposed FY 2026 productivity adjustment from the proposed FY 2026 market basket percentage increase. (For additional details on our established methodology for adjusting the market basket percentage increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).) In addition, for FY 2026, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points.

In this FY 2026 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2026 market basket percentage increase of 3.4 percent (based on IGI's fourth quarter 2024 forecast of the 2022-based LTCH market basket) by the proposed FY 2026 productivity adjustment of 0.8 percentage point (based on IGI's fourth quarter 2024 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2026 of 2.6 percent (that is, the proposed LTCH PPS market basket percentage increase of 3.4 percent less the proposed productivity adjustment of 0.8 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we are proposing to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.6 percent (that is, the proposed 2.6 percent LTCH market basket update minus 2.0 percentage points) for FY 2026 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we also are proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket percentage increase and productivity adjustment), we would use such data, if appropriate, to determine the FY 2026 market basket percentage increase and productivity adjustment in the final rule. We note that, consistent with historical practice, we are also proposing to adjust the FY 2026 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.6. of the Addendum to this proposed rule).

X. Proposed Quality Data Reporting Requirements for Specific Providers

A. Overview

In section X. of the preamble of this proposed rule, we are seeking comment on and proposing changes to the following Medicare quality reporting programs:

- In section X.B. of the preamble of this proposed rule, we are including the Toward Digital Quality Measurement in CMS Quality Programs—Request for Information.
- In section X.C. of the preamble of this proposed rule, the Hospital IQR Program.
- In section X.D. of the preamble of this proposed rule, the PCHQR Program.

- In section X.E. of the preamble of this proposed rule, the LTCH QRP.
- In section X.F. of the preamble of this proposed rule, the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

B. Toward Digital Quality Measurement in CMS Quality Programs—Request for Information

We have previously issued requests for information (RFIs) to gather public input on the transition to digital quality measurement (dQM) for CMS programs.[267] This RFI provides updates on our progress and seeks input as we continue our path forward in the dQM transition.

In this RFI, we are soliciting comments on our anticipated approach to the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in electronic clinical quality measure (eCQM) reporting. Several CMS programs currently use, or are considering using, eCQMs for various clinicians, facilities, providers, and other organizations to report their respective quality performance. These CMS programs include the Hospital Inpatient Quality Reporting (IQR) Program, the Hospital Outpatient Quality Reporting (OQR) Program, and the Medicare Promoting Interoperability Program. We are seeking feedback in this RFI on FHIR-based eCQM activities in these programs. We anticipate including a similar request in the CY 2026 Physician Fee Schedule (PFS) proposed rule to solicit comments on FHIR-based eCQM activities in the Medicare Shared Savings Program and the Merit-based Incentive Payment System (MIPS) quality performance category.

In this RFI, we are also soliciting comments on our anticipated approach to FHIR-based patient assessment reporting in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. While we seek comments in this RFI for the IPFQR Program in this proposed rule (as a majority of IPFs are hospital-based),[268] we anticipate seeking similar feedback in the FY 2026 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) proposed rule.

We will consider the feedback we receive as we refine our dQM transition efforts and plan the strategic modernization of our quality measurement enterprise.

1. Background

Having immediate access to electronic health information, in near real-time, supports quality measurement efforts, provides the ability to use these data for patient care considerations, and may lead to improved clinical outcomes. To support this, we aim to transition to a fully dQM landscape that promotes interoperability and increases the value of reporting quality measure data. In the coming years, we will continue to seek ways to advance technical infrastructure, update program regulations, and engage Federal partners and the public to support this dQM transition.[269]

We are collaborating with Federal agencies, including the Assistant Secretary for Technology Policy (ASTP) and Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP) [270] to support data standardization and alignment of requirements for the development and reporting of digital quality measures. Advancements in the interoperability of healthcare data and corresponding requirements from ASTP have created the technical foundation across health information technology (IT) systems to pursue modernization of CMS' quality measurement systems. The 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program final rule (85 FR 25642) and the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) final rule (89 FR 1192) advanced policy approaches that enable flexible, granular data sharing from the certified health IT systems used by many healthcare providers, facilities, and clinicians. Aligning technology requirements for healthcare providers, payers, public health agencies, and health IT developers allows for advancement of an interoperable health IT infrastructure that ensures providers and patients have access to health data when and where it is needed.

We continue to collaborate with ASTP on future versions of the United States Core Data for Interoperability (USCDI),[271] which establishes a baseline set of data elements referenced in health information exchange certification criteria under the ONC Health IT Certification Program. In addition, the ASTP USCDI+ program supports identification and establishment of domain-specific datasets that build on the USCDI foundation.[272] The USCDI+ Quality domain,[273] which we discuss in more detail in section X.2.b. of the preamble of this proposed rule, aims to harmonize data needs for quality measurement across Federal agencies and other interested parties, and inform supplemental standards necessary to support quality measurement. We also continue to work with ASTP to advance the interoperability of patient assessment data through collaboration with interested parties to develop FHIR standards through the CMS-sponsored Post-Acute Care Interoperability (PACIO) Project.[274]

Moreover, the CMS Innovation Center's Enhancing Oncology Model recently completed its first reporting period in which FHIR-based application programming interfaces (APIs) were used by model participants to submit clinical data elements to CMS. This specification for reporting was developed as part of the USCDI+ Cancer domain, in close collaboration with ASTP, the National Institutes of Health (NIH), and the National Cancer Institute (NCI).[275]

We are also collaborating with the Centers for Disease Control and Prevention (CDC) and the Health Resources and Services Administration (HRSA) in our dQM transition strategy. The CDC National Healthcare Safety Network (NHSN) is leading the development of fully electronic and automated digital quality measures for patient safety and public health surveillance, preparedness, and

[267] We refer readers to the following rules which contain the previous RFIs: FY 2022 IPPS/LTCH PPS final rule (86 FR 45342 through 86 FR 45349); FY 2023 IPPS/LTCH PPS final rule (87 FR 49181 through 87 FR 49188); CY 2022 Physician Fee Schedule (PFS) final rule (86 FR 65377 through 86 FR 65382); CY 2023 PFS proposed rule (87 FR 46259 through 87 FR 46262); CY 2022 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule (86 FR 63815 through 86 FR 63822); and CY 2022 End-Stage Renal Disease (ESRD) PPS final rule (86 FR 61941 through 86 FR 61948).

[268] We refer readers to the FY 2025 IPF PPS-Rate Update final rule, Table 24 (89 FR 64670). Based on this data, 59.3 percent of IPFs were hospital-based units, a figure derived by dividing the sum of urban and rural units by the total number of facilities.

[269] Read more about the dQM transition in the Electronic Clinical Quality Improvement (eCQI) Resource Center here: *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=about-dqms*.

[270] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (89 FR 60903).

[271] *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi*.

[272] *https://www.healthit.gov/topic/interoperability/uscdi-plus*.

[273] *https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=7ddf78228745b95098e5edb90cbb3525&view=sp*.

[274] *https://pacioproject.org/*.

[275] *https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model*.

response.[276] We are working together with NHSN to explore a modernized approach for reporting quality measures to CMS via the NHSN data pipeline. There are currently nine digital quality measures reported to NHSN that are used in CMS programs.[277] CMS and CDC are working together to transition to fully automated digital quality measures using a two-pronged approach: (1) Develop new measures to address patient safety gaps; and (2) Update current measures to a FHIR-based format.

The NHSN dQM approach uses a reusable reporting framework (NHSN Digital Quality Measure Reporting Implementation Guide (IG)) [278] in conjunction with content based in national, interoperable data standards (USCDI and USCDI+) that are aligned with CMS requirements, and submitted via secure data transfer via open-source FHIR API (NHSNLink).[279] Promoting the use of these standards-based, flexible, advanced data reporting methods will reduce the reporting burden on facilities while increasing timeliness and completeness, and will improve the accuracy and quality of data, enhancing health system readiness and response capacity through near real-time data collection.

Our partners at HRSA are also making efforts to modernize reporting of eCQMs.[280] As part of the Uniform Data System (UDS) modernization, HRSA has developed the Uniform Data Systems Plus (UDS+), which provides for the electronic submission (using FHIR) of de-identified patient-level data including data elements aligned to select CMS eCQMs that health centers are required to report.[281] HRSA developed a UDS+ FHIR IG, which specifies the FHIR API requirements for structuring and transmitting these data elements based on program requirements.

All of these efforts to leverage standardized data and the FHIR model are intended to accelerate and support the transition to a data-driven healthcare system that will ultimately reduce provider burden, support the patient experience, and improve quality of care. Shifting towards approaches based on the FHIR standard will help us pave the way for future digital quality measures.[282]

We thank the public for providing feedback through industry conferences, direct conversations with CMS and our Federal partners, and submitting comments to RFIs in previous rulemaking. As we support healthcare providers, facilities, and clinicians, the health IT industry, and Federal partners in their respective activities, we are requesting public input on this RFI to better inform our ongoing strategy to transition to a fully digital quality landscape. Note that any substantive updates to program-specific requirements related to providing data for quality measurement and reporting would be addressed through future notice-and-comment rulemaking, as necessary.

2. Approach to eCQM Reporting Using FHIR in CMS Quality Programs

In this section, we describe the current state and request input on key components of the ongoing dQM transition related to FHIR-based eCQMs for the Hospital IQR Program, the Hospital OQR Program, and the Medicare Promoting Interoperability Program. These components include: (1) FHIR-based eCQM conversion progress; (2) Data standardization for quality measurement and reporting; (3) The timeline under consideration for FHIR-based eCQM reporting; and (4) Measure development and reporting tools.

a. eCQM FHIR Conversion Activities

Currently, eligible hospitals are required to report eCQMs for the Hospital IQR Program and the Hospital OQR Program, and eligible hospitals and critical access hospitals (CAHs) must report eCQMs through the Medicare Promoting Interoperability Program. Additionally, Medicare Shared Savings Program Accountable Care Organizations (ACOs) and eligible clinicians participating in the Merit-based Incentive Payment System (MIPS) can report eCQMs for their quality reporting. Electronic health record (EHR) and other health IT systems certified under the ONC Health IT Certification Program use patient data to calculate the results for each eCQM based upon the measure specifications for the eCQM.[283]

An important initial step in our dQM strategy is to ensure current eCQMs are specified using the FHIR standard and allow these measures to be calculated consistently using standardized data represented in FHIR. Standardized digital data can support multiple use cases, including quality measurement, quality improvement efforts, clinical decision support, research, and public health. The eCQMs currently use structured data defined by the Quality Data Model (QDM) and measure logic in Clinical Quality Language to evaluate a clinician's, provider's, facility's, or organization's performance on a measure concept.[284]

As we move to FHIR-based eCQMs, we continue to convert current eCQMs (authored using the QDM) to eCQMs authored using the HL7 FHIR® Quality Improvement Core (QI-Core) IG, updating to new versions as appropriate. We are conducting advanced validation of FHIR data exchange through ongoing HL7 Connectathons and integrated systems testing, leveraging and refining IGs to enhance interoperability and data standardization.[285] While new eCQMs continue to be developed, proposed, and adopted in existing CMS programs, we are working with measure developers to ensure existing eCQMs are converted to FHIR and that new eCQMs are also natively developed in FHIR. In the future, we are considering a requirement that all measures proposed for addition to CMS programs be specified in FHIR.

Additional information and updates regarding eCQMs and the dQM transition can be found on the Electronic Clinical Quality Improvement (eCQI) Resource Center website, available at: *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap*. We continue to explore potential applications of the FHIR standard to the reporting and use of different types of quality measurement data.

We seek feedback on the following questions:

- Are there specific eCQMs or elements of existing eCQMs that you anticipate presenting particular challenges in specifying in FHIR?
- Are there gaps in the QI-Core IG that are likely to impact our ability to effectively specify current CMS eCQMs in FHIR?
- What supplementary activities would encourage additional engagement in FHIR testing activities (such as

[276] *https://www.cdc.gov/nhsn/fhirportal/index.html.*

[277] *https://www.cdc.gov/nhsn/cms/index.html.*

[278] *https://build.fhir.org/ig/HL7/nhsn-dqm/.*

[279] *https://www.cdc.gov/nhsn/fhirportal/about.html.*

[280] *https://bphc.hrsa.gov/data-reporting/uds-training-and-technical-assistance/uniform-data-system-uds-modernization-initiative.*

[281] *https://www.fhir.org/guides/hrsa/uds-plus/dataelements.html.*

[282] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=about-dqms.*

[283] *https://ecqi.healthit.gov/sites/default/files/eCQM-Basics-508.pdf.*

[284] *https://ecqi.healthit.gov/sites/default/files/Digital%20Quality%20Measurement%20eCQMs%20reference%20brief_508ed.pdf.*

[285] Summaries are available and more information on the most recent Connectathon is available at: *https://confluence.hl7.org/spaces/FHIR/pages/281218287/2025+-+01+Clinical+Reasoning.*

Connectathons) that support the development of current and future IGs to advance adoption and use of FHIR-based eCQMs?

b. Data Standardization for Quality Measurement and Reporting

We are continuing to collaborate with ONC as it develops a certification approach to enable reporting of FHIR-based eCQMs using technology certified under the ONC Health IT Certification Program. This approach aims to repurpose and harmonize existing FHIR requirements in the ONC Health IT Certification Program whenever possible.[286] It also aims to incorporate industry-developed standards for the exchange of quality measurement data using FHIR.

In this section we discuss the standards and other artifacts which CMS and ONC are evaluating to serve as the basis for new health IT certification criteria supporting FHIR-based quality measurement and reporting. New health IT certification criteria for quality measurement and reporting could include requirements for certified health IT modules to support the consistent capture and exchange of quality data using FHIR APIs. New criteria could also support standardized reporting rules to ensure successful submission of quality measure data for the Hospital IQR Program, the Hospital OQR Program, and the Medicare Promoting Interoperability Program.

A key artifact we are reviewing as part of this approach is the QI-Core IG, which defines a set of FHIR profiles within a common logic model for clinical quality measurement and clinical decision support intended for use for multiple use cases across domains.[287] As described previously, this IG is used to represent the data elements necessary to support current eCQMs.

The QI-Core IG builds on the HL7 FHIR® US Core IG (US Core IG) which is currently referenced under the ONC Health IT Certification Program and implements the USCDI in FHIR. The US Core IG is incorporated in the ''Standardized API for patient and population services'' health IT certification criterion [288] and is widely implemented across certified health IT systems. Accordingly, we anticipate that developers implementing the QI-Core IG will be able to leverage existing work from implementing the US Core IG. QI-Core is expected to evolve over time to reflect subsequent versions of the US Core IG. For example, QI-Core 6.0 builds upon US Core version 6.1.0, which provides consensus-based capabilities aligned with USCDI version 3 (v3) data elements for FHIR APIs. In the HTI–1 final rule (89 FR 1196), ASTP finalized the expiration of USCDI v1 on January 1, 2026, and adopted USCDI v3 as the new baseline version of USCDI after USCDI v1 expires.

We also anticipate alignment between the QI-Core IG and the USCDI+ Quality data element list, which incorporates additional data elements beyond USCDI. We have collaborated with ASTP around the development of USCDI+ Quality as an extension to USCDI to improve healthcare interoperability across quality programs, establishing a consistent baseline of harmonized data elements for a wide range of quality measurement use cases.[289] Specifically for CMS programs, USCDI+ Quality includes the data elements to support program-specific measures.[290]

We are also considering the Data Exchange for Quality Measures (DEQM) IG [291] as part of the framework supporting the transition to FHIR-based eCQMs, in particular for supporting FHIR-based reporting to CMS. The DEQM IG provides a framework that defines conformance profiles and guidance to enable the exchange of quality information and enable FHIR-based quality measure reporting. It is based upon other related work in the FHIR and quality measure realm, including the US Core IG, the Healthcare Effectiveness Data and Information Set (HEDIS) IG, and Quality Reporting Document Architecture (QRDA) Category I and III reporting specifications. We are considering the use of the DEQM IG with quality measures specified in accordance with QI-Core.

To facilitate the exchange of significant volumes of data to support quality measurement, we are also evaluating the use of HL7 FHIR ® Bulk Data, both on its own [292] or through the DEQM IG.[293] The existing Bulk Data Access IG defines a standardized, FHIR-based approach for exporting bulk data from a FHIR server to an authenticated and authorized client. ASTP has adopted the Bulk Data Access IG STU 1, version 1.0.0, published on August 8, 2019 (hereafter referred to as version 1), and has incorporated it into the ONC Health IT Certification Program.[294] The Bulk Data Access IG has recently seen considerable revisions and enhancements over version 1 from the HL7 standards community. A new version of the Bulk Data Access IG, planned to be balloted in 2025, is expected to introduce new features such as the capacity to organize output by patient and criteria-based cohort creation, which could significantly enhance the quality reporting use case for the IG.[295] The HL7 community will also continue to prepare additional enhancements to the Bulk Data Access IG throughout 2025, with the Argonaut Project announcing Bulk Import as a 2025 project.[296] Bulk Import is already being used by HRSA in their UDS+ IG,[297] and has the potential to enhance the quality reporting use case more broadly. It defines a standardized mechanism for data submitters to upload or submit their Bulk FHIR data to a receiving system when they have their Bulk FHIR data ready to submit, rather than having to reactively respond to a Bulk FHIR export request initiated by a receiving system.

We seek feedback on the following questions:

- Can you share any experiences or challenges reviewing, implementing, or testing the QI-Core, DEQM, or Bulk FHIR standards, including any experiences or challenges unique to Bulk FHIR Import versus Bulk FHIR Export?
- Are there any deficiencies or gaps in the DEQM IG that must be addressed before it can potentially be used for reporting to CMS on eCQMs using FHIR APIs?
- Are there additional baseline requirements or capabilities that need to be considered before FHIR-based eCQMs could be reported to CMS using Bulk FHIR?

c. Timeline Under Consideration for FHIR-Based eCQM Reporting

As we noted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49183), we are considering proposing a transition

[286] See 45 CFR 170.315(g)(10)—*Standardized API for patient and population services* FHIR certification in the ONC Health IT Certification program.

[287] *https://hl7.org/fhir/us/qicore/index.html.*

[288] 45 CFR 170.315(g)(10).

[289] *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[290] For more information about the USCDI+ Quality data element list please visit *https://uscdiplus.healthit.gov/.*

[291] *https://build.fhir.org/ig/HL7/davinci-deqm/.*

[292] *https://hl7.org/fhir/uv/bulkdata/.*

[293] *https://hl7.org/fhir/us/davinci-deqm/OperationDefinition-bulk-submit-data.html.*

[294] ONC has adopted the Bulk Data Access IG, version 1, in 45 CFR 170.215, and has incorporated this IG into the ONC Health IT Certification Program as part of the ''Standardized API for patient and population services'' certification criterion in 45 CFR 170.215(g)(10).

[295] See Argonaut Bulk Optimize project: *https://confluence.hl7.org/spaces/AP/pages/227213555/Bulk+Optimize.*

[296] *https://confluence.hl7.org/spaces/AP/pages/325453837/Bulk+Import.*

[297] *https://www.fhir.org/guides/hrsa/uds-plus/OperationDefinition-import.html.*

period during which healthcare providers may report using either QDM- or FHIR-based eCQMs. This period would provide time for quality program participants, health IT developers, and CMS to engage in learning to optimize systems and processes. During this period, participants would still be required to report on the number of eCQMs finalized for an applicable reporting program, but program participants would be able to choose to submit either QDM-based *or* FHIR-based eCQMs to meet respective reporting requirements. For instance, program participants who are implementing updated certified health IT and gaining experience with FHIR-based eCQMs could continue submitting QRDA files to meet program requirements, while those who are ready to report FHIR-based eCQMs would be able to do so, for a specified period. For the purposes of this RFI, we refer to this concept as the ''reporting options'' period.

We acknowledge that participants in the identified CMS programs may proceed with updating certified health IT and implementing dQMs at different speeds. Hence, we are considering the reporting options period in order to provide additional time for providers to make the transition, in advance of any future proposal to require FHIR-based reporting. We are considering at least a two-year reporting options period before any future proposal to require mandatory reporting. Note that any updates to specific program requirements related to providing data for quality measurement and reporting would be addressed through future notice-and-comment rulemaking, as necessary.

We seek feedback on the following questions:

- Would a minimum of 24 months from the effective date of a FHIR-based eCQM reporting option using ONC Health IT Certification Program criteria to support quality program submission provide sufficient time for implementation (including measure specification review, certified health IT updates, workflow changes, training, and testing)?
- What resources or guidance could CMS provide to assist with the transition to submission of FHIR-based eCQM data?
- What, if any, challenges do you anticipate with the reporting timeline of FHIR-based eCQMs (beginning with at least a two-year reporting options period before any future proposal to require FHIR-based reporting)?
- What resources, guidance, or other support can we provide to encourage and facilitate the early adoption and reporting of FHIR-based eCQMs during the reporting options period?

d. Measure Development and Reporting Tools

We develop and maintain tools and resources to assist measure developers in the different stages of the Measure Lifecycle.[298] The Measure Authoring Development Integrated Environment (MADiE) is a free software tool that supports the eCQM development and testing process through dynamic authoring and testing within a single application.[299] MADiE supports QI-Core profile-informed authoring, testing, and verification of the behavior of FHIR-based eCQMs.[300] We encourage measure developers to continue using this environment for the development of FHIR-based eCQMs.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49183), we described plans to modernize programmatic data receiving systems through a unified CMS FHIR receiving system that would provide a single point of data receipt for quality reporting programs. We may also consider separate FHIR receiving systems for some programs initially as the shift to FHIR across CMS programs will be incremental. CMS will provide information on the form and manner for reporting for each program in respective notice-and-comment rulemaking, as necessary. Our vision remains to ultimately develop and implement a single point of data receipt via a unified CMS FHIR receiving system.

In the CMS Digital Quality Measurement Strategic Roadmap, we noted the development of a FHIR-based measure calculation tool (MCT).[301] After further consideration and testing, we have decided not to advance the MCT as previously described.

We seek feedback on the following question:

- What capabilities would be most useful for CMS to support in a FHIR-based eCQM reporting model?
- What, if any, additional concerns should CMS take into consideration when developing FHIR-based reporting requirements for systems receiving quality data?

e. Additional FHIR Transition Activities for ACOs

While this RFI focuses on the Hospital IQR Program, the Hospital OQR Program, and the Medicare Promoting Interoperability Program, we also intend to seek similar feedback in future rulemaking, including in the CY 2026 PFS proposed rule for MIPS. In addition, in the near future, we intend to solicit feedback on how the dQM transition and use of FHIR-based approaches to quality reporting would impact eligible clinicians participating in MIPS as well as in ACOs. ACOs have encountered challenges with aggregating, deduplicating, and matching quality data necessary to report using the eCQM and MIPS Clinical Quality Measure (CQM) collection types, as ACOs may bring together healthcare providers using disparate EHR systems from which data must be extracted and aggregated. We anticipate seeking feedback on how the transition to FHIR-based reporting of eCQMs could help to mitigate these challenges.

3. Approach to FHIR Patient Assessment Reporting in the IPFQR Program

Section 4125(b) of the Consolidated Appropriations Act of 2023 (CAA, 2023) (Pub. L. 117–328, Dec. 29, 2022) [302] amended section 1886(s)(4) of the Act by adding a new subparagraph (E), which requires an inpatient psychiatric facility (IPF) participating in the IPFQR Program to collect and submit specified standardized patient assessment data using a new standardized patient assessment instrument, for rate year 2028 and each subsequent year.

As noted in the RFI [303] in the FY 2025 IPF Prospective Payment System (PPS)-Rate Update proposed rule, achieving interoperability is an essential part of our goal to facilitate safe and secure data sharing, access, and utilization of electronic health information to enhance decision-making and create a more efficient healthcare system (89 FR 23201). We also stated that we are considering ways to ensure that the IPF Patient Assessment Instrument (IPF–PAI) can be represented using FHIR standards (89 FR 23201). As part of that RFI, we requested and received input on topics including: Whether Standardized Patient Assessment Data Elements already in use in the CMS Data Element Library (DEL) [304] are appropriate and clinically relevant for the IPF setting, use of CMS reporting systems, and other interoperability-related considerations (89 FR 23201). In the FY 2025 IPF PPS final rule, we acknowledged a recommendation to align the IPF–PAI with USCDI and several commenters

[298] *https://mmshub.cms.gov/cms-tools.*

[299] *https://www.emeasuretool.cms.gov/.*

[300] *Ibid.*

[301] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap.*

[302] *https://www.congress.gov/117/plaws/publ328/PLAW-117publ328.pdf.*

[303] ''Patient Assessment Instrument Under IPFQR Program (IPF PAI) to Improve the Accuracy of PPS'' (89 FR 23200 through 23204).

[304] *https://del.cms.gov/DELWeb/pubHome.*

noted IPFs did not receive funding to adopt CEHRT, suggesting we consider how the implementation of the IPF–PAI would affect providers without EHRs (89 FR 64646).

We are considering opportunities to advance FHIR-based reporting of patient assessment data for the IPF–PAI mandated by the CAA, 2023. The questions in this section seek to gain an understanding of the current adoption and use of EHRs, other health IT, and data standards supporting interoperability (such as FHIR and USCDI) within IPFs. We also aim to identify the extent of technology adoption beyond certified health IT and EHRs and seek a better understanding of how FHIR-standardized data can be generated, used, and shared through other technologies, without use of EHRs. Our objective is to explore how IPFs typically integrate technologies with varying complexity into existing systems and how this affects IPF workflows. We seek to identify the challenges or opportunities that may arise during this integration, and determine the support needed to complete and submit the IPF–PAIs in ways that protect and enhance care delivery. This insight will help inform the technologies we may consider for use with the IPF–PAI and quality data reporting.

We seek feedback on the current state of health IT use, including EHRs, in IPFs:

- To what extent does your IPF use health IT systems to maintain and exchange patient records?
- If your facility has transitioned to using electronic records in whole or in part, what types of health IT does your IPF use to maintain electronic patient records? Are these health IT systems certified under the ONC Health IT Certification Program? Does your facility use EHRs or other health IT products or systems that are not certified under the ONC Health IT Certification Program? If so, do these systems exchange data using standards and implementation specifications adopted by HHS? [305] Please specify.
- Does your IPF submit patient data to CMS directly from your health IT system, without the assistance of a third-party intermediary? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your facility currently exchange health information with other healthcare providers or systems, specifically between IPFs and other provider types or with public health agencies? What challenges do you face with electronic exchange of health information?
- Are there any challenges with your current electronic devices (for example, tablets, smartphones, computers) that hinder your ability to easily exchange information across health IT systems? Please describe any specific issues you encounter.
- Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit patient data to CMS?
- What steps does your IPF take to ensure compliance in using health IT with security and patient privacy requirements such as the requirements of the regulations promulgated under the Health Insurance Portability and accountability Act (HIPAA) and related regulations?
- Does your IPF refer to the SAFER Guides (see newly revised versions published in January 2025 at *https://www.healthit.gov/topic/safety/safer-guides*) [306] to self-assess EHR safety practices?
- What challenges or barriers does your IPF encounter when submitting quality measure data to CMS as part of the IPFQR Program? Please identify any factors that hinder successful data submission. What opportunities or factors could improve your facility's successful data submission to CMS?
- What types of technical assistance, guidance, workforce training resources, and other resources would help IPFs to successfully implement FHIR-based technologies for submitting the IPF–PAI to CMS? What strategies can CMS, HHS, or other Federal partners take to ensure that technical assistance is both comprehensive and user-friendly? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?
- Is your facility using technology that utilizes APIs based on the FHIR standard to enable electronic data sharing? If so, with whom are you sharing data using the FHIR standard and for what purpose(s)? For example, have you used FHIR APIs to share data with public health agencies? Does your facility use any Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR [307] applications? If so, are the SMART on FHIR applications integrated with your EHR or other health IT?
- What benefits or challenges have you experienced with implementing technology that uses FHIR-based APIs? How can adopting technology that uses FHIR-based APIs to facilitate the reporting of patient assessment data impact provider workflows? What impact, if any, does adopting this technology have on quality of care?
- Does your facility have any experience using technology that shares electronic health information using one or more versions of the USCDI standard?
- Would your IPF and vendors or both be interested in participating in testing to explore options for transmission of assessments, for example, testing methods to transmit assessments that incorporate FHIR-enabled data to CMS?
- What other information should we consider to facilitate successful adoption and integration of FHIR-based technologies and standardized data for patient assessment instruments like the IPF–PAI? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

4. General Solicitation of Comments

In conjunction with the previous questions, we are also seeking input on the following:

- Specific to FHIR-based quality reporting, are there any additional factors, or considerations to account for, that may help foster data harmonization and reduce reporting burden across entities?
- The Trusted Exchange Framework and Common Agreement™ (TEFCA™) framework supports nationwide health information exchange by connecting health information networks (HINs) across the country.[308] Additionally, TEFCA facilitates FHIR exchange by requiring Qualified HINs (QHINs) to perform patient discovery for those querying for data and providing data holders with FHIR endpoints to enable point-to-point exchange via FHIR APIs. How could this initiative potentially support exchange of FHIR-based quality measures and patient assessment submissions consistent with the FHIR Roadmap (available here: *https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/*)? How might TEFCA enable the use of patient assessment

[305] For instance, see standards adopted by ONC on behalf of HHS in 45 CFR part 170, subpart B.

[306] The SAFER Guides are an evidence-based set of recommendations in the form of nine stand-alone, subject-oriented chapters that present the health IT community, including eligible hospitals and CAHs that use health IT, with best practice recommendations to improve the safety and safe use of EHRs. See *https://www.healthit.gov/topic/safety/safer-guides.*

[307] *https://smarthealthit.org/.*

[308] For more information about TEFCA, see *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

data for secondary uses such as treatment and research?

C. Requirements for and Changes to the Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

The Hospital IQR Program is a pay-for-reporting program intended to measure the quality of hospital inpatient services, improve the quality of care provided to Medicare beneficiaries, and facilitate public transparency. Section 1886(b)(3)(B)(viii) of the Social Security Act (the Act) states that subsection (d) hospitals participating in the Hospital IQR Program that do not submit data required for measures selected with respect to such a year, in the form and manner required by the Secretary, will incur a 2.0 percentage point reduction to their annual payment update for the applicable fiscal year. We refer readers to our previous final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set.[309] We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations. We note that we are discontinuing the practice of retaining all subsections every year and have thus omitted subsections where there are no proposed changes.

2. Considerations in Expanding and Updating Quality Measures

(a) Measure Concepts Under Consideration for Future Years in the Hospital IQR Program—Request for Information (RFI): Well-Being and Nutrition

We are seeking input on well-being and nutrition measures for future years in the Hospital IQR Program. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.[310] This comprehensive approach emphasizes person-centered care by promoting the well-being of patients and family members. We are seeking comments on tools and measures that assess overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comments on the applicability of tools and constructs that assess for the integration of complementary and integrative health, skill building, and self-care. Please provide feedback on the relevant aspects of well-being for the Hospital IQR Program.

A second concept that we are seeking feedback on is for measures of nutrition. In the FY 2023 IPPS/LTCH PPS final rule, we adopted the Malnutrition Care Score (MCS)[311] electronic quality measure (eCQM) into the Hospital IQR Program, which assesses adults 65 years of age and older admitted to inpatient hospital services who received care appropriate to their level of malnutrition risk and malnutrition diagnosis (87 FR 49239 through 49246). In the FY 2025 IPPS/LTCH PPS final rule we modified the MCS eCQM to expand the population assessed to include patients 18 years of age and older (89 FR 69557 through 69560). We are seeking comments on tools and measures that assess optimal nutrition and preventive care in the Hospital IQR Program. Assessments for nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Such assessments may also include aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventive care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs. Please provide feedback on the relevant aspects of optimal nutrition and preventive care for the Hospital IQR Program.

While we will not be responding to specific comments in response to this RFI in the FY 2026 IPPS/LTCH PPS final rule, we intend to use this input to inform our future measure development efforts.

(b) Background

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 and 41148), in which we describe the Meaningful Measures Framework. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, addressing a wide variety of settings, interested parties, and measure requirements.[312]

There are statutory requirements that the Secretary of HHS make public certain quality and efficiency measures that the Secretary is considering for adoption through rulemaking under Medicare.[313] To comply with those requirements, the Consensus-Based Entity (CBE), currently Battelle, convenes the Partnership for Quality Measurement (PQM), which is comprised of clinicians, patients, measure experts, and health information technology specialists, to participate in the pre-rulemaking process and the measure endorsement process. We refer readers to the FY 2025 IPPS/LTCH PPS final rule and the PQM website[314] for a more detailed discussion on the updated pre-rulemaking measure reviews (PRMR) process (89 FR 69457 through 69459).

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

We propose refinements to two measures that are currently in the Hospital IQR Program measure set: (1) Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization, beginning with the July 1, 2023–June 30, 2025 reporting period/FY 2027 payment determination; and (2) Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April

[309] These rules are: the FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861); the FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181); the FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692); the FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150); the FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 82 FR 38348); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609); the FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509); the FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959); the FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426); the FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310); the FY 2024 IPPS/LTCH PPS final rule (88 FR 59144 through 59203); and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69515 through 69577).

[310] Well-Being Concepts. (2017). CDC Archives. Available at: *https://www.naspa.org/images/uploads/kcs/WHPL_Canon_WB_Well-Being_Concepts_HRQOL_CDC_2017.pdf*.

[311] The eCQM previously named Global Malnutrition Composite Score has been updated to Malnutrition Care Score. The short name has subsequently been updated to MCS eCQM.

[312] Centers for Medicare & Medicaid Services. (2025). Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*.

[313] See section 1890A(a)(2) of the Social Security Act (42 U.S.C. 1395aaa–1(a)(2)).

[314] Battelle, Partnership for Quality website. Available at: *https://p4qm.org/*.

1, 2023–March 31, 2025 reporting period/FY 2027 payment determination.

a. Proposed Modification of the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization Measure Beginning With the FY 2027 Payment Determination

(1) Background

Every year more than 795,000 people in the U.S. have a stroke.[315] In 2022, strokes were the fifth leading cause of death in the U.S.[316] Strokes are also associated with a high morbidity rate, causing over half of stroke survivors ages 65 years or older to suffer from reduced mobility.[317] Between 2019 and 2020 alone, stroke-related costs totaled almost $56.2 billion in the U.S., including costs for healthcare services, medications, and missed workdays.[318]

Stroke outcomes can vary greatly depending on the facility where patients receive care.[319] This was demonstrated in a study of Medicare patients ages 65 years or older admitted to a hospital for acute ischemic stroke, which found that stroke patients treated at hospitals with a higher volume of stroke patients had lower mortality rates and better outcomes.[320] This association is likely due to high-volume hospitals having more experience in treating strokes and developing improved processes of care.[321] Research has shown that improving processes for responding to strokes leads to better patient outcomes. For example, having a dedicated stroke team on call provides hospitals with expertise in a variety of relevant areas including emergency medicine, vascular neurology, radiology, pharmacology, and laboratory analysis. Similarly, setting up organized workflows for diagnosing and treating stroke improves response times for a condition for which patient outcomes are highly dependent on the timeliness of treatment.[322]

To improve stroke outcomes for patients, we adopted the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Ischemic Stroke Hospitalization measure (hereinafter referred to as the MORT–30–STK measure) in the Hospital IQR Program beginning with the FY 2016 payment determination (78 FR 50798 through 50802). The MORT–30–STK measure assesses the hospital-level, risk-standardized mortality rate after admission for acute ischemic stroke to any non-Federal acute care hospital. The measure includes Medicare fee-for-service (FFS) patients ages 65 years or older and the outcome is all-cause 30-day mortality.

When this measure was adopted, most Medicare patients were enrolled in the Medicare FFS Program.[323] However as of November 2024, roughly 50 percent of Medicare beneficiaries—34.4 million people—were enrolled in Medicare Advantage (MA) plans.[324] Including MA beneficiaries in hospital outcome measures would help ensure that hospital quality is measured across all Medicare beneficiaries, and would address concerns about differences in care quality for MA and Medicare FFS beneficiaries.[325] [326] Moreover, inclusion of MA beneficiaries increases the size of the measure's cohort, which enhances the reliability of the measure scores and allows more low-volume hospitals to receive measure results.

(2) Overview of Measure Updates

We propose modifications to the current MORT–30–STK measure with updates in the Hospital IQR Program beginning with the FY 2027 payment determination. Specifically, we propose to make two substantive updates to the MORT–30–STK measure: (1) we would expand the measure's inclusion criteria to include MA patients; and (2) we would shorten the performance period from 3 years to 2 years. The addition of MA encounter data to the measure roughly doubles the cohort size, improves measure reliability, and more accurately reflects the quality of care for both Medicare FFS and MA beneficiaries.

The proposed measure modifications align with our Meaningful Measures 2.0 priority area of ''Seamless Care Coordination'', which includes leveraging processes and activities to ensure successful transitions of care and coordination.[327] This measure promotes successful transitions of care for stroke patients discharged from acute care settings, as well as reduces short-term, preventable mortality rates. Patient outcomes depend on many aspects of care including communication between providers, prevention of and response to complications, patient safety, and coordinated transitions to the outpatient and rehabilitation care settings. The proposed modifications to the measure would better reflect overall patient outcomes in each hospital and inform quality improvement activities.

We propose to implement these changes beginning with the FY 2027 payment determination. The proposed new reporting period for the measure for the FY 2027 payment determination would be changed from July 1, 2022, through June 30, 2025, to July 1, 2023, through June 30, 2025.

(3) Technical Updates

We are also making two technical updates beginning with the FY 2027 payment determination. Specifically, the technical updates to the measure include: (1) updating the risk adjustment model to use individual International Classification of Diseases (ICD–10) codes instead of Hierarchical Condition Categories (HCCs) to improve the measure's risk adjustment methodology; and (2) removing the exclusion of patients with a secondary diagnosis code of COVID–19 coded as present on admission on the index admission claim. We refer readers to section X.C.5. of the preamble of this proposed rule for further discussion on removal of the COVID–19 diagnosis

[315] CDC. (2024). Stroke Facts. Available at: *https://www.cdc.gov/stroke/data-research/facts-stats/index.html*.

[316] CDC. (2024). Leading Causes of Death. Available at: *https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm*.

[317] CDC. (2024). Stroke Facts. Available at: *https://www.cdc.gov/stroke/data-research/facts-stats/index.html*.

[318] *Ibid.*

[319] Neves, G., Cole, T., Lee, J., Bueso, T., Shaw, C., & Montalvan, V. (2022). Demographic and institutional predictors of stroke hospitalization mortality among adults in the United States. eNeurologicalSci, 26, 100392. *https://doi.org/10.1016/j.ensci.2022.100392*.

[320] Stein LK, Mocco J, Fifi J, Jette N, Tuhrim S, Dhamoon MS. Correlations Between Physician and Hospital Stroke Thrombectomy Volumes and Outcomes: A Nationwide Analysis. Stroke. 2021 Aug;52(9):2858–2865. doi: 10.1161/STROKEAHA.120.033312. Epub 2021 Jun 7. PMID: 34092122.

[321] *Ibid.*

[322] Herpich, Franziska MD1,2; Rincon, Fred MD, MSc, MB.Ethics, FACP, FCCP, FCCM1,2. Management of Acute Ischemic Stroke. Critical Care Medicine 48(11):p 1654–1663, November 2020. | DOI: 10.1097/CCM.0000000000004597.

[323] Freed M, Biniek JF, Damico A, Neuman T. (2024). Medicare Advantage in 2024: Enrollment Update and Key Trends. Kaiser Family Foundation. Available at: *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/*.

[324] Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard*. Accessed on March 25, 2025.

[325] Ochieng N and Biniek JF. (2022). Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature. Available at: *https://www.kff.org/medicare/report/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature/*.

[326] Medicare Payment Advisory Commission. (2022). The Medicare Advantage program: Status report and mandated report on dual-eligible special needs plans. Available at: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf*.

[327] Centers for Medicare & Medicaid Services. (2025). Cascade of Meaningful Measures. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/cascade-measures*.

exclusion to measures in the Hospital IQR Program.

We are updating the measure's risk adjustment methodology to use individual ICD–10 codes. The current risk adjustment strategy for this measure involves grouping ICD–10 diagnosis codes from CMS's HCC system into clinically relevant categories. Then we evaluate the HCCs for statistical association with the measure's outcome.[328] However, research has indicated that using individual ICD–10 codes in place of HCCs could significantly improve the model performance of the mortality measures.[329] To better leverage the data and analytical advances since the measure was initially developed, we created a new approach to use individual ICD–10 codes for risk adjustment instead of grouping them into categories. With this new approach, the ability of the risk adjustment model to account for stroke severity was significantly better (c-statistic improved from 0.79 to 0.91).[330] We did not adjust for social risk variables in the measure as neither of the two social risk factors tested (Area Deprivation Index and dual eligibility) showed significant effect. Given these findings and the complex pathways that could explain any relationship between social risk and mortality/complications, we chose not to adjust the measure for social risk.[331]

For measure specification details on the updates to this measure, we refer readers to the 2024 Condition-Specific Measure Updates and Specifications Report available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

(4) Measure Calculation

The proposed modified MORT–30–STK measure would continue to measure 30-day, all-cause mortality. We define mortality as death from any cause within 30 days of the start of the index admission for patients discharged from the hospital with a principal discharge diagnosis of acute ischemic stroke. The cohort for the modified measure would include admissions for patients ages 65 years or older discharged from the hospital with a principal diagnosis of acute ischemic stroke, who were enrolled in Medicare FFS or MA for the 12 months prior to the date of admission, as well as enrolled in Medicare FFS or MA during the index admission.

The proposed updates to the measure exclude all of the following admissions from its cohort:

- Patients with inconsistent or unknown vital status, or other unreliable demographic data (for example, age and gender).
- Patients who were transferred from another acute care facility.
- Patients enrolled in the Medicare hospice program any time in the 12 months prior to the index hospitalization.
- Patients who were discharged against medical advice.

If a patient has more than one eligible stroke hospitalization during the reporting period, then we randomly select one index admission for inclusion in the cohort and exclude the other admissions within that reporting period.[332] The measure currently adjusts for factors including age, comorbidities, indications of patient frailty, and stroke severity upon admission when comparing a patient's risk of death at each facility.[333]

The proposed modifications to the MORT–30–STK measure would still be calculated using a risk-standardized mortality rate. This is calculated by first determining the ratio of the number of predicted deaths to the number of expected deaths and then multiplying the ratio by the national unadjusted mortality rate. The ratio is greater than one for hospitals that have more deaths than would be expected for an average hospital with similar cases and less than one if the hospital has fewer deaths than would be expected for an average hospital with similar cases. This approach is analogous to a ratio of an ''observed'' or ''crude'' rate to an ''expected'' or risk-adjusted rate used in other similar types of statistical analyses. It allows for a comparison of a particular hospital's performance to an average hospital's performance with the same case mix.

We propose to expand the applicable population to include MA patients ages 65 years or older in addition to Medicare FFS patients ages 65 years or older. Inclusion of MA beneficiaries has important benefits for the reliability and validity of the measure. The combination of MA beneficiaries with Medicare FFS beneficiaries significantly increases the size of the measure's cohort, which enhances the reliability of the measure scores, leading to more hospitals receiving results and increasing the chance of identifying meaningful differences in quality for some low-volume hospitals. With the improvements to the measure reliability, we propose to shorten the MORT–30–STK measure reporting period from 3 to 2 years. Based on our analysis that included MA patients in addition to the existing MORT–30–STK measure cohort, we found that the measure could achieve a satisfactory level of reliability with a two-year reporting period. The median reliability for the two-year performance period is 0.911, ranging from 0.623 to 0.994.[334] Shortening the reporting period would allow measure results to reflect more recent hospital performance, and therefore provide more actionable insights for quality improvement.

For more information regarding the proposed modifications to the MORT–30–STK measure specifications, we refer readers to the 2024 Condition-Specific Measure Updates and Specifications Report available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

(5) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the Pre-Rulemaking Measure Review (PRMR) Process

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69457 through 69458) for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 15 and 16, 2025, to review measures included by the Secretary on the publicly available ''2024 Measures Under Consideration List'' (MUC List), including the MORT–30–STK measure

[328] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[329] Krumholz, H.M., Coppi, A.C., Warner, F., Triche, E.W., Li, S.X., Mahajan, S., Li, Y., Bernheim, S.M., Grady, J., Dorsey, K., Lin, Z., & Normand, S.T. (2019). Comparative Effectiveness of New Approaches to Improve Mortality Risk Models From Medicare Claims Data. JAMA network open, 2(7), e197314. *https://doi.org/10.1001/jamanetworkopen.2019.7314*.

[330] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (March 2024). 2024 Supplemental Measure Methodology: Condition-and Procedure-Specific Mortality/Complications. Available at: *https://p4qm.org/measures/4595*.

[331] *Ibid.*

[332] Centers for Medicare & Medicaid Services. (2024). 2024 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[333] Centers for Medicare & Medicaid Services. (April 2024). 2024 Condition-Specific Measure Updates and Specifications Report: AMI, HF, COPD, Pneumonia, and Stroke Mortality. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[334] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (March 2024). 2024 Supplemental Measure Methodology: Condition-and Procedure-Specific Mortality/Complications. Available at: *https://p4qm.org/measures/4595*.

(MUC2024–043),[335] [336] and provided a recommendation on the potential use of this measure in the Hospital IQR Program.

The voting results of the PRMR Hospital Recommendation Committee for the proposed updates to the MORT–30–STK measure within the Hospital IQR Program were: 18 committee members recommended adopting the measure into the Hospital IQR Program without conditions; 7 committee members recommended adoption with conditions; 1 committee member voted not to recommend the measure for adoption.[337] Taken together, 96 percent of the votes were to recommend with conditions. Thus, the committee reached consensus and recommended the updates to the MORT–30–STK measure within the Hospital IQR Program with conditions.[338]

The conditions that the committee recommended were: (1) CBE endorsement; (2) CMS consider restructuring the measure to reduce the time lag and provide hospitals with more timely and useful data; and (3) CMS consider adding risk stratification for pre-existing do-not-resuscitate orders.[339] As discussed later in this section, the CBE voted to endorse the measure and therefore the first condition has been met. Regarding the second condition to reduce the reporting period, we propose to update the MORT–30–STK measure to shorten the reporting period from 3 to 2 years, which our current analysis shows is the shortest reporting period for which the results remain reliable and valid, and which significantly improves the timeliness of the data for this measure.

We also acknowledge the condition related to stratification of pre-existing do-not-resuscitate orders and will consider making this change in future updates to the measure, if our monitoring and evaluation of the measure demonstrate this stratification would be beneficial. We propose to adopt modifications to the MORT–30–STK measure in the Hospital IQR Program having taken into consideration the conditions raised by the PRMR Hospital Committee.

(b) Measure Endorsement

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69458 through 69459) for details on the measure endorsement and maintenance (E&M) process, including the measure evaluation procedures the E&M Committees use to evaluate measures and whether they meet endorsement criteria. The measure developer submitted the MORT–30–STK measure to the CBE in 2016 but it was not endorsed because the measure was not risk adjusted for stroke severity. When the measure developer submitted the measure to the CBE in 2021, the CBE did not endorse the measure because the committee did not reach consensus on whether in-hospital stroke mortality is an appropriate measure of quality and if there was sufficient evidence that clinical actions could be performed to reduce stroke mortality. The measure developer submitted the measure (CBE #4595) for endorsement again for the Fall 2024 cycle, which reflects the proposed modifications in the measure.[340] The CBE voted to endorse the measure on February 7, 2025.[341]

(6) Data Sources, Submission, and Public Reporting

This measure is calculated using administrative claims data routinely generated and submitted to CMS for all Medicare beneficiaries, which includes MA and Medicare FFS beneficiaries. Therefore, hospitals would not be required to report any additional data for this measure. We propose to add MA encounter data to the measure calculation in order to calculate measure results that include those patients. The MORT–30–STK measure would be calculated and publicly reported on an annual basis using a rolling 24 months of prior data for the measurement period, consistent with the approach currently used for the Thirty-day Risk-Standardized Death Rate Among Surgical Inpatients with Complications measure (89 FR 69545 through 69552) and the CMS Patient Safety and Adverse Events Composite (PSI 90) measure, currently reported in the Hospital-Acquired Condition (HAC) Reduction Program (78 FR 50712 through 50718). We would then publicly report measure results on the Compare tool, currently available at: *https://www.medicare.gov/care-compare,* beginning in July 2026 or as soon as feasible.

We invite public comment on our proposal to modify the MORT–30–STK measure beginning with the FY 2027 payment determination.

b. Proposed Modification to the Hospital-Level, Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) Measure Beginning With the FY 2027 Payment Determination

(1) Background

THA and TKA are commonly performed procedures for the Medicare population that improve quality of life.[342] From April 1, 2018–March 31, 2021, there were 563,236 THA and TKA procedures performed on Medicare FFS patients 65 years and older.[343] By 2040, the number of THA procedures is projected to increase by 176 percent and the number of TKA procedures is projected to increase by 139 percent.[344] While these procedures can dramatically improve a person's quality of life, they are costly. Based on projections of the annual demand for THA and TKA procedures, researchers estimate that Medicare expenditures on Total Joint Arthroplasty could climb to $50 billion by 2030.[345] Complications such as joint infections and sepsis following elective THA and TKA

[335] Centers for Medicare & Medicaid Services. (2024). 2024 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[336] Centers for Medicare & Medicaid Services. (2024). 2024 Overview of the List of Measures Under Consideration. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[337] Battelle—Partnership for Quality Measurement. (February 2025). 2024–2025 Pre-Rulemaking Measure Review (PRMR) Recommendations Report. Available at: *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[338] *Ibid.*

[339] *Ibid.*

[340] Battelle—Partnership for Quality Measurement. Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity. Available at: *https://p4qm.org/measures/4595.*

[341] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Endorsement Summary Report. This report will be available through this link: *https://p4qm.org/EM/news-events.*

[342] Barahona M, Bustos F, Navarro T, Chamorro P, Barahona MA, Carvajal S, Brañes J, Hinzpeter J, Barrientos C, Infante C. Similar Patient Satisfaction and Quality of Life Improvement Achieved with TKA and THA According to the Goodman Scale: A Comparative Study. J Clin Med. 2023 Sep 21;12(18):6096. Available at: *https://pubmed.ncbi.nlm.nih.gov/37763035/#:~:text=Regarding%20improvement%20in%20quality%20of,lower%20satisfaction%20rates%20for%20TKA.*

[343] 2022 Procedure-Specific Complication Measure Updates and Specifications Report: Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). Available at: *https://www.cms.gov/files/document/2022-measure-updates-procedure-specific-complication-measure-updates-and-specifications-report.pdf.*

[344] Gupta, N, Turnow M, Doad, J. et al., Trends in Reimbursement for All Billable Total Joint Replacement Procedures: An Analysis of the Medicare Part B Database from 2013–2011. J. Orthop. Ex. & Inn. 2024; 5(2). *https://doi.org/10.60118/001c.120219.* Available at: *https://journaloei.scholasticahq.com/article/120219-trends-in-reimbursement-for-all-billable-total-joint-replacement-procedures-an-analysis-of-the-medicare-part-b-database-from-2013-2021.*

[345] Wilson, N.A., et al., Hip and knee implants: current trends and policy considerations. Health Aff (Millwood), 2008. 27(6): p. 1587–98.

procedures are rare, but the results can be devastating. Evidence shows that periprosthetic joint infection rates following THA and TKA were 1.9 percent (1.5 percent to 2.2 percent) and 1.5 percent (1.3 percent to 1.7 percent) following TKA and THA, respectively.[346] From 2011 to 2021, reported 30- and 90-day death rates following THA are 0.49 percent and 0.47 percent, respectively.[347] Rates for pulmonary embolism following THA range from 0.5 percent to 1.22 percent [348] and range from 0.5 percent to 0.9 percent [349] following TKA. Rates for wound infection in Medicare population-based studies vary between 0.21 percent and 1.0 percent.[350] Rates for sepsis/septicemia range from 0.09 percent during the index admission to 0.3 percent 90 days following discharge for primary TKA. Rates for bleeding and hematoma following TKA range from 0.94 percent to 1.7 percent.[351]

The Hospital-Level, Risk-Standardized Complication Rate Following Elective Primary THA and or TKA measure (hereinafter referred to as the COMP–HIP–KNEE measure) was first adopted in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53521). The measure estimates a hospital-level, risk-standardized complication rate associated with elective primary THA and/or TKA procedures. More recently, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267), we adopted a re-evaluated COMP–HIP–KNEE measure into the Hospital IQR Program that included expanded outcomes. In the FY 2024 IPPS/LTCH PPS final rule (88 FR 59067 through 59070), the re-evaluated COMP–HIP–KNEE measure was adopted in the Hospital VBP Program in accordance with statutory requirements of section 1886(o)(2)(C)(i) of the Act and 42 CFR 412.164(b), which state that measures must be publicly reported for 1 year in the Hospital IQR Program prior to the beginning of the performance period in the Hospital VBP Program. In that same final rule, we finalized removal of the re-evaluated COMP–HIP–KNEE measure in the Hospital IQR Program beginning with the FY 2030 payment determination to prevent duplicative reporting of the measure in a quality reporting program and value-based program, and to simplify administration of both programs (88 FR 59168 through 59170). The clinical outcomes of the COMP–HIP–KNEE measure are a high priority for CMS and this measure provides important data on patient safety and complications. We are therefore proposing modifications to the COMP–HIP–KNEE measure in the Hospital IQR Program beginning with the FY 2027 payment determination, prior to its removal from the Hospital IQR Program beginning with the FY 2030 payment determination (88 FR 59168 through 59170). We refer readers to section VI.L.2.a. of the preamble of this proposed rule for more details on our proposal to adopt these same updates for the COMP–HIP–KNEE measure into the Hospital VBP Program beginning with the FY 2033 program year. If finalized, the proposed updated COMP–HIP–KNEE measure will have been publicly reported in the Hospital IQR Program for at least 1 year in accordance with statutory requirements before adoption into the Hospital VBP Program.

(2) Overview of Measure Updates

We propose modifications to the current COMP–HIP–KNEE measure in the Hospital IQR Program beginning with the FY 2027 payment determination. Specifically, we propose to modify the COMP–HIP–KNEE measure with two substantive updates: (1) expand the measure's inclusion criteria to include MA patients; and (2) shorten the performance period from 3 years to 2 years. The addition of MA encounter data to the measure roughly doubles the cohort size, improves measure reliability, and more accurately reflects the quality of care for both Medicare FFS and MA beneficiaries. If finalized, we would remove the updated COMP–HIP–KNEE measure in the Hospital IQR Program beginning with the FY 2030 payment determination, as finalized in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59168 through 59170), to prevent duplicative reporting of the measure in a quality reporting program and value-based program, and to simplify administration of both programs.

The proposed modifications of the updated COMP–HIP–KNEE measure would support the Meaningful Measures 2.0 priority area of ''Chronic Conditions'' that aims to improve disease-specific outcomes, reduce preventable emergency department usage and admissions, and reduce mortality.[352]

(3) Technical Updates

We are also making two technical updates to the proposed updated COMP–HIP–KNEE measure. Specifically, technical updates to the measure include: (1) update the risk adjustment model to use individual ICD–10 codes instead of HCCs to improve the measure's risk adjustment methodology; and (2) remove the exclusion of patients with a secondary diagnosis code of COVID–19 coded as present on admission on the index admission claim. We refer readers to section X.C.5. of the preamble of this proposed rule for further discussion on removal of the COVID–19 diagnosis exclusion to measures in the Hospital IQR Program.

We are updating the COMP–HIP–KNEE measure's risk-adjustment methodology to use individual ICD–10 codes using patient-level demographics (age), patient-level health status and clinical conditions (case-mix adjustment; severity of illness; comorbidities), and patient functional status (body function). These clinically relevant risk variables would be identified from inpatient and outpatient claims in the 12 months prior to the procedure. The current risk adjustment strategy for this measure involves grouping ICD–10 diagnosis codes from CMS's HCC system into clinically relevant categories. Then we evaluate the HCCs for statistical association with the measure's outcome.[353] However, research has indicated that using individual ICD codes in place of HCCs could significantly improve the model performance of the mortality measures.[354] To better leverage the data

[346] Jin X, Gallego Luxan B, Hanly M, et al., Estimating Incidence Rates of Periprosthetic Joint Infection After Hip and Knee Arthroplasty for Osteoarthritis Using Linked Registry and Administrative Health Data. Bone Joint J. 2022; 104–B(9): 1060–1066. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9948458.*

[347] Turan O, Pan X, Kunze KN, et al., 30-Day to 10-Year Mortality Rates Following Total Hip Arthroplasty: A meta-Analysis of the Last Decade. Hip Int. 2024; 34(1): 4–14. Available at: *https://pubmed.ncbi.nlm.nih.gov/36705090.*

[348] Arshi A, Leong NL, Wang C, Buser Z, Wang JC, SooHoo NF. Outpatient total hip arthroplasty in the United States: A population-based comparative analysis of complication rates. J Am Acad Orthop Surg. 2019;27(2):61–7.

[349] Khatod M, Inacio M, Paxton EW, et al. Knee replacement: epidemiology, outcomes, and trends in Southern California: 17,080 replacements from 1995 through 2004. Acta Orthop. 2008;79(6):812–819.

[350] Browne J, Cook C, Hofmann A, Bolognesi M. Postoperative morbidity and mortality following total knee arthroplasty with computer navigation. Knee. Mar 2010;17(2):152–156.

[351] Huddleston JI, Maloney WJ, Wang Y, Verzier N, Hunt DR, Herndon JH. Adverse Events After Total Knee Arthroplasty: A National Medicare Study. The Journal of Arthroplasty. 2009;24(6, Supplement 1):95–100.

[352] Centers for Medicare & Medicaid Services. (2025). Cascade of Meaningful Measures. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/cascade-measures.*

[353] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology.*

[354] Krumholz, H.M., Coppi, A.C., Warner, F., Triche, E.W., Li, S.X., Mahajan, S., Li, Y., Bernheim,

and analytical advances since the measure was initially developed, we created a new approach to use individual ICD–10 codes for risk adjustment instead of grouping them into categories. With this new approach, the discriminative performance of the risk adjustment model as measured by c-statistic was significantly better and the calibration performance also proved to be satisfactory.[355] We did not adjust for social risk variables in the measure as neither of the two social risk factors tested (Area Deprivation Index and dual eligibility) showed significant effect. Given these findings and the complex pathways that could explain any relationship between social risk and mortality/complications, we chose not to adjust the measure for social risk.

For measure specification details on the updates to this measure, we refer readers to the Measure Methodology Report in the Hip and Knee Arthroplasty Complications (ZIP) folder on the QualityNet website, available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology.*

(4) Measure Calculation

The outcome for the proposed updated COMP–HIP–KNEE measure would be a complication occurring during the index admission (not coded as present on admission) through 90 days post-date of the index admission. Complications are counted in the measure only if they occur during the index hospital admission or during a readmission. The complication outcome is a dichotomous (yes/no) outcome. If a patient experiences one or more of these complications in the applicable period, the complication outcome for that patient would be counted in the measure as a ''yes''.

The proposed updated measure includes one of the following complications:

- Acute myocardial infarction during the index admission or a subsequent inpatient admission that occurs within 7 days from the start of the index admission.
- Pneumonia or other acute respiratory complication during the index admission or a subsequent inpatient admission that occurs within 7 days from the start of the index admission.
- Sepsis/septicemia/shock during the index admission or a subsequent inpatient admission that occurs within 7 days from the start of the index admission.
- Surgical site bleeding or other surgical site complication during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission.
- Pulmonary embolism during the index admission or a subsequent inpatient admission within 30 days from the start of the index admission.
- Death during the index admission within 30 days from the start of the index admission or within 30 days from the start of the index admission.
- Mechanical complication during the index admission or a subsequent inpatient admission that occurs within 90 days from the start of the index admission.
- Periprosthetic joint infection/wound infection or other wound complication during the index admission or a subsequent inpatient admission that occurs within 90 days from the start of the index admission.

The code list used to define the mechanical complication outcome includes clinically vetted mechanical complication ICD–10 codes. For a full list of these codes, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49264).

We propose to expand the COMP–HIP–KNEE measure cohort to include both Medicare FFS and MA beneficiaries, aged 65 years or older, having a qualifying elective primary THA or TKA procedure during the index admission. Beneficiaries must be enrolled in Medicare FFS or MA for the 12 months prior to the date of admission and enrolled in Medicare FFS or MA during the index admission. Our analysis found that the addition of MA admissions into the COMP–HIP–KNEE measure approximately doubled the admissions in the cohorts and led to improved measure reliability and more hospitals and beneficiaries included for measure calculation.[356] Based on the results of that analysis, we found that the measure could achieve a satisfactory level of reliability (median reliability score 0.801, ranging from 0.560 to 0.997, with the 25th and 75th percentiles 0.683 and 0.891, respectively) with a 2-year reporting period and are therefore proposing to shorten the reporting period from 3 to 2 years.[357] This median reliability estimate exceeds the reliability of 0.6, which the CBE considers acceptable. Shortening the reporting period would allow measure results to reflect more recent hospital performance and, therefore, provide more actionable insights for quality improvement.

Consistent with the COMP–HIP–KNEE measure currently reported in the Hospital IQR Program, the proposed update to the COMP–HIP–KNEE measure would exclude patients from the measure cohort index admissions for patients who did not have at least 90 days post-discharge enrollment in Medicare FFS or MA, who were discharged against medical advice, or who had more than two THA/TKA procedure codes during the index hospitalization.[358]

The proposed modifications to the COMP–HIP–KNEE measure would still be calculated using a hospital risk-standardized complication rate by producing a ratio of the number of ''predicted'' complications (that is, the adjusted number of complications at a specific hospital based on its patient population) to the number of ''expected'' complications (that is, the number of complications if an average quality hospital treated the same patients) for each hospital and then multiplying the ratio by the national observed complication rate. For each hospital, the numerator of the ratio is the number of complications within the specified time period (up to 90 days) predicted on the basis of the hospital's performance with its observed case mix, and the denominator is the number of complications expected based on the Nation's performance with that hospital's case mix. This approach is analogous to a ratio of ''observed'' to ''expected'' used in other types of statistical analyses. It would allow for a comparison of a particular hospital's performance to an average hospital's performance with the same case mix.

For measure specification details on the updates to this measure, we refer readers to the Measure Methodology Report in the Hip and Knee Arthroplasty Complications (ZIP) folder on the QualityNet website, available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology.*

S.M., Grady, J., Dorsey, K., Lin, Z., & Normand, S.T. (2019). Comparative Effectiveness of New Approaches to Improve Mortality Risk Models From Medicare Claims Data. JAMA network open, 2(7), e197314. *https://doi.org/10.1001/jamanetworkopen.2019.7314.*

[355] Battelle—Partnership for Quality Measurement. (February 2025). 2024–2025 Pre-Rulemaking Measure Review (PRMR) Recommendations Report. Available at: *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[356] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (March 2024). 2024 Supplemental Measure Methodology: Condition-and Procedure-Specific Mortality/Complications. Available at: *https://p4qm.org/measures/1550.*

[357] *Ibid.*

[358] Battelle—Partnership for Quality Measurement. Hospital-level, risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. Available at: *https://p4qm.org/measures/1550.*

(5) Pre-Rulemaking Process and Measure Endorsement

(a) Recommendation From the Pre-Rulemaking Measure Review (PRMR) Process

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69457 through 69458) for details on the PRMR process including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Committee met on January 15 and 16, 2025, to review measures included by the Secretary on the publicly available 2024 Measures Under Consideration (MUC) List, including the COMP–HIP–KNEE measure (MUC2024–042),[359] and to vote on a recommendation regarding use of this measure in the Hospital IQR Program.

The PRMR Hospital Recommendation Committee reached consensus and voted to recommend this measure for the Hospital IQR Program with conditions.[360] Eighteen of 27 members of the committee recommended adopting the measure into the Hospital IQR Program without conditions; 8 members of the committee recommended adoption with conditions; 1 member of the committee did not recommend this measure for adoption. Taken together, 96 percent of the votes were to recommend this measure for the Hospital IQR Program with conditions. Thus, the committee reached consensus and recommended the updated COMP–HIP–KNEE measure for adoption into the Hospital IQR Program with conditions.[361]

The committee supported this measure, particularly with the addition of MA data to improve statistical reliability and make the measure more relevant for rural areas, with a call for transparency and analytical rigor to understand the impact of additional MA data. The committee raised concerns regarding the potentially uneven distribution of MA program participation, the shifting of benchmarks with new MA beneficiaries, and the implications of surgical procedures moving to ambulatory care settings which may leave more complex patients in inpatient facilities. Thus, the committee members submitted the following conditions for recommendations into the Hospital IQR Program: (1) stratified reporting; (2) providing hospitals with feedback on outcome variations between MA beneficiaries and Medicare Shared Savings Program (MSSP) populations; (3) breaking down performance data by payer; (4) re-evaluating the risk model as the measure matures to identify any adjustments needed for variation at the patient level across plans; and (5) considering if the reporting period is sufficient to avoid time lags that may hinder data usefulness and measure improvement.[362]

In response to concerns about uneven distributions among MA and Medicare FFS beneficiaries, based on our analysis, the observed complication rate for MA beneficiaries was 3.7 percent, 3.2 percent among Medicare FFS beneficiaries only, and 3.4 percent complication rate for MA and Medicare FFS beneficiaries, showing a difference of −0.5 percent between Medicare FFS only and MA only beneficiaries.[363] Thus, the variation between the two cohorts did not vary significantly for complication rates and does not raise concerns regarding uneven distribution of two cohorts for this measure. In regard to providing hospitals with stratified reporting results, we note that hospitals currently receive confidential feedback reports containing details on measure results, but they do not stratify results by payer. We will consider providing additional confidential feedback to hospitals in the future, including results stratified by MA and Medicare FFS beneficiaries. Regarding evaluating the risk adjustment model, as a part of routine measure maintenance, we conduct ongoing monitoring and evaluation analyses to watch for any unintended consequences. Regarding the condition related to lag time between performance and when results are received, one of the proposed updates is to shorten the reporting period from 3 to 2 years, which our current analysis shows is the shortest reporting period for which the results remain reliable and valid and which significantly improves the timeliness of the data for this measure. However, we will continue to analyze measure results and if the evidence shows that a reporting period that is shorter than 2 years produces valid and reliable measure results, we will consider proposing to adopt that shorter reporting period in the future. After taking these recommendations and concerns into consideration, we propose to adopt the updated COMP–HIP–KNEE measure in the Hospital IQR Program.

(b) Measure Endorsement

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 89 FR 69458 through 69459) for details on the E&M process including the procedures the CBE's E&M Committees use to evaluate measures and determine whether they meet endorsement criteria. The COMP–HIP–KNEE measure (CBE #1550) was reviewed by the CBE in the Fall 2020 cycle, and was re-endorsed July 2021.[364] The COMP–HIP–KNEE measure was most recently submitted to the CBE's E&M Cost and Efficiency Committee in the Fall 2024 E&M review cycle, which included the modifications we propose to adopt in this proposed rule as well as the technical updates to the risk methodology. The E&M Cost and Efficiency Committee voted, and did not reach consensus on this measure on February 10, 2025.[365] [366] Per the current CBE, consensus is reached when 75 percent of the committee vote to endorse, endorse with conditions, or remove endorsement or the combination of endorse and endorse with conditions reach 75 percent. Thus, with the combination of endorse and endorse with conditions only reaching 73 percent the measure was not re-endorsed by the CBE.[367] [368] The measure developer submitted an appeal for the endorsement decision with the following rationale: (1) procedural error in the endorsement process with an excessive focus on outpatient setting exclusions; and (2) misapplication of

[359] Centers for Medicare & Medicaid Services. (2024). 2024 Measures Under Consideration (MUC) List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[360] Battelle—Partnership for Quality Measurement. (February 2025). 2024–2025 Pre-Rulemaking Measure Review (PRMR) Recommendations Report. Available at: *https://p4qm.org/sites/default/files/2025-02/PRMR-2024-2025-MUC-Recommendations-Report-Final.pdf.*

[361] *Ibid.*

[362] *Ibid.*

[363] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (March 2024). 2024 Supplemental Measure Methodology: Condition-and Procedure-Specific Mortality/Complications. Available at: *https://p4qm.org/measures/1550.*

[364] Battelle—Partnership for Quality Measurement. Hospital-level, risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. Available at: *https://p4qm.org/measures/1550.*

[365] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Endorsement Summary Report. This report will be available through this link: *https://p4qm.org/projects/cost-and-efficiency.*

[366] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Endorsement Summary Report. This report will be available through this link: *https://p4qm.org/EM/news-events.*

[367] Battelle—Partnership for Quality Measurement. Hospital-level, risk- standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. Available at: *https://p4qm.org/measures/1550.*

[368] Battelle—Partnership for Quality Measurement. (July 2024). Endorsement and Maintenance (E&M) Guidebook. Available at: *https://p4qm.org/sites/default/files/2024-08/Del-3-6-Endorsement-and-Maintenance-Guidebook-Final_0.pdf.*

measure evaluation criteria, particularly risk adjustment.[369] The CBE convened the E&M Fall 2024 appeals committee meeting on March 31, 2025, where the committee voted on whether to uphold the appeals request based on the rationale. The committee voted to uphold the appeals request, with a vote of 100 percent for both rationales, thereby overturning the endorsement decision of non-consensus. Thus, the COMP–HIP–KNEE measure was endorsed with conditions. The two conditions for endorsement were: (1) explore the proportion of procedures done in the ambulatory surgical centers and hospital outpatient department setting and evaluate the need for adjustment based on the impact of case mix; and (2) explore additional approaches to the reliability assessment to account for low-volume facilities.

Regarding the first criteria, to evaluate the need for adjustments based on case mix of patients, we note that this measure focuses on higher-risk patients and is intentionally narrow to capture significant complications, such as sepsis, pulmonary embolism, or a second surgery which should be treated in the inpatient setting. We wish to emphasize that those having elective THA or TKA procedures within the inpatient setting must meet certain criteria, resulting in a smaller cohort of patients, and in communities where there are no ambulatory care centers the patient would be treated in the hospital outpatient department and would not be counted in this measure. Regarding the second condition for endorsement, to explore additional approaches to the reliability assessment to account for low-volume facilities, we emphasize that the goal of this measure and adjusting for low-volume is to make performance scores available for as many providers as possible while trying to avoid misclassification or profiling of providers. We note that scores are not available for facilities with fewer than 25 cases, because the number of cases may be too small for meaningful results. Based on our evaluation of the endorsement criteria, these conditions have been met, and therefore, we consider this measure endorsed.

(6) Data Source, Submission and Public Reporting

The proposed updated COMP–HIP–KNEE measure would use index admission diagnoses and in-hospital comorbidity data from Medicare FFS claims or MA claims/encounters, or both. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare FFS claims and MA encounters in the 12 months prior to index (initial) admission. Enrollment status would be obtained from the Medicare Enrollment Database which contains beneficiary demographic, benefit/coverage, and vital status information. This measure uses readily available administrative claims data routinely generated and submitted to CMS for all Medicare beneficiaries, which includes Medicare Advantage and Medicare FFS beneficiaries. The updated COMP–HIP–KNEE measure would be calculated and publicly reported on an annual basis using a rolling 24 months of prior data for the measurement period, consistent with the approach currently used for the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (89 FR 69545 through 69552) and CMS Patient Safety and Adverse Events Composite (PSI 90) measure, currently reported in the HAC Reduction Program (78 FR 50712 through 50718). As a claims-based measure, hospitals would not be required to submit data other than claims data, which we would use to calculate the measure. We are also proposing to adopt the modifications to the COMP–HIP–KNEE measure in the Hospital VBP Program in section VI.L.2.a. of the preamble of this proposed rule, beginning with the FY 2033 program year, after the updated measure has been publicly reported in the Hospital IQR Program for one year. Table X.C.1. summarizes the timelines for the current and proposed reporting of the COMP–HIP–KNEE measure in the Hospital IQR and VBP Programs.

TABLE X.C.1—SUMMARY OF CURRENT AND PROPOSED REPORTING OF THE COMP–HIP–KNEE MEASURE IN THE HOSPITAL IQR AND VBP PROGRAMS

In payment year or program year impacted	Version of measure in use	
	Hospital IQR Program	Hospital VBP Program
FY 2026	Modification 1 (Additional outcomes added) [1]	Original.[2]
FY 2027	Modification 2 (Add MA patients, shorten performance period) [3]	Original.
FY 2028	Modification 2	Original.
FY 2029	Modification 2	Original.
FY 2030	N/A	Modification 1.
FY 2031	N/A	Modification 1.
FY 2032	N/A	Modification 1.
FY 2033 and Subsequent Years	N/A	Modification 2.

[1] Modification 1 was finalized in the FY 2024 IPPS/LTCH PPS final rule.
[2] Original version of the measure was finalized in the FY 2015 IPPS/LTCH PPS final rule.
[3] Modification 2 is being proposed in this section of the proposed rule.

We propose to publicly report the updated COMP–HIP–KNEE measure in accordance with our previously established public reporting policy for the Hospital IQR Program.[370] Such reporting would be undertaken on the Compare tool available at: *https://www.medicare.gov/care-compare*, or its successor website, beginning in July 2026 or as soon as feasible.

We invite public comment on our proposal to adopt the updated COMP–HIP–KNEE measure into the Hospital IQR Program beginning with administrative claims and encounter data from April 1, 2023, through March 31, 2025, associated with the FY 2027 payment determination.

[369] Battelle—Partnership for Quality Measurement. (2025). E&M Fall 2024 Appeals Committee Meeting Summary Report. This report will be available through this link: *https://p4qm.org/EM/news-events.*

[370] See the FY 2025 IPPS/LTCH PPS final rule (89 FR 69577) for a brief overview of public display requirements under the Hospital IQR Program and our current public reporting policy.

4. Proposed Removals in the Hospital IQR Program Measure Set

We propose to remove four measures: (1) Hospital Commitment to Health Equity measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (3) Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination; and (4) Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. We provide more details on each of these proposals in the subsequent sections.

a. Proposed Removal of the Hospital Commitment to Health Equity Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

We refer readers to the FY 2023 IPPS/LTCH PPS final rule where we adopted the Hospital Commitment to Health Equity (hereafter referred to as HCHE) measure into the Hospital IQR Program (87 FR 49191 through 49201). We propose to remove the HCHE measure beginning with the FY 2026 payment determination due to the costs associated with achieving a high score on the measure outweighing the benefit of its continued use in the program. When adopted, we intended the collection of data described in the five domains of this measure to provide hospital leadership with meaningful and actionable health data to drive quality improvements to eliminate health disparities. Based on feedback received from hospitals as well as a re-focus on clinical outcome measures, for which the HCHE measure, as a structural measure, does not directly measure clinical outcomes, the burden of collecting this measure may outweigh the benefits. Removal of this measure would alleviate an estimated annual burden of approximately 525 hours, at a cost of $22,260, across all participating IPPS hospitals (87 FR 49385).

One of the goals of the Hospital IQR Program is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement in the quality of care provided to patients. Removing this measure from the Hospital IQR Program is an effective way to accomplish this goal. Our priority is a re-focus on measurable clinical outcomes as well as identifying quality measures on topics of prevention, nutrition, and well-being, and as such we refer readers to our request for comment on ''Measure Concepts under Consideration for Future Years in the Hospital IQR Program-Request for Information (RFI): Well-Being and Nutrition'' in section X.C.2.a. The Hospital IQR Program continues to incentivize the improvement of care quality and health outcomes for all patients through measurement and transparency with other measures. It may be costly for hospitals to continue reporting on the HCHE measure and achieve high performance scores, and removal of this measure would make room both in the program's measure set to enhance the program's focus on measurable clinical outcomes and for hospital leadership to focus on other priority quality and safety areas. We acknowledge that some hospitals may have expended resources to implement some or all of the activities described in the HCHE measure attestation statements in order to be able to attest ''yes'' for measure reporting purposes, however, hospitals that had already implemented such activities prior to adoption of the measure would have been able to attest ''yes'' without expending similar resources.

If finalized, hospitals that do not report their CY 2024 reporting period data for the HCHE measure to CMS would not be considered noncompliant with the measure for purposes of their FY 2026 payment determination (that is, hospitals that do not report CY 2024 reporting period data would not be penalized for FY 2026 payments due to this measure). Any HCHE measure data received by CMS would not be used for public reporting or payment purposes.

If not finalized, hospitals that do not report their CY 2024 reporting data for the HCHE measure to CMS would be considered noncompliant with the measure for their FY 2026 payment determination, and would receive a letter of noncompliance after August 1, 2025, at which time the required 30-day reconsideration period would begin. Payment adjustments would apply to FY 2026 payment determinations fee-for-service claims as previously finalized.

We invite public comment on our proposal to remove the HCHE measure from the Hospital IQR Program beginning with the FY 2026 payment determination.

b. Proposed Removal of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

We refer readers to the FY 2022 IPPS/LTCH PPS final rule where we adopted the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure (hereafter referred to as HCP COVID–19 Vaccination measure) into the Hospital IQR Program (86 FR 45374 through 45382) and the FY 2024 IPPS/LTCH PPS final rule where we modified the HCP COVID–19 Vaccination measure to account for updated vaccine guidance (88 FR 59137 through 59144).

We propose to remove the HCP COVID–19 Vaccination measure beginning with the CY 2024 reporting period/FY 2026 payment determination under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We note that reporting on this measure currently requires reporting data on COVID–19 vaccination coverage among HCP for at least 1 week every month. This requires hospitals to track current vaccination status for all employees, licensed independent practitioners, adult students/trainers and volunteers and other contract personnel and log in to the National Healthcare Safety Network (NHSN) system to report the data monthly either manually in NHSN or by uploading a comma-separated value (CSV) file (86 FR 45377). The estimated burden of collecting this information annually across all 3,050 hospitals is between $1,378,600 and $1,608,570 annually. We refer readers to section XIII.B.4.e. of this proposed rule for more details on this estimated burden calculation.

When we first adopted the HCP COVID–19 Vaccination measure, the U.S. was in a Public Health Emergency (PHE) with millions of cases and over 550,000 COVID–19 deaths (86 FR 45374). While preventing the spread of COVID–19 remains a public health goal, the PHE ended on May 11, 2023.[371] In addition, the number of deaths due to COVID–19 in the U.S. has decreased since the adoption of this measure. In March 2021, when this measure was being proposed, the United States was averaging over 5,000 deaths per week. In April 2023, the last full month of the PHE, weekly number of deaths due to COVID–19 averaged around 1,300.[372]

[371] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

[372] Provisional COVID–19 Deaths, by Week, in The United States, Reported to CDC. Accessed on March 27, 2025, via *https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00.*

With the end of the PHE and the decrease in COVID–19 deaths, we believe the continued costs and burden to providers of tracking and monthly reporting on this measure outweigh the benefit of continued information collection on COVID–19 vaccination coverage among HCP. As it may be costly for hospitals to continue to report on the HCP COVID–19 Vaccination measure, removal of this measure would allow for the Hospital IQR Program to focus on goals such as clinical outcomes.

If finalized, hospitals that do not report their CY 2024 reporting period data for the HCP COVID–19 Vaccination measure to CMS would not be considered noncompliant with the measures for purposes of their FY 2026 payment determination (that is, hospitals that do not report CY 2024 reporting period data would not be penalized for FY 2026 payments due to this measure). Any HCP COVID–19 Vaccination measure data received by CMS would not be used for public reporting or payment purposes.

If not finalized, hospitals that do not report their CY 2024 reporting data for the HCP COVID–19 Vaccination measure to CMS would be considered noncompliant with the measure for their FY 2026 payment determination, and would receive a letter of noncompliance after August 1, 2025, at which time the required 30-day reconsideration period would begin. Payment adjustments would apply to FY 2026 payment determinations fee-for-service claims as previously finalized.

We invite public comment on our proposal to remove the HCP COVID–19 Vaccination measure from the Hospital IQR Program beginning with the FY 2026 payment determination.

c. Proposed Removal of Two Social Drivers of Health Measures Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

We propose to remove two social drivers of health (SDOH) process measures from the Hospital IQR Program beginning with the FY 2026 payment determination: Screening for Social Drivers of Health (SDOH–1) measure (adopted at 87 FR 49201 through 49215); and Screen Positive Rate for Social Drivers of Health (SDOH–2) measure (adopted at 87 FR 49215 through 49220).

We propose to remove the SDOH measures beginning with the FY 2026 payment determination under removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We have previously heard from some hospitals concerned with the costs and resources associated with screening patients via manual processes, manually storing such data, training hospital staff, and altering workflows for these measures. In the FY 2023 IPPS/LTCH PPS final rule, we estimated a total annual burden of 700,000 hours including hospital and patient burden, at a cost of $21,917,000 to screen all admitted patients in accordance with measure specifications for SDOH–1 (87 FR 49385 through 49386). For SDOH–2, we estimated a total annual burden of 525 hours across all IPPS hospitals, at a cost of $22,260 (87 FR 49385 through 49386). Further, we note that these measures document an administrative process and report aggregate level results, and do not shed light on the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. We have concluded that the costs of the continued use of these measures in the Hospital IQR Program outweigh the benefits to providers and patients. Removal of these measures would alleviate the burden on hospitals to manually screen each patient and submit data each reporting cycle, allowing hospitals to focus resources on measurable clinical outcomes. This will also remove the patient burden associated with repeated SDOH screenings across multiple healthcare facilities. We refer readers to our request for comment, ''Measure Concepts under Consideration for Future Years in the Hospital IQR Program–Request for Information (RFI): Well-Being and Nutrition'' in section X.C.2.a. for more information regarding our areas of focus for new measures. We acknowledge that some hospitals may have expended resources to implement SDOH screenings, however, hospitals that had already implemented such screenings prior to adoption of the measures would not have expended similar resources. The objectives of the Hospital IQR Program continue to incentivize the improvement of care quality and health outcomes for all patients through transparency and use of appropriate quality measures.

If finalized, hospitals that do not report to CMS their CY 2024 reporting period data for the SDOH measures would not be considered noncompliant with the measures for purposes of their FY 2026 payment determination (that is, hospitals that do not report CY 2024 reporting period data would not be penalized for FY 2026 payments due to this measure). Any SDOH measure data received by CMS would not be used for public reporting or payment purposes.

If not finalized, hospitals that do not report their CY 2024 reporting data for the SDOH measures to CMS would be considered noncompliant with the measures for their FY 2026 payment determination, and would receive a letter of noncompliance after August 1, 2025, at which time the required 30-day reconsideration period would begin. Payment adjustments would apply to FY 2026 payment determinations fee-for-service claims as previously finalized.

We invite public comment on our proposal to remove the SDOH measures from the Hospital IQR Program beginning with the FY 2026 payment determination.

5. Technical Updates to the Specifications of the Hospital IQR Program Measures Beginning With the FY 2027 Program Year To Include Patients Diagnosed With COVID–19

We are removing the COVID–19 exclusion from all of the following Hospital IQR Program measures:

- MORT–30–STK, most recently discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50798 through 50802) and proposed for modification in this proposed rule.
- COMP–HIP–KNEE, most recently discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263) and proposed for modification in this proposed rule.
- Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction (AMI Excess Days), most recently modified in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49269 through 49272).
- Excess Days in Acute Care after Hospitalization for Heart Failure (HF Excess Days), most recently discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49682 through 49690).
- Excess Days in Acute Care after Hospitalization for Pneumonia (PN Excess Days), most recently discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57142 through 57148).
- Hybrid Hospital-Wide All-Cause Readmission Measure (HWR), most recently modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59165 through 59168) and proposed for modification in this proposed rule.
- Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM), most recently modified in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59161 through 59165) and proposed for modification in this proposed rule.

During the COVID–19 PHE, we updated the measures listed previously to exclude patients diagnosed with COVID–19, including a primary or

secondary diagnosis present on admission of COVID–19, from both the index admissions and readmissions. We stated that we were making these updates pursuant to the technical updates policy finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53504 through 53505). Under this policy, we finalized a subregulatory process to make nonsubstantive updates to measures used for the Hospital IQR Program (77 FR 53504 through 53505). We reiterated this policy in the FY 2020 IPPS/LTCH PPS final rule, for the HAC Reduction Program, stating our continued belief that the subregulatory process is the most expeditious manner possible to ensure that quality measures remain fully up to date while preserving the public's ability to comment on updates that so fundamentally change a measure that it is no longer the same measure that we originally adopted (84 FR 42385 through 42387).

We are providing notice in this proposed rule that we intend to remove the COVID–19 exclusion from the measures listed previously beginning with the FY 2027 program year. The exclusion began as a response to the COVID–19 PHE which expired May 11, 2023. This technical update will modify these measures to remove the exclusion of COVID–19 diagnosed patients from the index admissions and readmissions, including the removal of the exclusion of certain ICD–10 codes that represented patients with a secondary diagnosis of COVID–19, and the history of COVID–19 risk variable. Given the PHE expired approximately 2 years ago, hospitals have had adequate time to adjust to the presence of COVID–19 as an ongoing virus. Using data from the last 4 years, July 2020–June 2024, our internal analysis showed a decline of the number of patients excluded from the various measure cohorts. Therefore, removing the exclusion of COVID–19 patients will ensure that these measures continue to account for outcomes as intended and meet the goals of the Hospital IQR Program.

Technical specifications for all of the Hospital IQR Program measures, as well as additional resources, can be found on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/iqr*).

6. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the proposed and previously finalized Hospital IQR Program measure set for the FY 2027 payment determination:

TABLE X.C.2—MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short name	Measure name	CBE No.*
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID–19 Vaccination**	Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel.	3636
Claims-Based Patient Safety Measures		
Inpatient Surgical Complications Mortality Rate***.	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications.	4125
Claims-Based Mortality/Complications Measures		
MORT–30–STK****	Hospital 30-Day, All-Cause, Risk Standardized Mortality-Rate Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity.	4595
COMP–HIP–KNEE****	Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA.	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		
Hybrid HWM*****	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502e
Hybrid HWR*****	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP–1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
Age Friendly Hospital	Age Friendly Hospital Measure	N/A
Patient Safety	Patient Safety Structural Measure	N/A
HCHE**	Hospital Commitment to Health Equity	N/A

TABLE X.C.2—MEASURES FOR THE FY 2027 PAYMENT DETERMINATION—Continued

Short name	Measure name	CBE No.*
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids—Concurrent Prescribing	3316e
PC–02	Cesarean Birth	0471e
PC–07	Severe Obstetric Complications	3687e
STK–2	Discharged on Antithrombotic Therapy	0435e
STK–3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK–5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE–1	Venous Thromboembolism Prophylaxis	0371e
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372e
HH–HYPO	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH–HYPER	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH–ORAE	Hospital Harm—Opioid-Related Adverse Events	3501e
HH–PI	Hospital Harm—Pressure Injury	3498e
HH–AKI	Hospital Harm—Acute Kidney Injury	3713e
MCS******	Malnutrition Care Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults.	3663e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO–PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO–PM).	3559
Process Measures		
SDOH–1**	Screening for Social Drivers of Health	N/A
SDOH–2**	Screen Positive Rate for Social Drivers of Health	N/A

*We note that inclusion of a CBE number neither indicates endorsement or lack of endorsement. More information about current endorsement status can be found on the Partnership for Quality Measurement website: *https://p4qm.org/measures*.

**In this proposed rule, we propose removing the HCP COVID–19 Vaccination measure, the HCHE measure, and the SDOH measures beginning with the FY 2026 payment determination. We refer readers to section X.C.4. of the preamble of this proposed rule for more detailed discussion on proposed measure removals.

***The Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications measure short name has been updated to Inpatient Surgical Complications Mortality Rate.

****In this proposed rule, we propose refinements to the MORT–30–STK and the COMP–HIP–KNEE measures beginning with the FY 2027 payment determination. We refer readers to sections X.C.3.a. and X.C.3.b., respectively, of the preamble of this proposed rule for more detailed discussion.

*****In this proposed rule, we propose modified reporting thresholds for linking variables and CCDEs beginning with the FY 2028 payment determination and subsequent years. In the FY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) we finalized an extension of voluntary reporting of linking variables and core clinical data elements for the Hybrid HWR measure and the Hybrid HWM measure for the FY 2026 and FY 2027 payment determinations. We refer readers to section X.C.7.c. of the preamble of this proposed rule for more detailed discussion.

******The eCQM previously named Global Malnutrition Composite Score has been updated to Malnutrition Care Score. The short name has subsequently been updated to MCS eCQM.

b. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2028 Payment Determination

This table summarizes the proposed and previously finalized Hospital IQR Program measure set for the FY 2028 payment determination:

TABLE X.C.3—MEASURES FOR THE FY 2028 PAYMENT DETERMINATION

Short name	Measure name	CBE*
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID–19 Vaccination**	COVID–19 Vaccination Coverage Among Healthcare Personnel	3636
CAUTI-Onc***	Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations.	0138
CLABSI-Onc***	Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations.	0139

TABLE X.C.3—MEASURES FOR THE FY 2028 PAYMENT DETERMINATION—Continued

Short name	Measure name	CBE *
Claims-Based Patient Safety Measures		
Inpatient Surgical Complications Mortality Rate ****.	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications.	4125
Claims-Based Mortality/Complications Measures		
MORT–30–STK *****	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke.	N/A
COMP–HIP–KNEE *****	Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA.	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims and Electronic Data Measures		
Hybrid HWM ******	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502e
Hybrid HWR ******	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP–1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
Age Friendly Hospital	Age Friendly Hospital Measure	N/A
Patient Safety	Patient Safety Structural Measure	N/A
HCHE **	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids—Concurrent Prescribing	3316e
PC–02	Cesarean Birth	0471e
PC–07	Severe Obstetric Complications	3687e
STK–2	Discharged on Antithrombotic Therapy	0435e
STK–3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK–5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE–1	Venous Thromboembolism Prophylaxis	0371e
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372e
HH–HYPO	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH–HYPER	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH–ORAE	Hospital Harm—Opioid-Related Adverse Events	3501e
HH–PI	Hospital Harm—Pressure Injury	3498e
HH–AKI	Hospital Harm—Acute Kidney Injury	3713e
HH–FI	Hospital Harm—Falls with Injury	4120e
HH–RF	Hospital Harm—Postoperative Respiratory Failure	4130e
MCS *******	Malnutrition Care Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults.	3663e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO–PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO–PM).	3559
Process Measures		
SDOH–1 **	Screening for Social Drivers of Health	N/A
SDOH–2 **	Screen Positive Rate for Social Drivers of Health	N/A

* We note that inclusion of a CBE number neither indicates endorsement or lack of endorsement. More information about current endorsement status can be found on the Partnership for Quality Measurement website: *https://p4qm.org/measures*.

** In this proposed rule, we propose removing the HCP COVID–19 Vaccination measure, the HCHE measure, and the SDOH measures beginning with the FY 2026 payment determination. We refer readers to section X.C.4. of the preamble of this proposed rule for more detailed discussion on proposed measure removals.

*** We are updating our NHSN measures in alignment with CDC's efforts to rebaseline using CY 2022 data. We refer readers to section VI.M.2.b. of the preamble of this proposed rule for more detailed discussion of technical updates to rebaseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program.

**** The Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications measure short name has been updated to Inpatient Surgical Complications Mortality Rate.

***** In this proposed rule, we propose refinements to the MORT–30–STK and the COMP–HIP–KNEE measures beginning with the FY 2027 payment determination. We refer readers to sections X.C.3.a. and X.C.3.b., respectively, of the preamble of this proposed rule for more detailed discussion.

****** In this proposed rule, we propose modified reporting thresholds for linking variables and CCDEs beginning with the FY 2028 payment determination and subsequent years. In the FY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) we finalized an extension of voluntary reporting of linking variables and core clinical data elements for the Hybrid HWR measure and the Hybrid HWM measure for the FY 2026 and FY 2027 payment determinations. We refer readers to section X.C.7.c. of the preamble of this proposed rule for more detailed discussion.

******* The eCQM previously named Global Malnutrition Composite Score has been updated to Malnutrition Care Score. The short name has subsequently been updated to MCS eCQM.

c. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2029 Payment Determination and for Subsequent Years

This table summarizes the proposed and previously finalized Hospital IQR Program measure set for the FY 2029 payment determination and for subsequent years:

TABLE X.C.4—MEASURES FOR THE FY 2029 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Short name	Measure name	CBE *
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
HCP COVID–19 Vaccination **	COVID–19 Vaccination Coverage Among Healthcare Personnel	3636
CAUTI-Onc ***	Catheter-Associated Urinary Tract Infection (CAUTI) Standardized Infection Ratio Stratified for Oncology Locations.	0138
CLABSI-Onc ***	Central Line-Associated Bloodstream Infection (CLABSI) Standardized Infection Ratio Stratified for Oncology Locations.	0139
Claims-Based Patient Safety Measures		
Inpatient Surgical Complications Mortality Rate ****.	Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications.	4125
Claims-Based Mortality/Complications Measures		
MORT–30–STK *****	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate (RSMR) Following Acute Ischemic Stroke Hospitalization with Claims-Based Risk Adjustment for Stroke Severity.	4595
COMP–HIP–KNEE *****	Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA.	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims and Electronic Data Measures		
Hybrid HWM ******	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502e
Hybrid HWR ******	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879e
Chart-Abstracted Clinical Process of Care Measures		
SEP–1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
Age Friendly Hospital	Age Friendly Hospital Measure	N/A
Patient Safety	Patient Safety Structural Measure	N/A
HCHE **	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids—Concurrent Prescribing	3316e
PC–02	Cesarean Birth	0471e
PC–07	Severe Obstetric Complications	3687e

TABLE X.C.4—MEASURES FOR THE FY 2029 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS—Continued

Short name	Measure name	CBE *
STK–2	Discharged on Antithrombotic Therapy	0435e
STK–3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK–5	Antithrombotic Therapy by the End of Hospital Day Two	0438e
VTE–1	Venous Thromboembolism Prophylaxis	0371e
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372e
HH–HYPO	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH–HYPER	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH–ORAE	Hospital Harm—Opioid-Related Adverse Events	3501e
HH–PI	Hospital Harm—Pressure Injury	3498e
HH–AKI	Hospital Harm—Acute Kidney Injury	3713e
HH–FI	Hospital Harm—Falls with Injury	4120e
HH–RF	Hospital Harm—Postoperative Respiratory Failure	4130e
MCS *******	Malnutrition Care Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults.	3663e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO–PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO–PM).	3559
Process Measures		
SDOH–1 **	Screening for Social Drivers of Health	N/A
SDOH–2 **	Screen Positive Rate for Social Drivers of Health	N/A

* We note that inclusion of a CBE number neither indicates endorsement or lack of endorsement. More information about current endorsement status can be found on the Partnership for Quality Measurement website: *https://p4qm.org/measures*.

** In this proposed rule, we propose removing the HCP COVID–19 Vaccination measure, the HCHE measure, and the SDOH measures beginning with the FY 2026 payment determination. We refer readers to section X.C.4. of the preamble of this proposed rule for more detailed discussion on proposed measure removals.

*** We are updating our NHSN measures in alignment with CDC's efforts to rebaseline using CY 2022 data. We refer readers to section VI.M.2.b. of the preamble of this proposed rule for more detailed discussion of technical updates to rebaseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program.

**** The Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications measure short name has been updated to Inpatient Surgical Complications Mortality Rate.

***** In this proposed rule, we propose refinements to the MORT–30–STK and the COMP–HIP–KNEE measures beginning with the FY 2027 payment determination. We refer readers to sections X.C.3.a. and X.C.3.b., respectively, of the preamble of this proposed rule for more detailed discussion.

****** In this proposed rule, we propose modified reporting thresholds for linking variables and CCDEs beginning with the FY 2028 payment determination and subsequent years. In the FY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) we finalized an extension of voluntary reporting of linking variables and core clinical data elements for the Hybrid HWR measure and the Hybrid HWM measure for the FY 2026 and FY 2027 payment determinations. We refer readers to section X.C.7.c. of the preamble of this proposed rule for more detailed discussion.

******* The eCQM previously named Global Malnutrition Composite Score has been updated to Malnutrition Care Score. The short name has subsequently been updated to MCS eCQM.

7. Proposed Updates to the Form, Manner, and Timing of Hospital IQR Program Data Submission

We propose changes to our reporting and submission requirements for eCQMs and hybrid measures. We provide more details on these proposals in the subsequent sections. We are not proposing changes to the following requirements, and we have therefore omitted the following subsections from the Form, Manner, and Timing of Quality Data Submission section: procedural requirements; data submission requirements for chart-abstracted measures; sampling and case thresholds for chart-abstracted measures; HCAHPS Survey administration and submission requirements; data submission requirements for structural measures; data submission and reporting requirements for CDC NHSN measures; and data submission and reporting requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs). We refer readers to the QualityNet website at: *https://qualitynet.cms.gov/inpatient/iqr* (or other successor CMS designated websites) for more details on the Hospital IQR Program data submission and procedural requirements.

a. Background

Sections 1886(b)(3)(B)(viii)(I) and (b)(3)(B)(viii)(II) of the Act state that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner and at a time specified by the Secretary. To participate successfully in the Hospital IQR Program, hospitals must comply with the specific procedural, data collection, submission, and validation requirements that we specify for the program.

b. Maintenance of Technical Specifications for Quality Measures

Section 412.140(c)(1) of title 42 of the Code of Federal Regulations (CFR) generally requires that a subsection (d) hospital participating in the Hospital IQR Program must submit to CMS data

on measures selected under section 1886(b)(3)(B)(viii) of the Act in a form and manner, and at a time, specified by CMS. The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications for eCQMs. The Annual Update also contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2025 reporting period/FY 2027 payment determination, hospitals are collecting and will submit eCQM data using the May 2024 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data as described at 42 CFR 412.140(a). See 45 CFR part 160 and subparts A, C, and E of 45 CFR part 164.

c. Proposed Modification to the Reporting of the Hybrid Hospital-Wide All-Cause Readmission (HWR) and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measures

(1) Background

The Hospital IQR Program previously adopted two hybrid measures: (1) the Hybrid HWR measure; and (2) the Hybrid HWM measure. Hybrid measures use more than one data source for measure calculation. Specifically, the Hybrid HWR and Hybrid HWM measures are calculated using core clinical data elements (CCDEs), linking variables, and claims data (80 FR 49698). CCDEs are a set of clinical variables derived from electronic health records (EHRs) that can be used to risk adjust hospital outcome measures (80 FR 49699). Linking variables are administrative data that can be used to link or merge the CCDEs and claims data for measure calculation (80 FR 49703). These measures are designed to enhance risk adjustment of claims-based outcome measures by utilizing patient clinical data captured in EHRs (80 FR 49698).

Hospitals are currently required to report CCDEs (both vital signs and laboratory test results) on 90 percent of discharges and to submit four linking variables on 95 percent of discharges for both the Hybrid HWR and Hybrid HWM measures in a given reporting period beginning with mandatory reporting for the FY 2028 payment determination (89 FR 94495 through 94499). Hospitals must report 13 CCDEs (six vital signs and seven laboratory test results) for the Hybrid HWR measure and 10 CCDEs (four vital signs and six laboratory test results) for the Hybrid HWM measure.

(2) Proposed Decrease of the Hybrid Measures CCDE and Linking Variable Submission Thresholds Beginning With the FY 2028 Payment Determination

As a part of measure maintenance, we routinely monitor hospital performance on the Hospital IQR Program measures. The results of 2024 voluntary reporting for both the Hybrid HWR and Hybrid HWM measures indicated that three-fourths of the participating hospitals that submitted measure data during this voluntary period did not meet submission thresholds of 90 percent of discharges for the CCDEs and 95 percent of discharges for the linking variables. It is therefore likely that an even larger percentage of hospitals would not have met the current hybrid measure CCDE and linking variable submission thresholds if they had been required to report them during the July 1, 2022, through June 30, 2023, performance period. The hospitals that participated in voluntary reporting of these data consisted mostly of large, non-rural, non-critical access, and non-safety net hospitals.

In the CY 2025 OPPS/ASC final rule, we summarized feedback received on the reporting of the Hybrid HWR and Hybrid HWM measures (89 FR 94495 through 94499). Several commenters described challenges meeting the 90 percent thresholds for CCDEs and the 95 percent thresholds for linking variables and recommended reducing the required threshold percentages. A few commenters specifically recommended lowering the threshold for reporting laboratory results, which are included in the CCDEs. While lowering the thresholds would have been out-of-scope for the CY 2025 OPPS/ASC final rule, we stated our intent to propose lowering the thresholds in the FY 2026 IPPS/LTCH PPS proposed rule.

Based on the feedback from commenters and our analysis of the results from the voluntary reporting for both the Hybrid HWR and Hybrid HWM measures, we considered whether lowering the thresholds for CCDE and linking variables would increase the number of hospitals that were able to successfully report the hybrid measures without significantly decreasing reliability. The results of an internal analysis indicated that for both the Hybrid HWR and Hybrid HWM measures, allowing (1) fewer CCDEs to be submitted—up to two missing lab values and up to two missing vital signs—combined with (2) lowering the percentage of discharges meeting the CCDE lab values and vital signs threshold to 70 percent of discharges, significantly improves hospitals' ability to meet the measure reporting thresholds.[373] The same effect was observed for linking variables when lowering the threshold to 70 percent of discharges. While we established the current 90 and 95 percent thresholds for CCDEs and linking variables, respectively, based on initial measure testing to encourage data completeness, our recent analysis shows that these lower thresholds still demonstrate good reliability for measure calculation, while increasing the number of hospitals that were able to successfully report the hybrid measures.[374] [375] [376]

Therefore, we now propose to reduce the submission thresholds for both CCDE and linking variables to at least 70 percent of discharges for both the Hybrid HWR and Hybrid HWM measures. We selected the threshold of 70 percent to ensure successful submission for as many hospitals as possible, while still maintaining statistical validity.[377] We also propose to lower the number of required CCDE data elements for both the Hybrid HWR and Hybrid HWM measures to allow for up to two missing laboratory results and up to two missing vital signs. A hospital that submits CCDE and linking variable data for less than 70 percent of applicable patient discharges or that submits CCDE data with more than two missing laboratory results or more than two missing vital signs under either hybrid measure would not satisfy the measure's Hospital IQR Program requirements and would receive a one-fourth reduction to its Annual Payment Update (APU) for the applicable fiscal year.

We invite public comment on our proposals to reduce the number of required CCDEs, to allow up to two missing lab values and two missing vital signs, and to lower the required

[373] CMS. Internal Analysis. September 2024.

[374] CMS. Internal Analysis. September 2024.

[375] Battelle—Partnership for Quality Measurement. Hybrid Hospital-Wide Readmission (HWR) Measure with Claims and Electronic Health Record Data. Available at: *https://p4qm.org/measures/2879e*.

[376] Battelle—Partnership for Quality Measurement. Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Claims and Electronic Health Record Data. Available at: *https://p4qm.org/measures/3502e*.

[377] CMS Internal Analysis. September 2024.

percentage of discharges meeting the CCDE and linking variable thresholds to 70 percent of discharges for the Hybrid HWR and Hybrid HWM measures beginning with the FY 2028 payment determination, which has a performance period of July 1, 2025, through June 30, 2026.

8. Hospital IQR Program Extraordinary Circumstances Exception (ECE) Policy

a. Background

Under our current Extraordinary Circumstances Exception (ECE) regulations, we have granted exceptions with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of a hospital (42 CFR 412.140(c)(2)). An exception may be granted for extraordinary circumstances including, but not limited to, natural disasters or systemic problems with data collection systems.[378] We refer readers to 42 CFR 412.140(c)(2) for our current ECE regulations, as well as the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651), FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and FY 2015 IPPS/LTCH PPS final rule (79 FR 50277) for further background and details of our ECE policy. We also refer readers to the QualityNet website for the specific requirements for submission of an ECE request in the Hospital IQR Program.[379]

Our ECE policy provides flexibility for Hospital IQR Program participants to ensure continuity of quality care delivery and measure reporting in the event of an extraordinary circumstance. For instance, we recognize that, in circumstances where a full exception is not applicable, it is beneficial for a hospital to report data later than the reporting deadline. Delayed reporting authorized under our ECE policy allows temporary relief for a hospital experiencing an extraordinary circumstance while preserving the benefits of data reporting, such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to update our regulations to specify that an ECE could take the form of an extension of time for a hospital to comply with a data reporting requirement if CMS determines that this type of relief would be appropriate under the circumstances.

b. Proposal To Update the Extraordinary Circumstances Exception (ECE) Policy for the Hospital IQR Program

We propose to update the current ECE policy codified at 42 CFR 412.140(c)(2) to include extensions of time as a form of relief and to further clarify the policy. Specifically, at proposed § 412.140(c)(2)(i), we propose that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance—defined as an event beyond the control of a hospital (for example a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

We propose that the steps for requesting or granting an ECE would remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[380] At proposed § 412.140(c)(2)(ii)(A), we propose that a hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Our current policy allows a request within 90 days; however, this proposed change would align the Hospital IQR policy with CMS systems implementation requirements across all quality reporting programs. Under this proposed codified policy, we clarify that CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred. At proposed § 412.140(c)(2)(ii)(B), we propose that CMS notify the requestor with a decision in writing. In the event that CMS grants an ECE to the hospital, the written decision will specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

Additionally, at § 412.140(c)(2)(iii), we propose that CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that: a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement, or that an extraordinary circumstance has affected an entire region or locale. As is the case under our current policy, any ECE granted will specify whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

This proposed ECE policy would provide further reporting flexibility for hospitals and clarify the ECE process.

We invite public comment on our proposals.

D. Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program, authorized by section 1866(k) of the Act, applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567) for a general overview of the PCHQR Program. We also refer readers to 42 CFR 412.24 for codified PCHQR Program requirements.

2. PCHQR Program Measures

a. Proposed Removal of the Hospital Commitment to Health Equity Measure Beginning With CY 2024 Reporting Period/FY 2026 Program Year and for Subsequent Years

We refer readers to the FY 2024 IPPS/LTCH PPS final rule (88 FR 59204 through 59210) where we adopted the Hospital Commitment to Health Equity (hereinafter referred to as HCHE) measure into the PCHQR Program. We propose to remove the HCHE measure beginning with the CY 2024 reporting period/FY 2026 program year due to the costs associated with achieving a high score on the measure outweighing the benefit of its continued use in the program. When adopted, we intended the collection of data described in the five domains of this measure to provide hospital leadership with meaningful and actionable health data to drive quality improvements to eliminate health disparities. Based on feedback received from hospitals as well as a re-focus on clinical outcome measures, for which the HCHE measure, as a structural measure, does not directly measure clinical outcomes, the burden of collecting this measure may outweigh the benefits. Removal of this measure would alleviate an estimated annual burden of approximately 2 hours, at a cost of $90, across all PCHs (88 FR 59317).

One of the goals of the PCHQR Program is to move forward in the least burdensome manner possible, while maintaining a parsimonious set of the most meaningful quality measures and continuing to incentivize improvement

[378] Centers for Medicare & Medicaid Services (CMS) Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form. (2025). QualityNet. Available at: *https://qualitynet.cms.gov/files/677e843f50ed8df7419f60e1?filename=HQR_ECE_Req_Form_CY_2025.pdf.*

[379] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

[380] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

in the quality of care provided to patients. Removing this measure from the PCHQR Program is an effective way to accomplish this goal. Our priority is a re-focus on measurable clinical outcomes as well as identifying quality measures on topics of prevention and well-being. It may be costly for hospitals to continue reporting on the HCHE measure, and removal of this measure would make room in the program's measure set to enhance the program's focus on measurable clinical outcomes. We acknowledge that some hospitals may have expended resources to implement some or all of the activities described in the HCHE measure attestation statements in order to be able to attest ''yes'' for measure reporting purposes, however, hospitals that had already implemented such activities prior to adoption of the measure would have been able to attest ''yes'' without expending similar resources.

If finalized, any HCHE measure data received by CMS would not be used for public reporting purposes.

We invite public comment on our proposal to remove the HCHE measure from the PCHQR Program beginning with the CY 2024 reporting period/FY 2026 program year.

b. Proposed Removal of Two Social Drivers of Health Measures Beginning With CY 2024 Reporting Period/FY 2026 Program Year and for Subsequent Years

We propose to remove two social drivers of health (SDOH) process measures from the PCHQR Program beginning with the CY 2024 reporting period/FY 2026 program year:

- Screening for Social Drivers of Health measure (adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59210 through 59219)); and
- Screen Positive Rate for Social Drivers of Health measure (adopted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59219 through 59222)).

We propose to remove the SDOH measures beginning with the CY 2024 reporting period/FY 2026 program year under removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in the program. We have previously heard from some hospitals concerned with the costs and resources associated with screening patients via manual processes, manually storing such data, training hospital staff, and altering workflows for these measures. In the FY 2023 and FY 2024 IPPS/LTCH PPS final rules, we estimated a total annual burden of 101 hours across all PCHs at a cost of $2,092 to screen all patients in accordance with measure specifications for Screening for Social Drivers of Health measure (88 FR 59317 through 59318). For Screen Positive Rate for Social Drivers of Health measure, we estimated a total annual burden of 2 hours across all PCHs at a cost of $90 (88 FR 59318). Further, we note that these measures document an administrative process and report aggregate level results, and do not shed light on the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. We have concluded that the costs of the continued use of these measures in the PCHQR Program outweigh the benefits to beneficiaries and providers. Removal of these measures would alleviate the burden on hospitals to manually screen each patient and submit data each reporting cycle, allowing hospitals to focus resources on measurable clinical outcomes. This will also remove the patient burden associated with repeated SDOH screenings across multiple healthcare facilities. We acknowledge that some hospitals may have expended resources to implement SDOH screenings, however, hospitals that had already implemented such screenings prior to adoption of the measures would not have expended similar resources. The objectives of the PCHQR Program continue to incentivize the improvement of care quality and health outcomes for all patients through transparency and use of appropriate quality measures.

If finalized, any SDOH measure data received by CMS would not be used for public reporting purposes.

We invite public comment on our proposal to remove the SDOH measure from the PCHQR Program beginning with the CY 2024 reporting period/FY 2026 program year.

c. Summary of Previously Adopted PCHQR Program Measures for the CY 2026 Reporting Period/FY 2028 Program Year and Subsequent Years

Table X.D.–01 summarizes the previously adopted measures for the PCHQR Program measure set beginning with the CY 2026 reporting period/FY 2028 program year.

TABLE X.D.–01—PREVIOUSLY ADOPTED MEASURES FOR THE PCHQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2026 REPORTING PERIOD/FY 2028 PROGRAM YEAR

Short name	Consensus-based entity (CBE) No.	Measure name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI *	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure.
CLABSI *	0139	NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure.
Flu HCP Vaccination	0431	Influenza Vaccination Coverage Among Healthcare Personnel (HCP).
COVID–19 HCP Vaccination	N/A	COVID–19 Vaccination Coverage Among HCP.
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery).
MRSA *	1716	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure.
CDI *	1717	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
N/A	N/A	Patient Safety Structural Measure.
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer—Receiving Chemotherapy in the Last 14 Days of Life.

TABLE X.D.–01—PREVIOUSLY ADOPTED MEASURES FOR THE PCHQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2026 REPORTING PERIOD/FY 2028 PROGRAM YEAR—Continued

Short name	Consensus-based entity (CBE) No.	Measure name
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer—Not Admitted to Hospice.
Intermediate Clinical Outcome Measures		
EOL–ICU	0213	Proportion of Patients Who Died from Cancer—Admitted to the ICU in the Last 30 Days of Life.
EOL–3DH	0216	Proportion of Patients Who Died from Cancer—Admitted to Hospice for Less Than Three Days.
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey.
N/A	N/A	Documentation of Goals of Care Discussions Among Cancer Patients.
Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy.
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients.
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer.
Health Equity Measures		
HCHE **	N/A	Hospital Commitment to Health Equity.
SDOH–1 **	N/A	Screening for Social Drivers of Health.
SDOH–2 **	N/A	Screen Positive Rate for Social Drivers of Health.

*We are updating our NHSN measures in alignment with CDC's efforts to rebaseline using CY 2022 data. We refer readers to section VI.M.2.b. for more detailed discussion of technical updates to rebaseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program.

**In section X.D.2. of the preamble of this proposed rule, we are proposing to remove the HCHE measure and the SDOH measures beginning with the CY 2024 reporting period/FY 2026 program year.

3. Public Display Requirements

Under section 1866(k)(4) of the Act, the Secretary must establish procedures for making data submitted under the PCHQR Program available to the public.

a. Summary of Previously Finalized Public Display Policies for the PCHQR Program

Table X.D.–02 summarizes our current public display requirements for the PCHQR Program measures. The measure performance data are made publicly available on a CMS website, which is currently the Provider Data Catalog, available at: *https://data.cms.gov/provider-data/*.

TABLE X.D.–02—PREVIOUSLY FINALIZED PUBLIC DISPLAY POLICIES FOR THE PCHQR PROGRAM

Measures	Public display dates
• Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (CBE #0166)	2016 and subsequent years.
• American College of Surgeons—Centers for Disease Control and Prevention (ACS–CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (CBE #0753).	2019 and subsequent years.
• NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure* (CBE #1716).	
• NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure* (CBE #1717).	
• NHSN Influenza Vaccination Coverage Among Healthcare Personnel* (CBE #0431).	
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years.
• COVID–19 Vaccination Coverage Among Healthcare Personnel	October 2022 and subsequent years.
• CAUTI* (CBE #0138)	October 2022 and subsequent years.
• CLABSI* (CBE #0139).	
• 30-day Unplanned Readmissions for Cancer Patients (CBE #3188)	October 2023 and subsequent years.
• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (CBE #0210).	July 2024 and subsequent years.
• Proportion of Patients Who Died from Cancer Not Admitted to Hospice (CBE #0215).	
• Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (CBE #0213).	
• Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (CBE #0216).	
• Surgical Treatment Complications for Localized Prostate Cancer Measure (PCH–37)	July 2024 and subsequent years.

TABLE X.D.–02—PREVIOUSLY FINALIZED PUBLIC DISPLAY POLICIES FOR THE PCHQR PROGRAM—Continued

Measures	Public display dates
• Hospital Commitment to Health Equity**	January 2026 or as soon as feasible thereafter.
• Documentation of Goals of Care Discussions Among Cancer Patients	July 2026 or as soon as feasible thereafter.
• Patient Safety Structural Measure	October 2026 or as soon as feasible thereafter.
• Screening for Social Drivers of Health**	July 2027 or as soon as feasible thereafter.
• Screen Positive Rate for Social Drivers of Health**	July 2027 or as soon as feasible thereafter.

*We are updating our NHSN measures in alignment with CDC's efforts to rebaseline using CY 2022 data. We refer readers to section VI.M.2.b. of the preamble of this proposed rule for more detailed discussion of technical updates to re-baseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program.

**In section X.D.2. of the preamble of this proposed rule, we are proposing to remove the HCHE measure and the SDOH measures beginning with the CY 2024 reporting period/FY 2026 program year.

b. Proposal To Publicly Report PCHQR Data on Both the Provider Data Catalog and Compare Tool Website or Successor Websites

In FY 2022 IPPS/LTCH PPS final rule, we codified at 42 CFR 412.24(f) that data submitted by PCHs under the PCHQR Program are to be made publicly available on the Provider Data Catalog website (*https://data.cms.gov/provider-data/*) and that PCHs have an opportunity to review their data prior to publication during a preview period via the Hospital Quality Reporting (HQR) system (*https://hqr.cms.gov/hqrng/login*) with timelines for review published on the QualityNet website (*https://qualitynet.cms.gov*) and applicable listservs (86 FR 45435 through 45437; 86 FR 45518 through 45519). In this proposed rule, we propose to modify the public reporting requirements of the PCHQR Program to enable us to publicly report PCHQR data on both the Provider Data Catalog and the Compare tool (*https://www.medicare.gov/care-compare/*) or their successor websites. We also propose to make corresponding changes to the regulation text at § 412.24(f).

In 2020, CMS launched the Provider Data Catalog and the Compare tool websites to replace previous CMS healthcare comparison tools including Hospital Compare. Both the Provider Data Catalog and the Compare tool are valuable tools that allow patients, caregivers and families, providers, and other interested parties to find and compare information about the quality of care at participating PCHs and hospitals, respectively.

The Provider Data Catalog allows for downloading, exploration, and analysis of performance data. However, the Compare tool displays performance data in a format that is more user-friendly and more easily understood by consumers than the Provider Data Catalog. Data displayed on the Provider Data Catalog is a valuable resource that allows consumers, providers, and researchers to conduct analyses and compare quality of care delivery among PCHs. However, displaying data submitted by PCHs under the PCHQR Program in a more user-friendly format and making data more widely available would support consumer engagement and promote greater transparency. The Compare tool already includes quality measure information about hospitals participating in the Hospital Inpatient Quality Reporting Program, Hospital Outpatient Quality Reporting Program, Hospital-Acquired Condition Reduction Program, Hospital Readmissions Reduction Program, Inpatient Psychiatric Facility Quality Reporting Program, and Medicare Promoting Interoperability Program.

Therefore, to support greater data transparency and consumer engagement and to align with the other hospital quality programs, we propose to modify the public reporting requirements of the PCHQR Program to enable us to publicly report data from the PCHQR Program on both the Provider Data Catalog and the Compare tool (*https://www.medicare.gov/care-compare*) or their successor websites. We also propose corresponding changes to the regulation text at § 412.24(f) replacing references to ''Provider Data Catalog'' with ''CMS websites''.

We invite public comments on our proposal to publicly report PCHQR data on both the Provider Data Catalog and Compare tool or successor websites.

4. Proposal To Codify Updates to the Extraordinary Circumstances Exception Policy for the PCHQR Program

a. Background

Under our current Extraordinary Circumstances Exception (ECE) regulations, we have granted exceptions with respect to quality data reporting requirements in the event of extraordinary circumstances beyond the control of the PCH (42 CFR 412.24(e)). An exception may be granted for extraordinary circumstances including, but not limited to, natural disasters or systemic problems with data collection systems.[381] We refer readers to 42 CFR 412.24(e) for our current ECE regulations, as well as FY 2014 IPPS/LTCH PPS final rule (78 FR 50848); FY 2018 IPPS/LTCH PPS final rule (82 FR 38424 through 38425); and FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624) for further background and details of our ECE policy. We also refer readers to the QualityNet website for the specific requirements for submission of an ECE request in the PCHQR Program.[382]

Our ECE policy provides flexibility for PCHs to ensure continuity of quality care delivery and measure reporting in the event of an extraordinary circumstance. For instance, we recognize that in circumstances where a full exception is not applicable, it is beneficial for a PCH to report data later than the reporting deadline. Delayed reporting authorized under our ECE policy allows temporary relief for a PCH experiencing an extraordinary circumstance while preserving data reporting such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to update our regulations to specify that an ECE could take the form of an extension of time for a PCH to comply with a data reporting

[381] Centers for Medicare & Medicaid Services (CMS) Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form. (2025). QualityNet. Available at: *https://qualitynet.cms.gov/files/677e843f50ed8df7419f60e1?filename=HQR_ECE_Req_Form_CY_2025.pdf.*

[382] CMS QualityNet. Available at: *https://qualitynet.cms.gov/pch/pchqr/participation#tab2.*

requirement if CMS determines that this type of relief would be appropriate under the circumstances.

b. Proposal To Update the Extraordinary Circumstances Exception (ECE) Policy for the PCHQR Program

We propose to update the current ECE policy codified at 42 CFR 412.24(e) to include extensions of time as a form of relief and to further clarify the policy. Specifically, at proposed § 412.24(e)(1), we propose that CMS may grant an ECE with respect to reporting requirements in the event of an extraordinary circumstance—defined as an event beyond the control of a PCH (for example a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing)—that affected the ability of the PCH to comply with one or more applicable reporting requirements with respect to a fiscal year.

We propose that the process for requesting or granting an ECE would remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[383] At proposed § 412.24(e)(2)(i), we propose that a PCH may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Our current policy allows a request within 90 days; however, this proposed change would align the PCHQR policy with CMS systems implementation requirements across all quality reporting programs. Under this proposed codified policy, we clarify that CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred. At proposed § 412.24(e)(2)(ii), we propose that CMS notify the requestor with a decision in writing, via email. In the event that CMS grants an ECE to the PCH, the written decision will specify whether the PCH is exempted from one or more reporting requirements or whether CMS has granted the PCH an extension of time to comply with one or more reporting requirements.

Additionally, at § 412.24(e)(3), we propose that CMS may grant an ECE to one or more PCH that have not requested an ECE if CMS determines that: a systemic problem with CMS data collection systems directly impacted the ability of the PCH to comply with a data submission; or that an extraordinary circumstance has affected an entire region or locale. As is the case under our current policy, any ECE granted will specify whether the affected PCHs are exempted from one or more reporting requirements or whether CMS has granted the PCHs an extension of time to comply with one or more reporting requirements. At proposed § 412.24(e)(4), we propose that CMS may grant or deny an ECE based on the evaluation of the extraordinary circumstance including, but not limited to, whether the extraordinary circumstance occurred beyond the control of the PCH and affected the PCH's ability to meet data reporting requirements by the specified deadlines. We propose that CMS will notify the PCH of a denial of an ECE in writing via email to be codified at § 412.24(e)(5).

This proposed ECE policy would provide further reporting flexibility for PCHs and clarify the ECE process.

We invite public comment on our proposal to update the ECE policy for the PCHQR Program with corresponding updates to regulatory text at § 412.24(e).

E. Proposed Changes to the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Section 1886(m)(5)(A) requires the Secretary to reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year (FY)—if the LTCH has not submitted data to the Secretary in accordance with the LTCH QRP requirements specified for that FY. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the LTCH QRP. We have codified our program requirements in our regulations at 42 CFR 412.560.

In this proposed rule, we are proposing to modify reporting requirements for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure to exclude patients who have expired in the LTCH by removing an item on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) as described in section X.E.3. of the preamble of this proposed rule. We also propose to remove four items previously adopted as standardized patient assessment data elements under the social determinants of health (SDOH) category beginning with the FY 2028 LTCH QRP: one item for Living Situation, two items for Food, and one item for Utilities. Next, we propose to amend our reconsideration policy and process as described in section X.E.4 of the preamble of this proposed rule. Finally, we seek public comment on several requests for information (RFIs), specifically on: (1) future measure concepts for the LTCH QRP as described in section X.E.5 of the preamble of this proposed rule; (2) revisions to the data submission deadlines for assessment data collected for the LTCH QRP as described in section X.E.6. of the preamble of this proposed rule; and (3) advancing digital quality measurement (dQM) in the LTCH QRP as described in section X.E.7. of the preamble of this proposed rule.

2. General Considerations Used for the Selection of Measures for the LTCH QRP—Quality Measures Currently Adopted for the LTCH QRP

For a detailed discussion of the considerations, we use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (80 FR 49728). The LTCH QRP currently has 18 adopted measures, which are set out in Table X.E.–01. We are not proposing to adopt any new measures for the LTCH QRP.

For a discussion of the factors we use to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at § 412.560(b)(3).

[383] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

TABLE X.E.–01—QUALITY MEASURES CURRENTLY ADOPTED FOR THE LTCH QRP

Short name	Measure name & data source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury.
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay).
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients requiring ventilator support.
DRR	Drug Regimen Review Conducted with Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay.
Ventilator Liberation	Ventilator Liberation Rate.
TOH-Provider	Transfer of Health Information to the Provider Post-Acute Care (PAC).
TOH-Patient	Transfer of Health Information to the Patient Post-Acute Care (PAC).
DC Function	Discharge Function Score.
Patient/Resident COVID–19 Vaccine.	COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date.
National Healthcare Safety Network (NHSN)	
CAUTI *	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection Outcome Measure.
CLABSI *	National Healthcare Safety Network (NHSN) Central-Line associated Bloodstream Infection (CLABSI) Outcome Measure.
CDI *	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure.
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel.
HCP COVID–19 Vaccine	COVID–19 Vaccination Coverage among Healthcare Personnel (HCP).
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
DTC	Discharge to Community—Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP).

*We are updating our NHSN measures in alignment with CDC's efforts to rebaseline using CY 2022 data. We refer readers to section VI.M.2.b. of the preamble of the proposed rule for more detailed discussion of technical updates to rebaseline CDC's NHSN Healthcare-Associated Infection measures.

3. Proposed Modification of Reporting Requirements for COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2028 LTCH QRP

In the FY 2024 IPPS/LTCH PPS Final Rule (88 FR 59243 through 59250), we finalized the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure for the LTCH QRP beginning with the FY 2026 LTCH QRP. LTCHs collect and report data for this measure on the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS), the LTCH patient assessment instrument (88 FR 59247 and 59253). We added the Patient/Resident COVID–19 Vaccine item (O0350) on the LCDS discharge assessments (Planned Discharge, Unplanned Discharge, and Expired) for LTCHs to collect data on this measure for patients being discharged from the LTCH and who expire during their stay (88 FR 59253). We finalized that LTCHs must begin collecting data using the LCDS for this measure with patients discharged on October 1, 2024, for the FY 2026 LTCH QRP (88 FR 59247 and 59253).

Since the Patient/Resident COVID–19 Vaccine measure was adopted for the LTCH QRP and LTCHs began collecting data for this measure on October 1, 2024, LTCHs and other interested parties have expressed concerns about challenges and increased provider burden in collecting immunization data.[384] They have specifically noted challenges in identifying a patient's vaccination status once they have expired. We agree that collecting information regarding an expired patient's vaccination status is challenging because it may be difficult to interview the patient's family or other caregivers to ascertain the patient's vaccination status if it is not known during the expired assessment window (that is, no later than 5 days after the patient's date of death).[385] In addition, we agree that collecting this data creates unnecessary burden for LTCHs because this information is no longer actionable for LTCHs, since they can no longer help an expired patient stay up to date with regard to COVID–19 vaccinations. Removing the requirement to report this item when a patient expires in an LTCH will allow CMS to be responsive to LTCHs and reduce assessment collection burden.

We propose to modify the reporting requirements for the Patient/Resident COVID–19 Vaccine measure in the LTCH QRP to exclude patients who have expired in the LTCH beginning with the FY 2028 LTCH QRP. Specifically, we propose that, beginning with patients admitted on or after October 1, 2026, LTCHs would no longer be required to submit the Patient/Resident COVID–19 Vaccine item

[384] Standing Technical Expert Panel for the Development, Evaluation, and Maintenance of Post-Acute Care (PAC) and Hospice Quality Reporting Program (QRP) Measurement Sets Summary Report December 15, 2023, *https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf-1.*

[385] Chapter 2, Overview. LCDS Manual accessed in the Downloads section of: *https://www.cms.gov/medicare/quality/long-term-care-hospital/ltch-care-data-set-ltch-qrp-manual.*

(O0350) on the LCDS with respect to patients who have expired in the LTCH. We also propose to remove the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to item (O0350) from future LCDS forms that LTCHs use for expired patients. The remaining LCDS forms used for Planned Discharge and Unplanned Discharge would continue to include the Patient/Resident COVID–19 Vaccine item (O0350) for purposes of collecting and reporting data on the Patient/Resident COVID–19 Vaccine measure.

We invite public comment on our proposal to modify reporting requirements for the Patient/Resident COVID–19 Vaccine measure in the LTCH QRP to exclude patients who have expired in the LTCH beginning with the FY 2028 LTCH QRP.

4. Proposed Removal of Four Standardized Patient Assessment Data Elements Beginning With the FY 2028 LTCH QRP

We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69582 through 69593) where we finalized the adoption of four items as standardized patient assessment data elements under the social determinants of health (SDOH) category: one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330). As finalized in the FY 2025 IPPS/LTCH PPS final rule, LTCHs would be required to report these data elements using the LCDS beginning with patients discharged on or after October 1, 2026, through December 31, 2026, for purposes of the FY 2028 LTCH QRP and each program year after (89 FR 69597 and 69598).

In this proposed rule, we are proposing to remove these four standardized patient assessment data elements under the SDOH category as we acknowledge the burden associated with these items at this time. Further, as it is also standard evidence-based practice to assess and address these items in LTCHs, we would like to change the focus of CMS's data collection at this time. We continuously look for ways to balance the need of data collections regarding quality care and burden of these data collections on health care providers. CMS has a goal to facilitate improved health care delivery by requiring different systems and software applications to communicate and exchange data. Therefore, we would like to work towards the workflow for these data elements being part of a low burden interoperable electronic system. The focus will turn towards how the data and associated recommendations exchanged improves care coordination, efficiency, reduction in errors and improved patient experience. As health Information technology (HIT) advances and interoperability of data becomes more standardized, the burden to collect and share clinical data on these and other relevant patient information will become less burdensome allowing for better outcomes for LTCH patients and their families. The objectives of the LTCH QRP continue to be the improvement of care, quality and health outcomes for all patients through transparency and quality measurement, while not imposing undue burden on essential health providers.

Under our proposal, LTCHs would not be required to collect and submit Living Situation (R0310), Food (R0320A and R0320B), and Utilities (R0330) beginning with patients discharged on or after October 1, 2026, as previously finalized. Under this proposal, these items would not be necessary to meet LTCH QRP requirements beginning with the FY 2028 LTCH QRP. Removing these items from the data collection for the FY2028 LTCH QRP would keep the 330 LTCHs from incurring 2,601 hours of administrative burden at a cost of $182,330.10 (or $552.52 per LTCH) at this time. We refer readers to section XIII.B.6. of the preamble of this proposed rule for more details on this estimated burden reduction.

We invite public comment on our proposal to remove four standardized patient assessment data elements collected under the SDOH category from the LTCH QRP beginning with the FY 2028 LTCH QRP.

5. Proposals To Amend the Reconsideration Request Policy and Process

a. Background

In the fiscal year (FY) 2014 IPPS/LTCH PPS final rule (78 FR 50885 through 50887), we finalized the LTCH QRP Reconsiderations policy and process whereby an LTCH may request reconsideration of an initial determination that the LTCH did not comply with the LTCH QRP reporting requirements, warranting CMS reducing the LTCH's annual payment update by 2 percent for the applicable fiscal year as required by section 1886(m)(5)(A) of the Act. In that rule, we stated that the LTCH may file a request for reconsideration if they believe that the finding of non-compliance is erroneous, or if they were non-compliant, they have a valid and justifiable excuse for this non-compliance (78 FR 50886). We further stated that, after we review the request for reconsideration, we may reverse our initial finding of non-compliance if: (1) the LTCH provides proof of compliance with all requirements during the reporting period; or (2) the LTCH provides adequate proof of a valid or justifiable excuse for non-compliance if the LTCH was not able to comply with requirements during the reporting period (78 FR 50886). Finally, we stated that we will uphold an initial finding of non-compliance if the LTCH cannot show any justification for non-compliance (78 FR 50886).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 and 50318), we finalized amendments to the LTCH QRP reconsideration policy and process. Specifically, we stated that each LTCH would receive a notification of noncompliance with LTCH QRP requirements if we determine it had not correctly submitted data with respect to the applicable fiscal year (79 FR 50317). Then, the LTCH would have 30 days from the date of our initial notification of noncompliance to submit a request for reconsideration via email. We also provided that, in very limited circumstances, we may grant a request by an LTCH to extend the deadline to submit its reconsideration request, so long as the LTCH requested the extension and demonstrated that extenuating circumstances existed that prevented it filing a reconsideration request by the 30-day deadline (79 FR 50317). Finally, we provided that, as part of its reconsideration request, the LTCH must submit all supporting documentation and evidence demonstrating: (1) full compliance with all LTCH QRP reporting requirements during the reporting period; or (2) extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period (79 FR 50317). We stated that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request (79 FR 50317).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49755 and 49770), we codified the reconsideration policy and process for the LTCH QRP at § 412.560(d). In subsequent rulemakings, we have amended our reconsideration policy and process at § 412.560(d) for minor clarifications and technical updates (FY 2017 IPPS/LTCH PPS final rule (81 FR 57230 and 57231); FY 2019 IPPS/LTCH PPS final rule (83 FR 41633 and 41634; 83 FR 41705); and FY 2020 IPPS/LTCH PPS final rule (84 FR 42588 and 42615)). As codified, our regulation at § 412.560(d) addresses how we send our written notification of noncompliance to an LTCH, the process

for an LTCH to request reconsideration, what information an LTCH must include with its reconsideration request (for example, documentation that demonstrates the LTCH's compliance with LTCH QRP requirements), and how we notify the LTCH of our final decision regarding its reconsideration request.

We have become aware there are inconsistencies in our preamble and regulation text regarding LTCH requests for reconsideration. On this basis, in this proposed rule, we seek to clarify these areas.

b. Proposal To Allow LTCHs To Request an Extension To File a Request for Reconsideration

As noted previously, in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 and 50318), we provided that, in very limited circumstances, we may grant a request by an LTCH to extend the deadline to submit its reconsideration request, so long as the LTCH requested the extension and demonstrated that extenuating circumstances existed that prevented it filing a reconsideration request by the 30-day deadline (79 FR 50317). We did not codify this policy—permitting LTCHs to request an extension to file their reconsideration request—in our regulation text at § 412.560(d). In implementing this finalized policy, we have noted two areas where further clarity would be beneficial to LTCHs.

First, we have not clearly defined or explained the term ''extenuating circumstances,'' as used in our reconsideration policy. In contrast, we use the term ''extraordinary circumstances'' in our Extraordinary Circumstance Exception and Extension (ECE) policy, as codified at § 412.560(c). We did explain ''extraordinary circumstances'' in detail when we originally finalized this ECE policy in FY 2014 IPPS/LTCH PPS final rule (78 FR 50883).

On this basis, we are proposing to remove the term ''extenuating circumstances'' as used currently in our reconsideration policy and replace it with ''extraordinary circumstances.'' Specifically, we propose that an LTCH may request, and CMS may grant, an extension to file a reconsideration request if the LTCH was affected by extraordinary circumstances beyond the control of the LTCH (for example, a natural or man-made disaster). By modifying the basis by which an LTCH may request an extension to file a reconsideration request in this manner, we also propose to incorporate our prior explanation regarding the meaning extraordinary circumstances, as set forth in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50883 through 50885) as part of our Extraordinary Circumstance Exception and Extension (ECE) Policy.

Second, we have noted some areas in our policy where LTCHs may benefit from clearly demarcated deadlines. Although we believe an LTCH would have an interest in asking for an extension to file a reconsideration request prior to the deadline, our policy currently does not specify a deadline for an LTCH to submit its request for such extension (79 FR 50317). Our policy also provides that, to support such request, the LTCH must demonstrate that extenuating circumstances existed that prevented filing the reconsideration request by the 30-day deadline (79 FR 50317). However, we have not specified a temporal relationship between when the extenuating circumstances occurred and the reconsideration request deadline. We believe LTCHs may benefit from further specificity regarding these requirements for submitting a request to extend the deadline to file a reconsideration request.

On this basis, we propose to amend our reconsideration policy as codified at § 412.560(d) to permit LTCHs to request, and CMS to grant, an extension to file a request for reconsideration of a noncompliance determination if, during the period to request a reconsideration as set forth in § 412.560(d)(2), the LTCH was affected by an extraordinary circumstance beyond the control of the LTCH (for example, a natural or man-made disaster). We propose that the LTCH must submit its request for an extension to file a reconsideration request to CMS via email no later than 30 calendar days from the date of the written notification of noncompliance. We propose that the LTCH's extension request, submitted to CMS, must contain the following information: (1) the CCN for the LTCH; (2) the business name of the LTCH; (3) the business address of the LTCH; (4) certain contact information for the LTCH's chief executive officer or designated personnel; (5) a statement of the reason for the request for the extension; and (6) evidence of the impact of the extraordinary circumstances, including, for example, photographs, newspaper articles, and other media. We propose to codify this process at § 412.560(d)(4).

We further propose that CMS will notify the LTCH in writing of its final decision regarding its request for an extension to file a reconsideration of noncompliance request via an email from CMS. We propose to notify the LTCH in writing via email because this will allow for more expedient correspondence with the LTCH, given the 30-day reconsideration timeframe. We propose to codify this process at § 412.560(d)(5).

We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the LTCH QRP Reconsideration policy to permit LTCHs to requests an extension to file a reconsideration request and to codify this proposed policy and process at § 412.560(d)(4) and (5).

c. Proposal To Update the Bases on Which CMS Can Grant a Reconsideration Request

As discussed previously, in the FY 2014 IPPS/LTCH PPS final rule, we stated that, after we review an LTCH's request for reconsideration, we may reverse our initial finding of non-compliance if: (1) the LTCH provides proof of compliance with all requirements during the reporting period; or (2) the LTCH provides adequate proof of a valid or justifiable excuse for non-compliance if the LTCH was not able to comply with requirements during the reporting period (78 FR 50886). We also stated that we will uphold an initial finding of non-compliance if the LTCH cannot show any justification for non-compliance (78 FR 50886).

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50317 and 50318), we reiterated this position, and provided that, as part of its reconsideration request, the LTCH must submit all supporting documentation and evidence demonstrating: (1) full compliance with all LTCH QRP reporting requirements during the reporting period; or (2) extenuating circumstances that affected noncompliance if the LTCH was not able to comply with the requirements during the reporting period (79 FR 50317). We stated that we would not review any reconsideration request that fails to provide the necessary documentation and evidence along with the request (79 FR 50317).

As previously discussed, we codified our reconsideration policy at § 412.560(d) in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49755 and 49770). Our regulation at § 412.560(d)(2)(vii) requires that an LTCH's request for reconsideration include accompanying documentation that demonstrates the LTCH's compliance with the LTCH QRP requirements. Then, we will notify the LTCH in writing regarding our final decision on its reconsideration request (§ 412.560(d)(3)). We believe it would be beneficial for LTCHs if we codify our

specific bases for granting a reconsideration request in our regulation at § 412.560(d).

On these bases, we propose to modify our reconsideration policy to provide that we will grant a timely request for reconsideration, and reverse an initial finding of non-compliance, only if CMS determines that the long-term care hospital was in full compliance with the LTCH QRP requirements for the applicable program year. We would consider full compliance with the LTCH QRP requirements to include CMS granting an exception or extension to LTCH QRP reporting requirements under our ECE policy at § 412.560(c). However, to demonstrate full compliance with our ECE policy, the LTCH would need to comply with our ECE policy's requirements, including the specific scope of the exception or extension as granted by CMS.

We propose to revise § 412.560(d)(3) to codify this modified policy in our regulation. The remainder of the text at § 412.560(d)(3) would remain the same, subject to minor technical amendments.

We note that we are considering proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invite comment on these proposals to amend the bases by which we grant a reconsideration request under the LTCH QRP Reconsideration policy and to codify this proposed policy at § 412.560(d)(3).

6. LTCH QRP Measure Concepts Under Consideration for Future Years—Request for Information (RFI): Interoperability, Well-Being, Nutrition & Delirium

We are seeking input on the importance, relevance, appropriateness, and applicability of each of the quality measure concepts under consideration listed in Table X.E.–02 for future years in the LTCH QRP. In the FY 2024 LTCH PPS proposed rule (88 FR 27150 through 27152), we included a request for information (RFI) on a set of principles for selecting and prioritizing LTCH QRP measures, identifying measurement gaps, and suitable measures for filling these gaps. We refer readers to the FY 2024 LTCH PPS final rule (88 FR 59250 and 59251) for a summary of the public comments we received in response to the RFI.

We are seeking input on four concepts for future measures for the LTCH QRP.

TABLE X.E.–02—FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Quality measure concepts
Interoperability.
Well-being.
Nutrition.
Delirium.

a. Interoperability

We are seeking input on the quality measure concept of interoperability, focusing on information technology systems' readiness and capabilities in the LTCH setting. Title XXX of the Public Health Service Act defines ''interoperability'' in part, and with respect to health information technology, as health information technology that enables the secure exchange of electronic health information with, and use of electronic health information from, other health information technology without requiring special efforts by the user.[386] The definition further states that interoperability of health information technology allows for complete, including by providers and patients, access, exchange, and use of electronically accessible health information for authorized uses under applicable State or Federal Law.[387] We request input and comment on approaches to assessing interoperability in the LTCH setting, for instance, measures that address or evaluate the level of readiness for interoperable data exchange, or measures that evaluate the ability of data systems to securely share information across the spectrum of care. Please provide input on the relevant aspects of interoperability for the LTCH setting.

b. Well-Being

We are seeking input on a quality measure concept of well-being for future quality measures. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health [388] [389] while emphasizing preventive care to proactively address potential health issues. This comprehensive approach emphasizes person-centered care by promoting well-being of patients and their family members. We request input and comment on tools and measures that assess for overall health, happiness, and satisfaction in life that could include aspects of emotional well-being, social connections, purpose, fulfillment, and self-care work. Please provide input on the relevant aspects of well-being for the LTCH setting.

c. Nutrition

We are seeking input on a quality measure concept of nutrition for future quality measures. Assessment of an individual's nutritional status may include various strategies, guidelines, and practices designed to promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. This also includes aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventable care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs. We request input and comment on tools and frameworks that promote healthy eating habits, exercise, nutrition, or physical activity for optimal health, well-being, and best care for all. Please provide input on the relevant aspects of nutrition for the LTCH setting.

d. Delirium

Finally, we are seeking input on a quality measure concept of delirium for future quality measures. Delirium, often under-detected, is a common complication of illness or injury that leads to negative health outcomes like frailty, cognitive impairment, and functional decline. Post-acute care patients experiencing delirium symptoms are more likely to undergo rehospitalization, experience poor functional recovery outcomes, and have a higher 6-month mortality rate compared to patients without delirium.[390] We request input and comment on the applicability of measures that evaluate for the sudden, serious change in a person's mental

[386] Public Health Service Act, 42 U.S.C. 3000(9) (2025).

[387] Public Health Service Act, 42 U.S.C. 3000(9) (2025).

[388] Overall well-being. See more information at: *https://odphp.health.gov/healthypeople/objectives-and-data/overall-health-and-well-being-measures/overall-well-being-ohm-01.*

[389] Well-Being Measurement. See more information at: *https://www.va.gov/WHOLEHEALTH/professional-resources/well-being-measurement.asp.*

[390] Marcantonio, E.R., Kiely, D.K., Simon, S.E., John Orav, E., Jones, R.N., Murphy, K.M., & Bergmann, M.A. (2005). Outcomes of older people admitted to postacute facilities with delirium. *Journal of the American Geriatrics Society, 53*(6), 963–969. *https://doi.org/10.1111/j.1532-5415.2005.53305.x.*

state or altered state of consciousness that may be associated with underlying symptoms or conditions. Please provide input on the relevant aspects of delirium for the LTCH setting.

As we review new measure concepts, CMS will prioritize outcome measures that are evidenced-based.

7. Potential Revision of the Final Data Submission Deadline Period From 4.5 Months to 45 Days—Request for Information

Sections 1886(m)(5)(E) and 1899B(f) and (g) of the Act require CMS to provide feedback to LTCHs and to publicly report their performance on quality and other measures specified under the LTCH QRP. More specifically, sections 1886(m)(5)(E) and 1899B(f)(1) of the Act requires the Secretary to provide confidential feedback reports to LTCHs on their performance on the quality, resource use, and other measures specified for the LTCH QRP. Section 1899B(f)(2) of the Act provides that, to the extent feasible, the Secretary must make these confidential feedback reports available, except in the case of measures reported on an annual basis, in which case the confidential feedback reports may be made available annually. Additionally, sections 1886(m)(5) and 1899B(g)(1) of the Act require the Secretary to provide for the public reporting of each LTCH's performance on the measures specified for the LTCH QRP by establishing procedures for making the performance data available to the public. Sections 1886(m)(5)(E) and 1899B(g)(2) of the Act specifically require that such procedures must ensure, through a process consistent with the process applied under section 1886(b)(3)(B)(viii)(VII) of the Act, that LTCHs can review and submit corrections to the data and other information before it is made public.

In accordance with section 1888(m)(5)(C) of the Act, we have established policies specifying the form and manner, and timing, for LTCHs to submit data on the measures as specified. In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51755 and 51756), we initially finalized for assessment-based measures that LTCHs could submit their data related to the New or Worsened Pressure Ulcers measure allowing 4.5 months (approximately 135 days) after the end of each quarter for submission of assessment data for the FY 2014 and FY 2015 payment update determinations. In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53636 and 53637), we finalized that LTCHs submit data quarterly for each of the finalized measures in the FY 2013 rule, submitting their data within approximately 135 days after the end of each quarter by which all data collected during that quarter must be submitted for the FY 2015 payment determination. We also finalized in the FY 2013 rule that LTCHs would have a shorter data submission timeframe for each of the measures for the FY 2016 payment determination. Specifically, we finalized that, for each quarter of the FY 2016 payment determination, LTCHs would have approximately 45 days after the end of each quarter to submit data collected for that quarter (77 FR 53636 and 53637). However, in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49749 through 49751), we finalized requiring data submission within 4.5 months at the end of each calendar quarter, beginning with the FY 2017 LTCH QRP and FY 2018 LTCH QRP, unless otherwise specified for a measure. We proposed and finalized this modification to the LTCH QRP data submission deadline in order to align with the Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) and Hospital IQR Program (80 FR 49749 through 49751).

Public reporting data collected under quality reporting programs, such as the LTCH QRP, are designed to provide consumers and their families with the most current information, so they can make quality-informed decisions about where to receive their care. In the process of implementing the public reporting for the quality reporting programs, we have identified that the time between when data on measures is collected and submitted to us and when that data are publicly reported (that is, approximately nine months) may be too long to provide the most accurate and up to date information for the public. For example, through technical expert panels, we have received feedback from patient caregiver advocates that the aged data used in publicly reported quality measures diminishes their value to consumers.

Currently, the largest contributing factor to the nine-month lag between the end of the data collection period and when measures are publicly reported is the 4.5-month timeframe for data submission. If the data submission timeframe was reduced from 4.5 months to 45 days, then the lag time between the end of the data collection period and public reporting of that data could be reduced by up to 3 months. This revised timeframe would result in more timely public reporting of data that may provide more value for consumers and families as they make decisions about where they may want to receive their care. Additionally, this timeframe provides LTCHs with more recent data to use in their quality improvement activities.

An important consideration in reducing the data submission timeframe is the potential burden it may place on LTCHs, which could lead to fewer assessments submitted by the shorter 45-day data submission timeframe. We conducted an analysis to evaluate the potential impact of reducing the timeframe by determining how many assessments are currently being submitted within 45 days. Using 2023 data, we identified that only 2.5 percent of all LCDS assessments were submitted after the 45-day timeframe. Of those submissions, close to three-fourths (or 1.8 percent of the total) were submitted between 45 days and 4.5 months and hence have potential to be impacted.[391] On these bases, we believe reducing the LTCH QRP data submission deadline from 4.5 months to 45 days would improve the timeliness of public reporting by one quarter, which could be beneficial to both consumers and LTCHs with limited change in burden to LTCHs.

We are requesting feedback on this potential future reduction of the LTCH QRP data submission deadline from 4.5 months to 45 days that is under consideration. Specifically, we are requesting comment on—

- How this potential change could improve the timeliness and actionability of LTCH QRP quality measures;
- How this potential change could improve public display of quality information; and
- How this potential change could impact LTCH workflows or require updates to systems.

We intend to use this input to inform our program improvement efforts.

8. Advancing Digital Quality Measurement in the LTCH QRP—Request for Information

As part of our effort to advance the digital quality measurement (dQM) transition, we are issuing this request for information (RFI) to gather broad public input on the dQM transition in LTCHs. In section X.B. of the preamble of this proposed rule, we also issue an RFI seeking input on the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in certain CMS quality reporting and value-based purchasing programs.

a. Background

We are committed to improving healthcare quality through measurement, transparency, and public

[391] Internal CMS analysis of FY 2023 LCDS assessment data.

reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health information technology (IT) that enables information exchange using FHIR® standards. Proposing to require the use of such technology within the LTCH QRP in the future could potentially enable greater care coordination and information sharing, which is essential for delivering high-quality, efficient care and better outcomes at a lower cost (86 FR 25615). In the fiscal years 2020, 2021, 2022, and 2023 IPPS/LTCH PPS proposed rules,[392] we outlined several Department of Health and Human Services (HHS) initiatives aimed at promoting the adoption of interoperable health IT and facilitating nationwide health information exchange. Further, to inform our digital strategy, in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25615), we shared and sought feedback on the following:

- Our intent to explore the use of FHIR®-based standards to exchange clinical information through application programming interfaces (APIs).
- Enabling quality data submission to CMS through our internet Quality Improvement and Evaluation System (iQIES).
- To work with healthcare standards organizations to ensure their standards support our assessment tools.

We are considering opportunities to advance FHIR®-based reporting of patient assessment data for the submission of the LCDS and other existing systems such as CDC's National Healthcare Safety Network (NHSN) for which LTCHs have current CMS reporting requirements. Our objective is to explore how LTCHs typically integrate technologies with varying complexity into existing systems and how this affects LTCH workflows. In this RFI, we seek to identify the challenges and/or opportunities that may arise during this integration, and determine the support needed to complete and submit quality data in ways that protect and enhance care delivery.

We are also seeking input on future measures under consideration including applicability of interoperability as a future measure concept in post-acute care settings, including the LTCH QRP. Refer to section X.E.5. of the preamble of this proposed rule for more information.

[392] ''Advancing Health Information Exchange'' in: FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19170), FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32470), FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25085), and FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28122).

Any updates specific to the LTCH QRP program requirements related to quality measurement and reporting provisions would be addressed through separate and future notice-and-comment rulemaking, as necessary.

b. Solicitation for Comment

We seek feedback on the current state of health IT use, including electronic health records (EHRs), in LTCH facilities:

- To what extent does your LTCH use health IT systems to maintain and exchange patient records? If your facility has transitioned to using electronic records, in part or in whole, what types of health IT does your LTCH use to maintain patient records? Are these health IT systems certified by the Office of the National Coordinator for Health Information Technology (ONC Health IT) Certification Program? If your facility uses health IT products or systems that are not certified under the ONC Health IT Certification Program, please specify. Does your facility use EHRs or other health IT products or systems that are not certified under the ONC Health IT Certification Program? If no, what is the reason for not doing so? Do these other systems exchange data using standards and implementation specifications adopted by HHS? Does your facility maintain any patient records outside of these electronic systems? If so, are the data organized in a structured format, using codes and recognized standards, that can be exchanged with other systems and providers?
- Does your LTCH submit patient assessment data to CMS directly from your health IT system without the assistance of a third-party intermediary? If a third-party intermediary is used to report data, what type of intermediary service is used? How does your facility currently exchange health information with other healthcare providers or systems, specifically between LTCHs and other provider types? What about health information exchange with other entities, such as public health agencies? What challenges do you face with electronic exchange of health information?
- Are there any challenges with your current electronic devices (for example, tablets, smartphones, computers) that hinder your ability to easily exchange information across systems? Please describe any specific issues you encounter. Does limited internet or lack of internet connectivity impact your ability to exchange data with other healthcare providers, including community-based care services, or your ability to submit patient assessment data to CMS? Please specify.
- What steps does your LTCH take with respect to the implementation of health IT systems to ensure compliance with security and patient privacy requirements such as the requirements of the regulations promulgated under the Health Insurance Portability and Accountability Act (HIPAA) and related regulations?
- Does your LTCH refer to the Safety Assurance Factors for EHR Resilience (SAFER) Guides (see newly revised versions published in January 2025 at *https://www.healthit.gov/topic/safety/safer-guides*) to self-assess EHR safety practices?
- What challenges or barriers does your facility encounter when submitting quality measure data to CMS as part of the LTCH QRP? What opportunities or factors could improve your facility's successful data submission to CMS?
- What types of technical assistance, guidance, workforce trainings, and/or other resources would be most beneficial for the implementation of FHIR®-based technology in your facility for the submission of the LCDS to CMS and other existing systems such as CDC's National Healthcare Safety Network (NHSN) for which LTCHs have current CMS reporting requirements? What strategies can CMS, HHS or other Federal partners take to ensure that technical assistance is both comprehensive and user-friendly? How could Quality Improvement Organizations (QIOs) or other entities enhance this support?
- Is your facility using technology that utilizes APIs based on the FHIR® standard to enable electronic data sharing? If so, with whom are you sharing data using the FHIR® standard and for what purpose(s)? For example, have you used FHIR® APIs to share data with public health agencies? Does your facility use any Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR® applications? If so, are the SMART on FHIR® applications integrated with your EHR or other health IT?
- How do you anticipate the adoption of technology using FHIR®-based APIs to facilitate the reporting of patient assessment data could impact provider workflows? What impact, if any, do you anticipate it will have on quality of care?
- What benefits or challenges have you experienced with implementing technology using FHIR®-based APIs? How can adopting technology using FHIR®-based APIs to facilitate the reporting of patient assessment data impact provider workflows? What

impact, if any, does adopting this technology have on quality of care?

- Does your facility have any experience using technology that shares electronic health information using one or more versions of the United States Core Data for Interoperability (USCDI) standard? [393]
- Would your LTCH and/or vendors be interested in participating in testing to explore options for transmission of assessments, for example testing the transmission of a FHIR®-based assessment to CMS?
- How could the Trusted Exchange Framework and Common Agreement™ (TEFCA™) support CMS quality programs' adoption of FHIR®-based assessment submissions consistent with the FHIR® Roadmap (available here: *https://rce.sequoiaproject.org/three-year-fhir-roadmap-for-tefca/*)? How might patient assessment data hold secondary uses for treatment or other TEFCA exchange purposes?
- What other information should we consider to facilitate successful adoption and integration of FHIR®-based technologies and standardized data for patient assessment instruments like the LCDS? We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

We invite any feedback, suggestions, best practices, or success stories related to the implementation of these technologies and will use this input to inform our future dQM transition efforts.

9. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at § 412.560(b) for information regarding the current policies for reporting specified data for the LTCH QRP.

b. Proposal To Modify Reporting Requirements for the Patient/Resident COVID–19 Vaccine Measure Beginning With the FY 2028 LTCH QRP.

As discussed previously in section X.E.3. of the preamble of this proposed rule, we propose to modify reporting requirements for the Patient/Resident COVID–19 Vaccine measure in the LTCH QRP to exclude patients who have expired in the LTCH beginning with the FY 2028 LTCH QRP. Specifically, we propose that, beginning with patients admitted on or after October 1, 2026, LTCHs would no longer be required to submit the Patient/Resident COVID–19 Vaccine item (O0350) on the LCDS with respect to patients who have expired in the LTCH. We also propose to remove the Patient/Resident COVID–19 Vaccine item (O0350) from future LCDS forms that LTCHs use for expired patients. The remaining LCDS forms used for Planned Discharge and Unplanned Discharge would continue to include the Patient/Resident COVID–19 Vaccine item (O0350) for purposes of collecting and reporting data on the Patient/Resident COVID–19 Vaccine measure.

We invite public comment on our proposal to modify reporting requirements for the Patient/Resident COVID–19 Vaccine measure in the LTCH QRP to exclude patients who have expired in the LTCH beginning patients who have expired on or after October 1, 2026, for the FY 2028 LTCH QRP.

10. Policies Regarding Public Display of Measure Data for the LTCH QRP

We are not proposing any new policies regarding the public display of measure data in this proposed rule. For a more detailed discussion about our policies regarding public display of LTCH QRP measure data and procedures for the opportunity to review and correct data and information, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57231 through 57236).

F. Proposed Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act (as amended by the Health Information Technology for Economic and Clinical Health Act, Title XII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), Pub. L. 111–5) authorize downward payment adjustments under Medicare, beginning with FY 2015 for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for the applicable electronic health record (EHR) reporting periods. Section 602 of Title VI, Division O of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) added subsection (d) hospitals in Puerto Rico as eligible hospitals under the Medicare EHR Incentive Program and extended the participation timeline for these hospitals such that downward payment adjustments were authorized beginning in FY 2022 for section (d) Puerto Rico hospitals that do not successfully demonstrate meaningful use of CEHRT for the applicable EHR reporting periods.

2. Proposal To Define the EHR Reporting Period in CY 2026 and Subsequent Years

a. Proposal To Define the EHR Reporting Period

Under the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4, for eligible hospitals and CAHs in the Medicare Promoting Interoperability Program, the EHR reporting period in CY 2025 is a minimum of any continuous 180-day period within CY 2025 as finalized in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59259 through 59260). This applies to eligible hospitals and CAHs that are both new and returning participants in the Medicare Promoting Interoperability Program. We had previously maintained the EHR reporting period for a payment adjustment year as a minimum of any continuous 90-day period from CY 2015 through CY 2023 for eligible hospitals and CAHs for the Medicare Promoting Interoperability Program before increasing the length of the EHR reporting period to any continuous 180-days beginning with CY 2024. Maintaining a 180-day EHR reporting period for CY 2026 and subsequent years would provide consistency with the EHR reporting period established for CY 2025 and afford eligible hospitals and CAHs the flexibility they may need to work with their chosen EHR vendors on continuing to develop, update, implement, and test their EHR systems to maintain effective use of CEHRT.

Therefore, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, for the EHR reporting period in CY 2026 and subsequent years, we propose to maintain the EHR reporting period for a payment adjustment year as a minimum of any continuous 180-day period within the calendar year. A 180-day EHR reporting period would be the minimum length, and eligible hospitals and CAHs are encouraged to use longer periods, up to and including the full calendar year. We propose corresponding revisions to the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4. In collaboration with the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ONC) (collectively referred

[393] For more information about USCDI see *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.*

to as ASTP),[394] we will continue to monitor CEHRT utilization by eligible hospitals and CAHs to determine if a longer EHR reporting period may be appropriate in the future.

We invite public comment on this proposal to define the ''EHR reporting period for a payment adjustment year'' in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that calendar year for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program and to make corresponding revisions at 42 CFR 495.4.

b. Certified EHR Technology

In the FY 2025 IPPS/LTCH PPS final rule we discussed certain revisions to the CEHRT definition impacting eligible hospitals and CAHs. We refer readers to this discussion for more information (89 FR 69613 through 69614).

In this proposed rule, we remind readers of recent updates to ONC Health Information Technology (Health IT) Certification Program certification criteria that are referenced or incorporated within the definition of certified EHR technology (CEHRT) in 42 CFR 495.4. The definition of CEHRT includes EHR technology certified under the ONC Health IT Certification Program that meets the Base EHR definition at 45 CFR 170.102, technology certified to the criteria necessary to be a meaningful EHR user under the Medicare Promoting Interoperability Program and the Merit-Based Incentive Payment System (MIPS) Promoting Interoperability performance category, and technology certified to the criteria necessary to report on applicable objectives and measures.

In addition to the health IT certification criteria named in the CEHRT definition in 42 CFR 495.4, in order to meet the Base EHR definition, EHR technology [395] must, among other things, be certified to certain certification criteria specified in the Base EHR definition, while further health IT certification criteria in 45 CFR 170.315 are incorporated into the CEHRT definition as criteria necessary to be a meaningful EHR user consistent with paragraph (2)(ii) of the CEHRT definition in 42 CFR 495.4 (ONC health IT certification criteria required to meet Medicare Promoting Interoperability Program objectives and measures are listed in Table [X.F.–05]). As finalized in the Medicare and Medicaid Programs; CY 2024 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; Medicare Advantage; Medicare and Medicaid Provider and Supplier Enrollment Policies; and Basic Health Program final rule, technology meeting the CEHRT definition must meet ONC's health IT certification criteria ''as adopted and updated in 45 CFR 170.315'' (88 FR 79553). For EHR technology to meet the CEHRT definition in CY 2026, it will be required to be certified to applicable certification criteria in 45 CFR 170.315 in CY 2026.

In the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI–1) final rule (89 FR 1205 through 1210), ONC adopted the certification criterion, ''decision support interventions (DSI)'' in 45 CFR 170.315(b)(11) to replace the ''clinical decision support (CDS)'' certification criterion in 45 CFR 170.315(a)(9), the latter of which is included in the Base EHR definition (89 FR 1236). The finalized DSI criterion in 45 CFR 170.315(b)(11) requires that Health IT Modules must, among other functions, enable a limited set of identified users to select (that is, activate) evidence-based DSIs and Predictive DSIs (as defined in 45 CFR 170.102) [396] and support ''source attributes'' [397]—categories of technical performance and quality information—for both evidence-based and Predictive DSIs. ONC further finalized that a Health IT Module may meet the Base EHR definition by either being certified to the existing CDS version of the certification criterion in 45 CFR 170.315(a)(9) or being certified to the revised DSI criterion in 45 CFR 170.315(b)(11), for the period up to, and including, December 31, 2024. On and after January 1, 2025, ONC finalized that only the DSI criterion in 45 CFR 170.315(b)(11) is included in the Base EHR definition. ONC further finalized that the adoption of the criterion in 45 CFR 170.315(a)(9) expired on January 1, 2025 (89 FR 1281).

In addition to the DSI criterion, to which Health IT Modules must be certified to meet the Base EHR definition after January 1, 2025, ONC finalized other updates in the HTI–1 final rule, for which health IT developers must update and provide Health IT Modules to their customers by January 1, 2026. These include updates resulting from the following finalized policies:

- The ''Transmission to public health agencies—electronic case reporting'' criterion in 45 CFR 170.315(f)(5) was updated to specify consensus-based, industry-developed electronic standards and implementation guides (IGs) to replace functional, descriptive requirements in the existing criterion (89 FR 1226). We have identified this criterion as required for the Electronic Case Reporting measure.
- The United States Core Data for Interoperability (USCDI) version 3 was adopted in 45 CFR 170.213(b), and ONC finalized that USCDI version 1 in 45 CFR 170.213(a) will expire on January 1, 2026. This change impacts several ONC health IT certification criteria that reference the USCDI, including the ''transitions of care'' certification criterion in 45 CFR 170.315(b)(1), the ''Clinical information reconciliation and incorporation—Reconciliation'' certification criterion in 45 CFR 170.315(b)(2) and the ''View, download, and transmit to 3rd party'' certification criterion in 45 CFR 170.315(e) (89 FR 1210). The ''transitions of care'' certification criterion in 45 CFR 170.315(b)(1) is included in the ''Base EHR definition'' while the ''Clinical information reconciliation and incorporation—Reconciliation'' certification criterion in 45 CFR 170.315(b)(2) is required for the ''Support Electronic Referral Loops by Receiving and Reconciling Health Information'' measure and the ''View, download, and transmit to 3rd party'' certification criterion is required for the ''Provide Patients Electronic Access to their Health Information'' measure.
- The ''standardized application programming interface (API) for patient and population services'' certification criterion in 45 CFR 170.315(g)(10), which is included in the Base EHR definition, was updated to include newer versions of certain standards, including USCDI version 3 and updated functionality to support the criterion (89 FR 1283).

For complete information about the updates to ONC health IT certification criteria finalized in the HTI–1 final rule, we refer readers to the text of the final rule (89 FR 1192) as well as resources available on ASTP's website.[398]

[394] On July 29, 2024, notice was posted in the **Federal Register** that ONC would be dually titled to the Assistant Secretary for Technology Policy and Office of the National Coordinator for Health Information Technology (ASTP) (89 FR 60903).

[395] We refer here to ''EHR technology'' for the sake of simplicity. The definition of Base EHR in 45 CFR 170.102 applies to ''an electronic record of health-related information on an individual.''

[396] 45 CFR 170.315(b)(11)(iii)(A) and (B).

[397] 45 CFR 170.315(b)(11)(iv)(A) and (B).

[398] For more information, see: *https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program.*

3. Proposal To Modify the Security Risk Analysis Measure

a. Background on the Security Risk Analysis Measure

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), as implemented in the HIPAA Security Rule [399] (45 CFR part 160 and subparts A and C of 45 CFR part 164) contains, among other things, the administrative safeguards that covered entities and business associates (45 CFR 160.103) must implement, such as the standard and implementation specifications for security management process. Among those safeguards are implementation specifications that require covered entities and business associates to conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic protected health information (ePHI) held by the covered entity or business associate (45 CFR 164.308(a)(1)(ii)(A)) and to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with the general requirements of the HIPAA Security Rule at 45 CFR 164.306(a) and the risk management requirements at 45 CFR 164.308(a)(1)(ii)(B).

For eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program, ensuring the privacy and security of ePHI is essential for demonstrating meaningful use of CEHRT. In both the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 2 final rule (Stage 2 final rule) (77 FR 54002 through 54003) and the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (Stage 3 final rule) (80 FR 62793 through 62794), we discussed the benefits of safeguarding electronic health information and our determination that protecting electronic health information is essential to all other aspects of meaningful use. We also noted that unintended, unlawful, or both, disclosures of protected health information could diminish individuals' confidence in EHRs and electronic health information exchange and that ensuring that health information is adequately protected and secured will assist in addressing the unique risks and challenges that may be presented by EHRs.

We previously adopted the Security Risk Analysis measure based on the HIPAA Security Rule risk analysis requirement in 45 CFR 164.308(a)(1). Information on the adoption of this measure can be found in several rules that established Medicare and Medicaid EHR Incentive Programs requirements, including the Medicare and Medicaid Programs; Electronic Health Record Incentive Program final rule (Stage 1 final rule) (75 FR 44369), Stage 2 final rule (77 FR 54002 and 54003), Stage 3 final rule (80 FR 62793 through 62794), and the FY 2019 IPPS/LTCH PPS final rule (83 FR 41644). In the Stage 3 final rule (80 FR 62793 through 62795 and 62829 through 62832), we adopted the Protect Patient Health Information objective and include the Security Risk Analysis measure within this important objective.

The Security Risk Analysis measure requires eligible hospitals and CAHs to attest ''yes'' or ''no'' as to whether they have conducted or reviewed a security risk analysis, as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A). Eligible hospitals and CAHs must attest ''yes'' to the measure to be considered a meaningful EHR user. The measure is not scored and does not contribute any points to the total score for eligible hospitals and CAHs for the Protect Patient Health Information objective and measures. An attestation of ''no'' results in the eligible hospital or CAH not meeting the measure and not satisfying the definition of a meaningful EHR user under 42 CFR 495.4, subjecting the eligible hospital or CAH to a downward payment adjustment.

b. Proposal To Modify the Security Risk Analysis Measure Beginning With the EHR Reporting Period in CY 2026

While the Security Risk Analysis measure currently requires eligible hospitals and CAHs to attest to conducting a security risk analysis as required under the HIPAA Security Rule, the Security Risk Analysis measure does not currently require eligible hospitals and CAHs to manage their security risk conduct or to attest to having implemented security measures to manage their security risk. Codified at 45 CFR 164.308(a)(1)(ii)(B), the HIPAA Security Rule implementation specification for risk management requires the implementation of security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306(a). We note the HIPAA Security Rule does not prescribe a specific methodology for conducting and documenting a risk analysis or managing risk (45 CFR 164.308(a)(1)(ii) and 164.316(b)(1)). We refer readers to the Security Risk Assessment Tool (*https://www.healthit.gov/topic/privacy-security-and-hipaa/security-risk-assessment-tool*), for informational purposes, that may help guide some organization types. This tool was developed by ASTP in collaboration with the U.S. Department of Health and Human Services (HHS) Office for Civil Rights (OCR), and OCR's cybersecurity newsletters,[400] for educational resources on conducting a security risk assessment as required by the HIPAA Security Rule. Additional information is also available in the National Institute of Standard and Technology (NIST) special publication, *Implementing the Health Insurance Portability and Accountability Act (HIPAA) Security Rule: A Cybersecurity Resource Guide.*[401]

We propose to modify the existing Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required under the HIPAA Security Rule implementation specification for risk management. This would be in addition to the current requirement under the measure for eligible hospitals and CAHs to attest ''yes'' to having conducted or reviewed a security risk analysis. Under the proposed modified measure, eligible hospitals and CAHs would be required to attest that they have implemented policies and procedures to support analyzing and managing the security risks to ePHI associated with the implementation and use of EHRs as required by the HIPAA Security Rule implementation specifications for risk analysis and risk management as described in 45 CFR 164.308(a)(1)(ii)(A) and (B). The modifications we propose to the Security Risk Analysis measure would increase accountability among eligible hospitals and CAHs that have not taken steps to reduce risks and vulnerabilities to ePHI as required by the HIPAA Security Rule and would provide transparency regarding the efforts of eligible hospitals and CAHs that are already taking steps to manage this risk.

The proposed text of the measure is as follows, with new or revised proposed text in italics:

[399] The Department has proposed to modify the HIPAA Security Rule to strengthen the cybersecurity of electronic protected health information, including proposals to revise the existing requirements to conduct a risk analysis and risk management. See generally HIPAA Security Rule To Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898).

[400] *See* generally *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.*

[401] *See* NIST SP 800–66, rev. 2. *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

Conduct or review a security risk analysis *and conduct security risk management activities,* in accordance with the requirements under 45 CFR 164.308(a)(1)*(ii)(A) and (B),* including addressing the security of data created or maintained by CEHRT (*to include encryption*), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the *eligible hospital's or CAH's* risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

To meet the requirements of the modified measure, we propose eligible hospitals and CAHs would need to separately attest ''yes'' to both components of the proposed revised measure. An eligible hospital or CAH would be required to both attest ''yes'' that they have met the existing security risk analysis requirement component, *and* attest ''yes'' that they have met the security risk management component of the modified Security Risk Analysis measure to be considered a meaningful EHR user beginning with the EHR reporting period in CY 2026. This proposed modification would not impact the provision that actions included in the Security Risk Analysis measure may occur any time during the calendar year in which the EHR reporting period occurs and that an eligible hospital or CAH must use the capabilities and standards as defined for CEHRT at 42 CFR 495.4. The proposal to modify the Security Risk Analysis measure would not change the current scoring approach and would not contribute any points towards the eligible hospital or CAH's total score for the objectives and measures. An eligible hospital or CAH that attests ''no'' to either the risk analysis component or the risk management component, or to both components, would not meet the proposed measure requirements and would not satisfy the definition of a meaningful EHR user under 42 CFR 495.4, subjecting the eligible hospital or CAH to a downward payment adjustment.

We invite public comment on this proposal to modify the Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management in addition to the current requirement under the measure for eligible hospitals and CAHs to attest ''yes'' to having conducted or reviewed a security risk analysis as required under the HIPAA Security Rule. We also invite public comment regarding compliance with security risk management requirements and the potential impact the proposed modification to the Security Risk Analysis measure would have on risk management compliance and any potential burden from this proposal.

4. Proposal To Modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides Measure

a. Background on the SAFER Guides Measure

The SAFER Guides are an evidence-based set of recommendations in the form of nine stand-alone, subject-oriented chapters that present the health IT community, including eligible hospitals and CAHs that use health IT, with best practice recommendations to improve the safety and safe use of EHRs.[402] The SAFER Guides were first released in 2014 and updated in 2016. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45479 through 45481), we adopted the SAFER Guides measure under the Protect Patient Health Information objective beginning with the EHR reporting period in CY 2022. In the FY 2024 IPPS/LTCH PPS final rule, we modified the requirements for the SAFER Guides measure beginning with the EHR reporting period in CY 2024 to require eligible hospitals and CAHs to attest ''yes'' to conducting an annual self-assessment using all nine of the 2016 SAFER Guides to be considered a meaningful EHR user (88 FR 59262 through 59266).

b. Proposal To Modify the SAFER Guides Measure Beginning With the EHR Reporting Period in CY 2026

In January 2025, ASTP published an updated set of SAFER Guides (hereafter referred to as the 2025 SAFER Guides, located at *https://www.healthit.gov/topic/safety/safer-guides*). The 2025 SAFER Guides consist of eight guides organized into three broad groups of Foundational Guides, Infrastructure Guides, and Clinical Process Guides.[403] All guides have been edited and contain new recommendations as well as the comprehensive consolidation of recommendations that were similar and overlap in function or intent with the 2016 SAFER Guides. For example, the ''System Configuration'' and ''System Interfaces'' chapters have been consolidated into a single chapter titled, ''System Management.'' The entirety of the content recommendations, bibliography, and implementation guidance have been organized into a comprehensive table, which promotes the adoption of best safety practices for health IT. This update represents the most comprehensive revision of the SAFER Guides since they were first released. Table X.F.–01 provides the titles of the various guides, and chapters within the guides, that collectively comprise the 2016 SAFER Guides and the 2025 SAFER Guides, respectively.

TABLE X.F.–01—COMPARISON OF THE 2016 SAFER GUIDES AND THE 2025 SAFER GUIDES

Category	2016 SAFER Guides	2025 SAFER Guides
Foundational Guides	• High Priority Practices	• High Priority Practices.
	• Organizational Responsibilities	• Organizational Responsibilities.
Infrastructure Guides	• Contingency Planning	• Contingency Planning.
	• System Configuration	• System Management.
	• System Interfaces	
Clinical Process Guides	• Patient Identification	• Patient Identification.
	• Computerized Provider Order Entry with Decision Support.	• Computerized Provider Order Entry with Decision Support.
	• Test Results Reporting and Follow-Up	• Test Results Reporting and Follow-Up.
	• Clinician Communication	• Clinician Communication.

We propose to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using all eight 2025 SAFER Guides to be considered a meaningful EHR user,

[402] ASTP SAFER Guides—*https://www.healthit.gov/topic/safety/safer-guides.*

[403] ASTP SAFER Guides—*https://www.healthit.gov/topic/safety/safer-guides.*

beginning with the EHR reporting period in CY 2026. During FY 2024 IPPS/LTCH PPS rulemaking, some commenters believed the 2016 SAFER Guides were outdated and recommended that CMS and ONC review and make updates. Some commenters questioned the relevancy of the [2016] SAFER Guides to patient safety in hospitals due to the rapid advancement of health IT (88 FR 59264 through 59265). Our proposal to update the SAFER Guides measure will address these concerns because the 2025 SAFER guides have been updated and streamlined to focus on the highest risk, most commonly occurring issues that can be addressed through technology or practice changes to build system resilience and have been condensed into eight SAFER Guides rather than nine.

The proposed text of the measure is as follows: Conduct an annual self-assessment using all eight of the 2025 SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, beginning with the EHR reporting period in CY 2026 and subsequent years. We note that our proposed version of the measure referencing the 2025 SAFER Guides would only be effective starting with EHR reporting periods in CY 2026. During EHR reporting periods in CY 2025, eligible hospitals and CAHs should continue to use the 2016 SAFER Guides. Both the 2016 and the 2025 SAFER Guides are available on the ASTP website: *https://www.healthit.gov/topic/safety/safer-guides*. We encourage eligible hospitals and CAHs to begin to familiarize themselves with the 2025 SAFER Guides during CY 2025.

We invite public comment on this proposal for eligible hospitals and CAHs to conduct an annual self-assessment using all eight of the 2025 SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, beginning with the EHR reporting period in CY 2026 and subsequent years.

5. Proposal To Modify the Public Health and Clinical Data Exchange Objective: Adoption of an Optional Bonus Measure for Public Health Reporting Using the Trusted Exchange Framework and Common Agreement™ (TEFCA)

a. Background on the Public Health and Clinical Data Exchange Objective

The Medicare Promoting Interoperability Program for eligible hospitals and CAHs encourages health information exchange for public health purposes through the Public Health and Clinical Data Exchange objective. Effective and efficient responses to public health events require rapid, accurate exchange of electronic health information between health care providers, including eligible hospitals and CAHs, and Federal, State, Tribal, local, and territorial public health agencies (PHAs). Health care providers, including eligible hospitals and CAHs, collect this electronic health information for patient care, and PHAs use the information for public health purposes such as tracking a disease, initiating contact tracing, or pinpointing the source of a disease or outbreak of foodborne illness.

There are currently eight measures under the Public Health and Clinical Data Exchange objective: Immunization Registry Reporting, Syndromic Surveillance Reporting, Electronic Case Reporting, Electronic Laboratory Reporting, Antimicrobial Use Surveillance, Antimicrobial Resistance Surveillance, Public Health Registry Reporting, and Clinical Data Registry Reporting. Six of these measures are required under the objective, while two, the Public Health Registry Reporting and Clinical Data Registry Reporting, are optional bonus measures. Eligible hospitals and CAHs may receive a total of 5 bonus points for reporting on one or both optional bonus measures.

Measures under the Public Health and Clinical Data Exchange objective promote the exchange of health information for specific public health use cases with PHAs and other entities using CEHRT. However, one difficulty with the electronic exchange of health information for many different public health purposes is that exchange between PHAs and eligible hospitals and CAHs requires different processes. For instance, health information exchange for Electronic Case Reporting may be based on several point-to-point connections among eligible hospitals, CAHs, intermediaries, and PHAs, but these connections and agreements are different for other use cases such as Electronic Laboratory Reporting or Syndromic Surveillance. We anticipate that participation in TEFCA could help reduce the difficulty of public health information exchange over time by creating a common governance and technical framework for health information exchange. Facilitating health information exchange with PHAs through the TEFCA framework has the potential to increase standardization of connections to PHAs and reduce reporting burden for eligible hospitals, CAHs, and PHAs.

b. Background on TEFCA

Section 4003(b) of the 21st Century Cures Act, enacted in 2016, amended section 3001(c) of the Public Health Service Act and required HHS to take steps to ensure full network-to-network exchange of health information. Specifically, in section 3001(c)(9)(A) of the Public Health Service Act, Congress directed the National Coordinator, in collaboration with NIST and other agencies within HHS, to ''develop or support a trusted exchange framework, including a common agreement among health information networks nationally.'' Since the enactment of the 21st Century Cures Act, HHS has pursued development of the TEFCA framework.

By standardizing health information exchange across many different networks, TEFCA helps to ensure nationwide network-to-network exchange of health information. Standardization across networks simplifies health information exchange by reducing the number of connections that health care providers, including eligible hospitals and CAHs, PHAs, and other interested parties need to make to send and receive health information. TEFCA supports this standardization by creating baseline governance, legal, and technical requirements that enable secure health information exchange across different networks nationwide, including: a common method for authenticating trusted network participants, a common set of rules for trusted exchange, organizational and operational policies to enable the exchange of health information among networks, and a process for filing and adjudicating noncompliance with the terms of the Common Agreement.[404] We anticipate that TEFCA can help expand the nationwide availability of secure health information exchange capabilities in public health reporting.

CMS, the Centers for Disease Control and Prevention (CDC), and ASTP have been working closely with PHAs and other interested parties to expand the use of TEFCA for sharing health information for public health purposes. TEFCA is an important part of a shared vision for building a modernized public health infrastructure that connects previously siloed public health and health care systems. Early efforts to enable public health reporting through TEFCA exchange have focused on electronic case reporting, which is likely

[404] Additional information on TEFCA can be found on the ASTP website, available at: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

to be the primary mechanism of public health information exchange supported by entities that are part of TEFCA during 2026.

c. Proposal To Add an Optional Bonus Measure Under the Public Health and Clinical Data Exchange Objective Beginning With the EHR Reporting Period in CY 2026

We propose to add an optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a PHA that occurs using TEFCA. Specifically, beginning with the EHR reporting period in CY 2026, we propose the following optional bonus measure:

- Public Health Reporting Using TEFCA. The eligible hospital or CAH: (1) participates as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP's website); (2) is not suspended; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange with the PHA.

Under our proposal, an eligible hospital or CAH would be able to claim 5 bonus points under the Public Health and Clinical Data Exchange objective if the eligible hospital or CAH has attested that they are in active engagement (Option 2) with a PHA to submit electronic production data for one or more of the measures under the Public Health and Clinical Data Exchange objective using TEFCA. As previously finalized in the FY 2023 IPPS/LTCH final rule (87 FR 49339), for the measures in the Public Health and Clinical Data Exchange objective, eligible hospitals and CAHs are required to report their level of active engagement as either Option 1 (pre-production and validation) or Option 2 (validated data production), and may only spend one EHR reporting period at the pre-production and validation level of active engagement (Option 1) before advancing to Option 2 (validated data production) to fulfill measure requirements. Under our proposal, the bonus measure would only be available where the eligible hospital or CAH is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective.

Furthermore, under our proposal, to attest ''yes'' for the Public Health Reporting Using TEFCA optional bonus measure, an eligible hospital or CAH must be a signatory to a TEFCA Framework Agreement,[405] meaning either the Common Agreement or an agreement that includes the Participant/Sub-participant Terms of Participation,[406] and is not suspended under the respective agreement.

In addition, to attest ''yes'' for this bonus measure, an eligible hospital or CAH must transmit electronic health information for at least one measure under the Public Health and Clinic Data Exchange objective using TEFCA.

For more information about exchange of public health data using TEFCA, we refer readers to the TEFCA Public Health Exchange Purpose Implementation Standard Operating Procedure (SOP).[407] The Public Health Exchange Purpose Implementation SOP currently identifies electronic case reporting and electronic laboratory reporting as exchange use cases, but the SOP can also be used for any allowable public health purpose. CDC, ASTP, and others are focused on establishing a foundation for health care providers, including eligible hospitals and CAHs, to use TEFCA to meet their public health reporting needs for the benefit of both public health and clinical care.

Finally, the eligible hospital or CAH must use the functions of CEHRT to engage in exchange with a PHA. We believe there are numerous certified health IT capabilities that can support exchange under a TEFCA Framework Agreement with a PHA. For instance, eligible hospitals or CAHs may exchange information under a TEFCA Framework Agreement by using technology certified to the health IT certification criteria, ''Transmission to public health agencies—reportable laboratory tests and value/results'' at 45 CFR 170.315(f)(3) and ''Transmission to public health agencies—electronic case reporting'' at 45 CFR 170.315(f)(5). Both criteria are associated with the exchange use cases currently identified under the TEFCA Public Health Exchange Purpose Implementation SOP. We further recognize that eligible hospitals and CAHs may connect to entities that connect directly or indirectly to a Qualified Health Information Network™ [408] (QHIN) using certified health IT in a variety of ways. This includes the other ONC health IT certification criterion at 45 CFR 170.315(f) associated with the Public Health and Clinical Data Exchange objective measures, and we believe that we should allow for substantial flexibility in how eligible hospitals and CAHs use certified health IT to exchange health information under a TEFCA Framework Agreement. We invite public comment on health IT certification criteria that can support the proposed bonus measure.

We propose that an eligible hospital or CAH may earn a total of 5 bonus points if it attests ''yes'' for one of the following optional bonus measures: the Public Health Reporting Using TEFCA measure, the Public Health Registry Reporting measure, or the Clinical Data Registry Reporting measure. Eligible hospitals and CAHs may attest ''yes'' to more than one, but the eligible hospital or CAH can only earn a total of 5 bonus points even if it attests ''yes'' to multiple bonus measures. Because the Public Health Reporting Using TEFCA measure would be an optional bonus measure, we are not proposing any exclusions. We are also proposing that if an eligible hospital or CAH uses TEFCA to fulfill any of the required Public Health and Clinical Data Exchange objective measures, such as Electronic Case Reporting or Electronic Laboratory Reporting, that eligible hospital or CAH would be able to claim the 5 bonus points if it attests ''yes'' to the Public Health Reporting Using TEFCA bonus measure in addition to earning points for fulfilling the requirements of the required measure(s).

We invite public comment on our proposal to adopt an optional bonus measure under the Public Health and Clinical Data Exchange Objective to permit an eligible hospital or CAH to earn a total of 5 bonus points if it is participating as a signatory to a TEFCA Framework Agreement, is not

[405] The Common Agreement defines ''Framework Agreement(s)'' as: ''any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.'' See Common Agreement for Nationwide Health Information Interoperability Version 2.1 (Nov 2024) *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf*.

[406] Participant/Subparticipant Terms of Participation (Apr. 2024), *https://rce.sequoiaproject.org/wp-content/uploads/2024/05/Common-Agreement-v2.0-Exhibit-1_508.pdf*.

[407] For more information, see *https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf*.

[408] A Qualified Health Information Network is a health information network that facilitates TEFCA exchange by undergoing technology and security testing, onboarding, and designation. For more information, see: *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca*.

suspended, and submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective, is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective, and uses the functions of CEHRT to exchange with the PHA.

6. Overview of Scoring Methodology for the EHR Reporting Period in CY 2026

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41641), we adopted a performance-based scoring methodology for eligible hospitals and CAHs reporting to the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019. This methodology included a minimum scoring threshold that eligible hospitals and CAHs were required to meet at 42 CFR 495.24(e)(1)(i)(B), in addition to the requirement to report on the objectives and measures of meaningful use under 42 CFR 495.24(e)(1)(i)(A), to be considered a meaningful EHR user under 42 CFR 495.4. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69616 through 69618), we finalized a proposal to increase the performance-based scoring threshold to at least 70 points for the EHR reporting period in CY 2025 and to at least 80 points beginning with the EHR reporting period in CY 2026 and continuing in the EHR reporting periods in subsequent years.

As shown in Table X.F.–02., the points associated with the required measures sum to 100 points, and reporting on one or more of the optional bonus measures offers an additional 5 total bonus points. The scores for each of the required measures and bonus measures are added together to calculate a total score of up to 105 possible points for each eligible hospital or CAH. We refer readers to Table X.F.–02. in this proposed rule, which reflects the objectives, measures, maximum points available, and whether a measure is required or optional for the EHR reporting period in CY 2026 and subsequent years based on our previously adopted policies and the proposals included in this proposed rule.

TABLE X.F.–02—PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN CY 2026 AND SUBSEQUENT YEARS

Objective	Measure	Maximum points	Required/optional
Electronic Prescribing (e-Prescribing) ...	e-Prescribing	10 points	Required.
	Query of Prescription Drug Monitoring Program (PDMP).	10 points	Required.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information.	15 points	Required (eligible hospitals and CAHs must choose one of the three reporting options).
	—AND—		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information.	15 points.	
	—OR—		
	HIE Bi-Directional Exchange	30 points.	
	—OR—		
	Enabling Exchange under TEFCA	30 points.	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information.	25 points	Required.
Public Health and Clinical Data Exchange.	Report the following six measures: ..... • Syndromic Surveillance Reporting. • Immunization Registry Reporting. • Electronic Case Reporting. • Electronic Laboratory Reporting.** • Antimicrobial Use Surveillance. • Antimicrobial Resistance Surveillance.	25 points	Required.
	Report one of the following measures: • Public Health Registry Reporting. • Clinical Data Registry Reporting. • Public Health Reporting Using TEFCA.*	5 points (*bonus*)	Optional.

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 are required but will not be scored. Reporting electronic clinical quality measures (eCQMs) is required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at the Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the following EHR reporting period. See the FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement. The ePrior Authorization measure is required beginning with the EHR reporting period in CY 2027.

* Signifies a proposal made in this FY 2026 IPPS/LTCH PPS proposed rule. For details on our proposal to add the Public Health Reporting Under TEFCA measure, we refer readers to section X.F.5. of the preamble of this proposed rule.

** In prior rulemaking, we inadvertently referenced the measure name incorrectly. To ensure accuracy, we are correcting the measure's name to Electronic Laboratory Reporting measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.

The maximum number of points available by measure in this proposed rule do not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We are not proposing any changes to our policy for point redistribution in the event an exclusion is claimed. We refer readers to Table X.F.–03. in the preamble of this proposed rule, which shows point redistribution among the objectives and

measures for the EHR reporting period in CY 2026 and subsequent years, in the event an eligible hospital or CAH claims an exclusion.

TABLE X.F.–03—EXCLUSION REDISTRIBUTION FOR THE EHR REPORTING PERIOD IN CY 2026 AND SUBSEQUENT YEARS

Objective	Measure	Redistribution if exclusion is claimed
e-Prescribing	e-Prescribing	10 points to Health Information Exchange Objective.
	Query of PDMP	10 points to e-Prescribing measure.
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information.	No exclusion.
	—AND—	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information.	No exclusion.
	—OR—	
	HIE Bi-Directional Exchange	No exclusion.
	—OR—	
	Enabling Exchange under TEFCA	No exclusion.
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information.	No exclusion.
Public Health and Clinical Data Exchange.	Report the following six measures: • Syndromic Surveillance Reporting. • Immunization Registry Reporting. • Electronic Case Reporting. • Electronic Laboratory Reporting.* • Antimicrobial Use Surveillance. • Antimicrobial Resistance Surveillance.	If an exclusion is claimed for each of the six measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure.

Notes: The ePrior Authorization measure is required beginning with the EHR reporting period in CY 2027.

* In prior rulemaking, we inadvertently referenced the measure name incorrectly. To ensure accuracy, we are correcting the measure's name to Electronic Laboratory Reporting measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.

7. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2026

For ease of reference, Table X.F.–04. lists objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2026, as revised to reflect the proposals in this proposed rule, and Table X.F.–05. lists the ONC Health IT Certification Program certification criteria required to meet the Medicare Promoting Interoperability Program objectives and measures.

TABLE X.F.–04—SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2026

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
Electronic Prescribing (e-Prescribing).	e-Prescribing: For at least one hospital discharge, medication orders for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT.*	The number of prescriptions in the denominator generated and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed, other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions, and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
e-Prescribing	Query of Prescription Drug Monitoring Program (PDMP): For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	(1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. (2) Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	N/A (measure is Y/N).
Health Information Exchange.	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Health Information Exchange.	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication—Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy—Review of the patient's known medication allergies; and (3) Current Problem List—Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

TABLE X.F.–04—SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2026—Continued

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
Health Information Exchange.	HIE Bi-Directional Exchange: The eligible hospital or CAH must attest to the following: (1) Participating in a Health Information Exchange system (HIE) in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (3) Using the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).
Health Information Exchange.	Enabling Exchange using the Trusted Exchange Framework and Common Agreement (TEFCA): The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).

Provider to Patient Exchange.	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface API in the eligible hospital's or CAH's CEHRT.	The number of patients in the denominator (or patient authorized representatives) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.
Public Health and Clinical Data Exchange.	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry or immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data are collected by its jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N).

TABLE X.F.–04—SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2026—Continued

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
Public Health and Clinical Data Exchange.	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit syndromic surveillance data from an emergency department (POS 23).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N).
Public Health and Clinical Data Exchange.	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the Electronic Case Reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data are collected by its jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N).

Public Health and Clinical Data Exchange.	Electronic Laboratory Reporting:** The eligible hospital or CAH is in active engagement with a PHA to submit Electronic Laboratory Reporting results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the Electronic Laboratory Reporting measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific Electronic Laboratory Reporting standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive Electronic Laboratory Reporting results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N).
Public Health and Clinical Data Exchange.	Antimicrobial Use Surveillance: The eligible hospital or CAH is in active engagement with CDC's National Health Safety Network (NHSN) to submit Antimicrobial Use data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Use data for the EHR reporting period.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have electronic medication administration record (eMAR)/barcode medication administration (BCMA) electronic records or an admission, discharge, transfer (ADT) system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.	N/A (measure is Y/N).
Public Health and Clinical Data Exchange.	Antimicrobial Resistance Surveillance: The eligible hospital or CAH is in active engagement with CDC's NHSN to submit Antimicrobial Resistance data for the EHR reporting period and receives a report from NHSN indicating its successful submission of Antimicrobial Resistance data for the EHR reporting period.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH may be excluded from the measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by NHSN during the EHR reporting period; (2) Does not have a laboratory information system (LIS) or ADT system during the EHR reporting period; or (3) Does not have a data source containing the minimal discrete data elements that are required for reporting.	N/A (measure is Y/N).
Public Health and Clinical Data Exchange.	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).

TABLE X.F.–04—SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2026—Continued

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
Public Health and Clinical Data Exchange.	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).
Public Health and Clinical Data Exchange.	Public Health Reporting Using TEFCA:* The eligible hospital or CAH (1) participates as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ASTP's website); (2) is not suspended; (3) submits health information using TEFCA to a PHA consistent with one or more of the measures under the Public Health and Clinical Data Exchange objective; (4) is in active engagement Option 2 (validated data production) with a PHA to transfer health information for one or more of the measures under the Public Health and Clinical Data Exchange objective; and (5) uses the functions of CEHRT to exchange with the PHA.	N/A (measure is Y/N)*	N/A (measure is Y/N)*	None*	N/A (measure is Y/N)*.
Protect Patient Health Information.	Security Risk Analysis:* Conduct or review a security risk analysis and conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B), including addressing the security of data created or maintained by CEHRT (to include encryption), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the eligible hospital's or CAH's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.*	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).

Protect Patient Health Information.	Safety Assurance Factors for EHR Resilience (SAFER) Guides: * Conduct an annual self-assessment using all eight of the 2025 SAFER Guides at any point during the calendar year in which the EHR reporting period occurs, beginning with the EHR reporting period in CY 2026 and subsequent years.*	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N).

* Signifies a proposal made in this FY 2026 IPPS/LTCH PPS proposed rule that would apply to the EHR reporting period in CY 2026 and subsequent years.

** In prior rulemaking, we inadvertently referenced the measure name incorrectly. To ensure accuracy, we are correcting the measure's name to Electronic Laboratory Reporting measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.

TABLE X.F.–05—MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND ONC HEALTH IT CERTIFICATION PROGRAM CERTIFICATION CRITERIA FOR THE EHR REPORTING PERIOD IN CY 2026

Objective	Measure	ONC Health IT Certification Program certification criteria as defined in the following sections of title 45 CFR
e-Prescribing	e-Prescribing	170.315(b)(3) e-Prescribing.
	Query of PDMP	170.315(b)(3) e-Prescribing.
Health Information Exchange	Support electronic referral loops by sending health information.	170.315(b)(1) Transitions of care.
	Support electronic referral loops by receiving and reconciling health information.	170.315(b)(1) Transitions of care. 170.315(b)(2) Clinical information reconciliation and incorporation.
Health Information Exchange (alternative).	Health Information Exchange Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are *not* limited to technology certified to the following criteria: 170.315(b)(1) Transitions of care. 170.315(b)(2) Clinical information reconciliation and incorporation. 170.315(g)(7) Application access—patient selection. 170.315(g)(9) Application access—all data request. 170.315(g)(10) Standardized API for patient and population services.
Health Information Exchange (alternative).	Enabling Exchange under TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are *not* limited to technology certified to the following criteria: 170.315(b)(1) Transitions of care. 170.315(b)(2) Clinical information reconciliation and incorporation. 170.315(g)(7) Application access—patient selection. 170.315(g)(9) Application access—all data request. 170.315(g)(10) Standardized API for patient and population services.
Provider to Patient Exchange	Provide patients electronic access to their health information.	170.315(e)(1) View, download, and transmit to 3rd party. 170.315(g)(7) Application access—patient selection. 170.315(g)(9) Application access—all data request. 170.315(g)(10) Standardized API for patient and population services.
Public Health and Clinical Data Exchange.	Immunization registry reporting	170.315(f)(1) Transmission to immunization registries.
	Syndromic surveillance reporting	170.315(f)(2) Transmission to public health agencies—syndromic surveillance.
	Electronic case reporting	170.315(f)(5) Transmission to public health agencies—electronic case reporting.
	Public health registry reporting	170.315(f)(7) Transmission to public health agencies—health care surveys.
	Clinical data registry reporting	No ONC health IT certification criteria at this time.
	Public health reporting using TEFCA*	Examples of certified health IT capabilities to support the actions of this measure may include but are *not* limited to technology certified to the following criteria: 170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results. 170.315(f)(5) Transmission to public health agencies—electronic case reporting.
	Electronic laboratory reporting**	170.315(f)(3) Transmission to public health agencies—reportable laboratory tests and value/results.
	Antimicrobial Use Surveillance	170.315(f)(6) Transmission to public health agencies—antimicrobial use and resistance reporting.
	Antimicrobial Resistance Surveillance	170.315(f)(6) Transmission to public health agencies—antimicrobial use and resistance reporting.
Electronic Clinical Quality measures (eCQMs).	eCQMs for eligible hospitals and CAHs	170.315(c)(1). 170.315(c)(2). 170.315(c)(3)(i) and (ii).
Protect Patient Health Information	Security Risk Analysis*	No ONC health IT certification criteria at this time.
	SAFER Guides*	No ONC health IT certification criteria at this time.

*Signifies a measure with a proposal made in this FY 2026 IPPS/LTCH PPS proposed rule.
**In prior rulemaking, we inadvertently referenced the measure name incorrectly. To ensure accuracy, we are correcting the measure's name to Electronic Laboratory Reporting measure. This is a non-substantive change and does not impact the measure's specifications or reporting requirements.

8. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Background on Clinical Quality Measurement for Eligible Hospitals and CAHs

Under sections 1814(l)(3)(A) and 1886(n)(3)(A) of the Act and the definition of ''meaningful EHR user'' under 42 CFR 495.4, eligible hospitals and CAHs must report on clinical quality measures selected by the Secretary using CEHRT (also referred to as electronic clinical quality measures, or eCQMs), as part of the Medicare Promoting Interoperability Program.

Table X.F–06. summarizes the previously finalized required and self-selected eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the CY 2026 reporting period and subsequent years.

TABLE X.F.–06—PREVIOUSLY FINALIZED eCQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2026 REPORTING PERIOD AND SUBSEQUENT YEARS

Short name	Measure name	CBE No.***
Safe Use of Opioids*	Safe Use of Opioids—Concurrent Prescribing	3316e
PC–02*	Cesarean Birth	0471e
PC–07*	Severe Obstetric Complications	3687e
STK–2	Discharged on Antithrombotic Therapy	0435e
STK–3	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436e
STK–5	Antithrombotic Therapy by End of Hospital Day Two	0438e
VTE–1	Venous Thromboembolism Prophylaxis	0371
VTE–2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH–HYPO*	Hospital Harm—Severe Hypoglycemia	3503e
HH–HYPER*	Hospital Harm—Severe Hyperglycemia	3533e
HH–OREA*	Hospital Harm—Opioid-Related Adverse Events	3501e
HH–PI**	Hospital Harm—Pressure Injury	3498e
HH–AKI**	Hospital Harm—Acute Kidney Injury	3713e
HH–FI	Hospital Harm—Falls with Injury	4120e
HH–RF	Hospital Harm—Postoperative Respiratory Failure	4130e
MCS****	Malnutrition Care Score	3592e
IP-ExRad	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Inpatient).	3663e

* Signifies a required measure for the CY 2026 reporting period and subsequent years.
** Signifies a required measure added for the CY 2027 reporting period and subsequent years.
*** We note that inclusion of a CBE number neither indicates endorsement or lack of endorsement. More information about current endorsement status can be found on the Partnership for Quality Measurement website: *https://p4qm.org/measures*.
**** The eCQM previously named Global Malnutrition Composite Score has been updated to Malnutrition Care Score. The short name has subsequently been updated to MCS eCQM.

We are not proposing any changes to the eCQMs for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program in this proposed rule.

9. Request for Information (RFI) Regarding the Query of Prescription Drug Monitoring Program (PDMP) Measure

a. Background on PDMPs and the Query of PDMP Measure

PDMPs are electronic databases that monitor the use of controlled substances, including prescription drug usage and prescription drug history. PDMPs are critical decision support tools for addressing prescription drug use, misuse, and diversion. Recent legislation has continued to advance the use of PDMPs, including the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT for Patients and Communities Act) (Pub. L. 115–271), enacted in 2018, that authorizes important investments in combating the opioid epidemic. Among other provisions, the SUPPORT for Patients and Communities Act included new requirements and Federal funding for the enhancement, integration, and interoperability of PDMPs to help reduce opioid misuse and overprescribing and to help promote the overall effective prevention and treatment of opioid use disorders.

Today, all 50 States, the District of Columbia, Guam, Puerto Rico, and the Northern Mariana Islands host PDMPs.[409] PDMPs play an important role in patient safety by enabling clinicians to check PDMP data for prescription opioids and other controlled medications received by a patient from other clinicians to determine whether a patient is put at high risk for overdose. A literature review of recent studies on PDMP effectiveness compiled by the PDMP Training and Technical Assistance Center (TTAC) at the Institute for Intergovernmental Research and published in the *PDMP Administrators' Orientation Guide of PDMPs* highlights the role of PDMPs in reducing the following: high-risk opioid prescribing and dispensing behaviors; overall supply of opioid prescriptions; multiple provider episodes (for example, doctor or pharmacy shopping); opioid-related overdose rates; and admissions to treatment facilities for prescription drug misuse.[410]

Increased integration of PDMPs into EHRs and EHR systems continues to reduce barriers to and burden of PDMP review by incorporating PDMP queries into the provider workflow. A PDMP TTAC assessment of PDMP Policies and Capabilities[411] published in December 2024 found that 49 of the 54 PDMPs have taken steps to integrate with EHR or health information exchange systems (HIEs), pharmacy dispensing systems (PDSs), or both. We refer readers to Table X.F.–07. for more detailed information.

TABLE X.F.–07—PDMP INTEGRATION AS OF 2024[412]

Type of integration	Number of PDMPs
EHR, HIE, and PDS	18
EHR and PDS	24
EHR and HIE	1
EHR only	5
HIE only	1

We continue to work with Federal partners and industry stakeholders to advance common standards for the exchange of information between PDMPs, EHRs, pharmacy dispensing systems, and exchange networks. ASTP convened the PDMP and health IT system communities to standardize data

[409] PDMP TTAC, PDMP Policies and Capabilities: 2023 Assessment Results, January 2024, available at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf*.

[410] PDMP TTAC, PDMP Administrators Orientation Package, November 2024, available at: *https://www.pdmpassist.org/Content/Documents/pdf/PDMP_admin/PDMP_Administrators_Orientation_Package_revision_20241105.pdf*.

[411] PDMP TTAC, PDMP Policies and Capabilities: 2024 Assessment Results, December 2024, available at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf*.

[412] PDMP TTAC, PDMP Policies and Capabilities: 2024 Assessment Results, December 2024, available at: *https://www.pdmpassist.org/Content/Documents/pdf/resources/PDMP%20Policies%20and%20Capabilities%202023%20Assessment%20Results_final_20240108.pdf*.

format and transport protocols to exchange controlled substances prescription data between PDMP and health IT systems, which produced a PDMP–EHR Integration Toolkit.[413] Moreover, ASTP continues to collaborate with industry partners furthering the development of a Health Level 7® (HL7) Fast Healthcare Interoperability Resources® (FHIR) IG that allows EHRs and other health IT systems to support more seamless exchange of prescription data with PDMP systems.[414]

On August 5, 2024, the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI–2) proposed rule appeared in the **Federal Register** (89 FR 63498). The HTI–2 proposed rule includes a proposal for a PDMP certification criterion in 45 CFR 170.315(f)(9), titled ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter,'' that would enable the bi-directional interaction and electronic health information exchange between certified Health IT Modules and PDMP databases using a consistent approach to querying PDMP data (89 FR 63547). Specifically, the proposed certification criterion would enable the query of prescription drug monitoring systems and the receipt, validation, parsing, and filtering of medication information from PDMPs. The proposed criterion would be a functional criterion agnostic to a specific PDMP standard, but would include transport, content, and vocabulary standards where appropriate. ASTP has not finalized the proposal to date.

In the FY 2019 IPPS/LTCH PPS final rule, CMS adopted the Query of PDMP measure under the e-Prescribing objective of the Medicare Promoting Interoperability Program to support HHS initiatives aimed at improving the treatment of opioid and substance use disorders by helping eligible hospitals and CAHs avoid inappropriate prescriptions (83 FR 41648 through 41653). The Query of PDMP measure provides that for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of their PDMP for prescription drug history (89 FR 69607).

We are interested in continuing to make improvements to the Medicare Promoting Interoperability Program that promote patient safety and encourage appropriate prescribing of controlled substances while minimizing provider burden. We further believe improved technology approaches and increased PDMP integration into EHR systems can enable increased utilization of PDMPs and associated positive outcomes for patients. We are also considering recent studies of how outcome-oriented quality measures that are not currently included in the Medicare Promoting Interoperability Program, such as the Concurrent Use of Opioids and Benzodiazepines measure, could potentially be included in the Medicare Promoting Interoperability Program associated with the Query of PDMP measure or as an eCQM to provide additional data and support quality improvement in our efforts to address the inappropriate prescribing of controlled substances.[415]

Therefore, we are seeking public comment through this RFI to potentially inform future rulemaking for the Query of PDMP measure related to the following policy considerations: (1) changing the Query of PDMP measure from an attestation-based measure (''yes'' or ''no'') to a performance-based measure (numerator and denominator), as well as alternative measures designed to more effectively assess the degree to which participants are utilizing PDMPs, and (2) expanding the types of drugs to which the Query of PDMP measure could apply.

b. RFI on Changing the Query of PDMP Measure From an Attestation-Based Measure to a Performance-Based Measure

The Query of PDMP measure was initially finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41649 through 41653) as a performance-based measure with a numerator and denominator described as follows:

- Denominator: Number of Schedule II opioids[416] electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.
- Numerator: The number of Schedule II opioid prescriptions in the denominator for which data from CEHRT is used to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42595), we modified the Query of PDMP measure to become an attestation-based measure beginning with the EHR reporting period in CY 2019, and an optional measure for the EHR reporting period in CY 2020, noting that it was premature to require the Query of PDMP measure and to score it based on performance. We received feedback that incorporating the ability to count the number of PDMP queries in the EHR would require implementation of manual processes due to the wide variation in approaches by eligible hospitals and CAHs querying PDMPs, and that the costs of additional development if further standardization was introduced later would likely be passed on to eligible hospitals and CAHs. We refer to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42593 through 42596), FY 2021 IPPS/LTCH PPS final rule (85 FR 58967 through 58969), and FY 2022 IPPS/LTCH PPS final rule (86 FR 45462 through 45464) for discussions of stakeholder concerns with implementing the Query of PDMP measure as a performance-based measure.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49322 through 49323), beginning with the EHR reporting period in CY 2023, we finalized the Query of PDMP measure to require a ''yes'' or a ''no'' attestation from eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. A ''yes'' response would indicate that for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49327), we stated that we believed our efforts to promote interoperability for accessing data through PDMPs, including standardized functionality, would enable the potential future modification of the Query of PDMP measure to be performance-based. Given recent progress in a variety of areas, there is now a clearer trajectory moving forward

[413] PDMP–EHR Integration Toolkit, available at: *https://www.healthit.gov/topic/health-it-health-care-settings/prescription-drug-monitoring-programs.*

[414] HL7 FHIR PDMP IG; available at: *https://build.fhir.org/ig/HL7/fhir-pdmp/.*

[415] For example, see Gabriel, Meghan; Montavon, Joel; Digmann, Rachel; Ferris, Lindsey M.; Spiro, Shelly. A Novel Approach to PDMP Reporting: Adapting Opioid Quality Measures to PDMP Data. Journal for Healthcare Quality 45(2): p 107–116, March/April 2023. For measure specifications and additional information for the Concurrent Use of Opioids and Benzodiazepines measure, we refer readers to the eCQI Resource Center website at: *https://ecqi.healthit.gov/ecqm/eh/2024/cms0506v6?qt-tabs_measure=measure-information.*

[416] In the FY 2019 IPPS/LTCH PPS final rule, the Query of PDMP only included Schedule II opioids (83 FR 41649 through 41653). We finalized the expansion of the Query of PDMP measure to include Schedule II opioids and Schedules III and IV drugs beginning with the EHR reporting period in CY 2023 in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49323 through 49325).

to enhance the Medicare Promoting Interoperability Program's capacity to incentivize use of PDMPs, and thereby, to improve the quality of health care and promote care coordination. Notably, PDMPs are now widely available across all 50 states and several localities, and PDMP integration with HIEs, EHRs, and PDSs has increased since the Query of PDMP measure was finalized as an attestation measure. Therefore, to further promote the utilization of PDMPs and to support appropriate prescribing for controlled substances, we are inviting public comment and feedback on the potential modification of the Query of PMDP measure from an attestation measure to a performance-based measure to inform potential future rulemaking and include the following questions:

- Should CMS propose to adopt a performance-based (numerator/denominator) reporting requirement for the Query of PDMP measure? If so, how should the numerator and denominator be defined?

For example, one approach we are considering to potentially inform future rulemaking is the following description of a numerator and a denominator, which is updated from the numerator and denominator established in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41649 through 41653), when the Query of PDMP measure was initially finalized as a performance-based measure and only included Schedule II opioids:

++ Denominator: Number of Schedule II opioid or Schedule III or IV drugs electronically prescribed using CEHRT by the eligible hospital or CAH during the EHR reporting period.

++ Numerator: The number of prescriptions of Schedule II opioid or Schedule III or IV drugs in the denominator for which data from CEHRT is used at the time of prescribing to conduct a query of a PDMP for prescription drug history except where prohibited and in accordance with applicable law.

- What are potential barriers for eligible hospitals and CAHs meeting the Query of PDMP measure as a performance-based measure?
- How should CMS account for varying levels of readiness and capacity for performance-based reporting, particularly for small and rural providers, including eligible hospitals and CAHs?
- Are there specific exclusions that we should consider for performance-based reporting?
- What timeframe would allow for systems and process changes to account for a change of the Query of PDMP measure from an attestation measure to a performance-based measure while minimizing burden?
- Would adoption and use of Health IT Modules certified to the ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter'' certification criterion proposed by ONC in the HTI–2 proposed rule (89 FR 63547), if this criterion were to be finalized, help to mitigate previously identified burden associated with implementing and reporting on a performance-based ''Query of PDMP'' measure?
- How would the adoption and use of Health IT Modules certified to the proposed ''Prescription Drug Monitoring Program (PDMP) Databases—Query, receive, validate, parse, and filter'' certification criterion, if it were finalized, impact the numerator and denominator of a potential performance-based PDMP measure?

We are also requesting feedback on a broader set of performance-based measurement concepts that could help to advance our priorities with respect to the use of PDMPs to support the prevention and treatment of opioid use disorders. We are specifically interested in creating performance-based measures that allow eligible hospitals and CAHs to leverage technology to improve care and reduce burden.

- What are other measure concepts we should consider that would allow us to focus on outcomes related to overdose prevention?
- Should we explore measures related to monitoring data from PDMPs that could assess multiple opioid prescriptions, opioid prescriptions from multiple prescribers, combined opioid and benzodiazepine prescriptions, or very high standardized dosage of opioids prescribed?
- What measure concepts related to the use of PDMPs are likely to involve the lowest effort and provide the highest value to the health care community?

c. RFI on the Modification of the Query of PDMP Measure To Include All Schedule II Drugs

Under the Controlled Substances Act (CSA),[417] the Drug Enforcement Administration classifies drugs, substances, and certain chemicals used to make drugs into five distinct categories or schedules depending upon the drug's acceptable medical use and the drug's abuse or dependency potential. A drug's abuse rate is a factor used to determine its classification; for example, Schedule I medications have the highest abuse potential while medications in Schedule V have a low abuse potential.[418] We refer readers to Table X.F.–08. for information on each Schedule, including abuse potential, medicinal use, if any, and drug examples. For additional information, we refer readers to the listing of drugs and their schedule located at CSA Scheduling at *https://www.deadiversion.usdoj.gov/schedules/orangebook/c_cs_alpha.pdf*.

TABLE X.F.–08—CONTROLLED SUBSTANCE SCHEDULES, DESCRIPTIONS, AND EXAMPLES [419]

Schedule	Description	Examples
Schedule I	No accepted medical use, are unsafe, and hold a high potential for abuse.	Heroin and LSD.
Schedule II	Accepted medical use, high potential for abuse, abuse could lead to severe psychological or physical dependence.	Hydrocodone, methadone, meperidine, oxycodone, morphine, codeine, and amphetamine.
Schedule III	Accepted medical use, less potential for abuse than schedule I or II substances, abuse may lead to moderate or low physical dependence or high psychological dependence.	Ketamine and anabolic steroids.
Schedule IV	Accepted medical use, low potential for abuse relative to schedule III substances, abuse may lead to limited physical or psychological dependence relative to schedule III substances.	Alprazolam, clonazepam, diazepam, and tramadol.

[417] Public Law 91–513, tit. II, 84 Stat. 1236, 1242–84 (1970); codified, as amended, at 21 U.S.C. 801 *et seq.*

[418] United States Drug Enforcement Administration, website; available at: *https://www.dea.gov/drug-information/drug-scheduling.*

[419] GAO–21–22, Prescription Drug Monitoring Programs: Views on Usefulness and Challenges of Programs; 21 U.S.C. 812; and the U.S. Drug Enforcement Administration, website, available at: *https://www.dea.gov/drug-information/drug-scheduling.*

TABLE X.F.–08—CONTROLLED SUBSTANCE SCHEDULES, DESCRIPTIONS, AND EXAMPLES [419]—Continued

Schedule	Description	Examples
Schedule V	Accepted medical use, low potential for abuse relative to schedule IV substances, abuse may lead to limited physical or psychological dependence relative to schedule IV substances.	Pregabalin, cough preparations containing less than 200 mg per 100 mL or 100 g of codeine.

PDMPs are operated at the state level, and individual state requirements for reporting and use differ from state to state.[420] Currently, almost every state collects data on Schedules II, III, and IV drugs that are prescribed.[421]

In the FY 2023 IPPS/LTCH PPS final rule, we finalized the expansion of the Query of PDMP measure to not only include Schedule II opioids, but also include Schedule III and IV drugs, beginning with the EHR reporting period in CY 2023 (87 FR 49323 through 49325). We also finalized the measure description: for at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history. We noted that expanding the Query of PDMP measure to include Schedule III and IV drugs in addition to Schedule II opioids would offer eligible hospitals and CAHs a broader clinical picture aimed at overall patient safety efforts and would support better alignment with state regulations. We also clarified in response to public comment that the Query of PDMP measure does not include or apply to Schedule II drugs that are not opioids (for example, central nervous system stimulants) (87 FR 49325). For additional information on the Query of PDMP measure policies, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49320 through 49327).

To further promote the Medicare Promoting Interoperability Program's capacity to incentivize the electronic exchange of health information through the use of PDMPs, and thereby improve the quality of care by supporting appropriate prescribing of controlled substances, we are considering proposing in future rulemaking to expand the Query of PDMP measure to include all Schedule II drugs, rather than only including Schedule II opioids. Notably, this would expand the Query of PDMP measure to include controlled substances that are categorized as Schedule II drugs that are not opioids, such as central nervous system stimulants that can be prescribed for Attention-Deficit Hyperactivity Disorder (ADHD). We refer readers to Table X.F.–09. for examples of Schedule II opioid drugs and other Schedule II drugs.

TABLE X.F.–09—EXAMPLES OF SCHEDULE II OPIOID DRUGS AND OTHER SCHEDULE II DRUGS [422]

Schedule II opioid drugs	Other Schedule II drugs
• Codeine • Fentanyl • Hydrocodone • Meperidine • Methadone • Morphine • Oxycodone	• Amphetamine • Lisdexamfetamine • Methamphetamine • Methylphenidate • Pentobarbital

For this RFI, we are inviting public comment and feedback on possible future expansion of the Query of PDMP measure to include all Schedule II (Schedule II opioids and other Schedule II drugs), Schedule III, and Schedule IV drugs in future rulemaking. We are also seeking responses to the following specific questions:

- What challenges exist, if any, around expanding the Query of PDMP measure to include all Schedule II drugs?
- What are the potential benefits versus risks of expanding the Query of PDMP measure to include all Schedule II drugs?
- Would expanding the Query of PDMP measure to Schedule II non-opioid drugs create barriers for patients appropriately prescribed Schedule II non-opioid drugs (for example, central nervous stimulants appropriately prescribed for ADHD)?
- How should CMS account for varying levels of readiness and capacity for eligible hospitals and CAHs to meet an expanded scope of the measure, particularly for small and rural providers, including eligible hospitals and CAHs?
- What exclusions should be considered, if any?

10. RFI Regarding Performance-Based Measures

As finalized in the FY 2023 IPPS/LTCH final rule (87 FR 49339), the measures under the Public Health and Clinical Data Exchange objective require eligible hospitals and CAHs to indicate their level of active engagement with a PHA (Option 1 or Option 2) but do not measure the degree to which eligible hospitals and CAHs are exchanging the data specified under each measure. Historically, the Public Health and Clinical Data Exchange objective has included measures that required reporting via attestation to account for factors such as the ongoing development of connections between eligible hospitals and CAHs and PHAs, as well as variation across state and local requirements which govern reporting requirements for eligible hospitals and CAHs (77 FR 54022). However, given the ongoing advancements in public health reporting infrastructure across the nation, we are exploring whether alternatives to the current attestation-based measures can drive further improvements in the quality and consistency of reporting to PHAs and associated public health outcomes. This approach would align with the Act's requirement to seek to improve the use of EHRs and health care quality over time (section 1886(n)(3)(A) of the Act).

In the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 36380), we included an RFI regarding the Public Health and Clinical Data Exchange objective, including questions that sought feedback on replacing current attestation-based measures with measures that would require reporting of a numerator and denominator to better assess performance on measures included under the Public Health and Clinical Data Exchange objective. Because we only require that an eligible hospital or CAH indicate their level of active engagement (Option 1 or Option 2), attestation-based reporting does not capture aspects of the health information shared with PHAs that we are seeking to improve, such as comprehensiveness, quality, or timeliness.

We appreciate the responses received on our RFI in the FY 2025 IPPS/LTCH PPS proposed rule, and we are seeking

[420] PDMP TTAC website, available at: *https://www.pdmpassist.org/State.*

[421] PDMP TTAC website, available at: *https://www.pdmpassist.org/Policies/Maps/PDMPPolicies.*

[422] For additional information on drug scheduling, we refer readers to the U.S. Drug Enforcement Administration website, available at: *https://www.dea.gov/drug-information/drug-scheduling.*

additional feedback from commenters through another RFI in this proposed rule. For this RFI, we are seeking to further refine our discussion of possible future measures to address commenter concerns and seek information to ensure any future proposals align with our goals of ultimately improving public health outcomes. Specifically, we are interested in new measure concepts for public health that would allow us to better focus on aspects of the data quality of public health reporting. We are seeking public comment on the following questions:

- What aspects of data quality and usability are most appropriate and valuable to measure in the context of the Public Health and Clinical Data Exchange objective of the Medicare Promoting Interoperability Program (for example, timeliness and completeness of reporting)?
- How could data completeness be defined? For instance, how should we define ''complete data''? Should we consider a threshold approach, under which eligible hospitals and CAHs would attest that they are successfully sending complete data for a minimum set of data elements to a PHA?

++ For example, for the Electronic Case Reporting measure, should we define a minimum threshold for completeness of certain data elements that are critical to public health and are supported in CEHRT (for example, data elements included in a specific version of the USCDI such as medications or medication dose)? If so, how should we define or set such thresholds?

++ For the Electronic Laboratory Reporting measure, should we require eligible hospitals and CAHs to report how many laboratory tests were ordered using Logical Observation Identifiers Names and Codes (LOINC) and how many results used Systematized Nomenclature of Medicine (SNOMED) codes?

- Are there other metrics available that we should consider in the Medicare Promoting Interoperability Program that more directly relate to actions and outcomes that public health reporting is intended to enable (for example, overdose prevention)?
- Of the current types of public health data exchange reflected in the Public Health and Clinical Data Exchange objective measures, what use cases should we prioritize for a focus on data quality that would provide the highest value to the health care community while resulting in the least burden?

As part of our exploration of alternative measure concepts to assess performance on different aspects of the Public Health and Clinical Data Exchange objective measures, we are considering revising our approach to scoring the measures under the objective.

We are seeking public comment on the following questions:

- Currently, eligible hospitals and CAHs can earn 25 points for reporting on all six required measures. Under a revised scoring approach, should we specify that eligible hospitals and CAHs could earn up to 5 points for each measure, for a total of 30 points for the objective, but must earn at least 1 point for each measure to earn a score for the Medicare Promoting Interoperability program, in addition to meeting the overall threshold for the program?
- Should we score all public health measures for which we finalize a numerator and denominator based on performance? Or should we only score a subset of measures based on performance?

In recent years, ONC has finalized updates to ONC Health IT Certification Program certification criteria that are included in CEHRT to provide technical capabilities based on FHIR, an advanced, modern interoperability standard developed by HL7 to facilitate efficient, scalable and standardized health information exchange.[423] For instance, technology certified to the ''Standardized API for patient and population services'' criterion at 45 CFR 170.315(g)(10) provides for a FHIR API in Health IT Modules for data in a version or versions of the USCDI. In the HTI–1 final rule, ONC finalized that Health IT Modules certified to the ''Electronic case reporting'' criterion at 45 CFR 170.315(f)(5) may meet the requirements of the criterion by certifying to the HL7 FHIR Implementation Guide: Electronic Case Reporting—US Realm 2.1.0—STU 2 US to support electronic case reporting (89 FR 1231). In the HTI–2 proposed rule, ONC also proposed several updates to public health certification criteria that include reference to FHIR implementation specifications (89 FR 63537). In 2024, ASTP released the Draft FHIR Federal Action Plan with a goal of building an ecosystem for innovation that strengthens consistent use of the FHIR standard.[424] ASTP, CMS, and CDC plan to continue to explore opportunities to leverage FHIR-based capabilities within certified health IT to support public health reporting, and we are seeking comment on how such future updates could impact the potential measure strategies discussed in this section. Specifically, we are seeking public comment on the following questions:

- What are the most promising uses of FHIR approaches to the public health reporting requirements under the Medicare Promoting Interoperability Program? What approaches have the most potential to reduce the burden of reporting on eligible hospitals and CAHs and increase the quality and timeliness of data submitted to PHAs?
- Approaches to public health reporting using FHIR have focused on greater automation of the interactions between health care providers and PHAs in order to reduce burden on providers, including eligible hospitals and CAHs, and increase PHAs' ability to obtain the information they need. How might FHIR approaches to the exchange of public health data impact measurement of eligible hospital and CAH performance?
- Use of FHIR APIs could ultimately result in consolidation of disparate functions in EHRs that are currently being used to support different types of public health data exchange, for instance, through availability of an API that makes data available for a range of public health use cases. If these approaches are implemented in certified health IT in the future, should we consider streamlining or reduce the number of measures required in the Medicare Promoting Interoperability Program?

11. RFI Regarding Data Quality

Gaps and discrepancies in data accuracy, completeness, reliability, and consistency undermine the integrity of health information exchange. We believe eligible hospitals and CAHs should be able to seamlessly exchange high-quality health information with patients, providers, and payers across systems. For the purposes of this discussion, we define data quality as the degree to which health information is accurate, complete, timely, consistent, and reliable. These factors increase the overall quality of health information that touches several aspects of the health care continuum: clinical information, patient safety, claims, provider data, eligibility, benefits, and administrative data.[425] Poor data quality poses direct threats to patient safety, especially when providers, including eligible hospitals and CAHs, treat patients based on inaccurate or

[423] Additional resources about FHIR can be found here: *https://www.healthit.gov/topic/standards-technology/standards/fhir.*

[424] *https://www.healthit.gov/isp/about-fhir-action-plan.*

[425] *https://www.nejm.org/doi/full/10.1056/nejmp1708704.*

incomplete information.[426] Accountability, transparency, and improvement efforts also suffer when health care actors evaluate—or are evaluated based on—care quality and outcomes that don't reflect true performance due to unreliable or low quality data.[427] Poor quality data also poses risks beyond health care delivery and administration. Because health care data captured by EHRs serve as the foundation for public health reporting and clinical research using real world evidence, widespread deficits in data quality can adversely affect clinical innovation and public health decision-making.[428]

We encourage eligible hospitals and CAHs to work with their health IT vendors to ensure the richest, highest quality data are sent to their exchange partners. This partnership can help ensure data validation; reduce burden between eligible hospitals and CAHs and their exchange partners; and reduce unintended consequences and risks that come with low-quality data. For example, timely, complete data are needed for monitoring adverse events such as antimicrobial resistance. When providers, including eligible hospitals and CAHs, send accurate data the first time, this reduces the need for prolonged testing and email exchanges between providers, PHAs, payers, and patients.

As the prevalence of electronic health information continues to grow, and as providers and payers continue to move to a value-based care model, the need for high-quality data will become increasingly important.[429] We want to both encourage and support eligible hospitals' and CAHs' use of modern technologies and standards to ensure data are usable, complete, accurate, timely, and consistent. We are seeking public comment on the following questions:

- What data quality challenges does your health care organization experience (for example, discrepancies in data accuracy, completeness, reliability, and consistency)? How are you working to address data quality challenges? What data quality challenges persist longitudinally across your patient population(s)?
- What are the primary barriers to collecting high-quality data? What resources do you believe could help your organization address these challenges?
- What solutions have eligible hospitals and CAHs found most effective to address data quality?
- What steps should CMS consider to drive further improvement in the quality and usability of health information being exchanged? How can CMS partner with eligible hospitals, CAHs, industry, and Federal agencies to drive further improvements in the quality and usability of health information being exchanged? What methods should CMS and other partners explore to further rectify data quality issues in the health care community?

XI. Other Provisions Included in This Proposed Rule

A. Proposed Changes to the Transforming Episode Accountability Model (TEAM)

1. Background

a. Purpose

TEAM is a 5-year mandatory alternative payment model tested by the CMS Innovation Center that will begin on January 1, 2026, and end on December 31, 2030. TEAM will test whether an episode-based pricing methodology linked with quality measure performance for select acute care hospitals reduces Medicare program expenditures while preserving or improving the quality of care for Medicare beneficiaries who initiate certain episode categories. Specifically, TEAM will test five surgical episode categories: Coronary Artery Bypass Graft Surgery (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel Procedure, Surgical Hip/Femur Fracture Treatment (SHFFT), and Spinal Fusion.

As discussed in greater detail in section XI.A.1.b. of the preamble of this proposed rule, TEAM was established through notice and comment rulemaking. While the model performance period has not yet begun, we noted in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that a few policies that were proposed were not finalized due to public comment concerns and other policies were not finalized because they needed further consideration, such as how to construct target prices when there are coding changes, which is addressed in section XI.A.2.c.(2) of the preamble of this proposed rule. Further, we indicated that for certain policies, such as the policy to address TEAM participants that have a low volume of episodes, we would go through rulemaking in the future to promulgate new policies that could be finalized before the model start date. Therefore, this proposed rule proposes updates to TEAM that would include the following modifications:

- A limited deferment period for certain hospitals.
- Linking Track 2 participation eligibility for hospitals with a Medicare Dependent Hospital (MDH) designation to the expiration of the MDH program.
- Adding the Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO–PM).
- Applying a neutral quality measure score for TEAM participants with insufficient quality data.
- A methodology to construct target prices when there are coding changes.
- Reconstructing the normalization factor and prospective trend factor.
- Replacing the Area Deprivation Index (ADI) with the Community Deprivation Index (CDI).
- Using a 180-day lookback period and Hierarchical Condition Categories (HCC) version 28 for beneficiary risk adjustment.
- Aligning the date range used for episode attribution.
- Removing health equity plans.
- Expanding the Skilled Nursing Facility (SNF) 3-Day Rule Waiver.
- Removing the Decarbonization and Resilience Initiative.

We are also soliciting comment, but not proposing updates, in the following policy areas:

- Indian Health Service (IHS) hospital outpatient episodes.
- Low volume hospitals;.
- Standardized prices and reconciliation amounts; and.
- Primary care services referral requirement.

The policies in this proposed rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

b. Statutory Authority and Background

Under the authority of section 1115A of the Act, through notice-and-comment rulemaking, the CMS Innovation Center established TEAM in the FY 2025 IPPS/LTCH PPS final rule that appeared in the August 28, 2024, **Federal Register** (89 FR 69626 through 69879). The intent of TEAM is to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: CABG, LEJR, major bowel procedure, SHFFT, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries.

[426] *https://hbr.org/2022/09/how-to-use-digital-health-data-to-improve-outcomes.*

[427] *https://pubmed.ncbi.nlm.nih.gov/39221336.*

[428] *https://pubmed.ncbi.nlm.nih.gov/32258941.*

[429] *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

Under Traditional Medicare, Medicare makes separate payments to providers and suppliers for the items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, providers may not be incentivized to invest in quality improvement and care coordination activities. As a result, care may be fragmented, unnecessary, or duplicative. By holding hospitals accountable for all items and services provided during an episode, providers would be better incentivized to coordinate patient care, avoid duplicative or unnecessary services, and improve the beneficiary care experience during care transitions.

Under TEAM, all acute care hospitals, with limited exceptions, located within the Core Based Statistical Areas (CBSAs) that CMS selected for model implementation will be required to participate in TEAM. CMS allowed a one-time opportunity for hospitals that participate until the last day of the last performance period in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model or the last day of the last performance year of the Comprehensive Care for Joint Replacement (CJR) Model, that are not located in a mandatory CBSA selected for TEAM participation, to voluntarily opt into TEAM. TEAM will have a 1-year glide path opportunity that will allow TEAM participants to ease into full financial risk as well as three different participation tracks to accommodate different levels of financial risk and reward. Track 1 is an upside only risk track available for all TEAM participants in the first performance year and available to safety net hospitals for the first three performance years. Track 2 is a two-sided risk track that has lower financial risk and reward, relative to Track 3, and will be available to select TEAM participants in performance years 2 through 5.[430] Track 3 is a two-sided risk track that has higher financial risk and reward, relative to Track 2, and will be available to all TEAM participants in performance years 1 through 5.

Episodes will include non-excluded Medicare Parts A and B items and services and will begin with an anchor hospitalization or anchor procedure and would end 30 days after hospital discharge. TEAM participants will continue to bill Medicare FFS as usual for items and services delivered to beneficiaries in an episode but will receive preliminary target prices for episodes prior to each performance year. Target prices will be based on three years of baseline data, prospectively trended forward to the relevant performance year, and calculated at the level of Medicare Severity Diagnosis Related Group/Healthcare Common Procedure Coding System (MS–DRG/HCPCS) episode type and region. Target prices will also include a discount factor and risk-adjustment. Participants will receive reconciliation (final) target prices that will incorporate a capped retrospective trend factor adjustment and a capped normalization factor.

Performance in the model will be assessed by comparing TEAM participants' actual Medicare FFS spending during a performance year to their reconciliation target price as well as by assessing performance on selected quality measures. TEAM participants may earn a payment from CMS, subject to a quality performance adjustment, if their spending is below the reconciliation target price. TEAM participants may owe CMS a repayment amount, subject to a quality performance adjustment, if their spending was above the reconciliation target price.

2. TEAM Provisions of This Proposed Rule

a. Participation

(1) Background

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69642) we indicated that testing TEAM will help us understand the impact of a mandatory episode-based payment model in selected geographic areas for acute care hospitals that initiate the episode categories included in the model. We stated that implementing TEAM among acute care hospitals in select geographic areas will allow CMS and TEAM participants to gain experience testing and evaluating an episode-based payment approach for certain episodes furnished by hospitals with a variety of historic utilization patterns; roles within their local markets, including with regard to accountable care organization participation or affiliation; volume of services provided; access to financial, community, or other resources; and population and health care provider density. Further, Medicare beneficiaries and providers in certain areas, such as rural areas, can be underrepresented in voluntary models, whereas under a mandatory model we have the ability to include these entities, with safeguards as appropriate, for participation so that all beneficiaries have access to care redesign approaches intended to improve the quality care, and such providers gain experience in value-based care. Lastly, we noted that participation of hospitals in selected geographic areas will allow CMS to test episode-based payments without introducing participant attrition or selection bias such as the selection bias inherent in the BPCI Advanced model due to self-selected participation in the model and self-selection of episode categories.

(2) Mandatory Participation

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69642), we defined two ways that an acute care hospital could be designated as a TEAM participant. First, a hospital is a TEAM participant if it initiates episodes and is paid under the IPPS with a CMS Certification Number (CCN) primary address located in one of the mandatory CBSAs selected for participation in TEAM. Second, a hospital that participates in either the Bundled Payments for Care Improvement Advanced (BPCI Advanced) Model or the Comprehensive Care for Joint Replacement (CJR) Model until the last day of the last performance period [or last performance year] of the respective model may voluntarily opt into TEAM participation.

These criteria for TEAM participants did not include any temporal restrictions, leading to potential uncertainty regarding the TEAM participant status of hospitals that open before or during the model performance period, which is defined at § 512.505 as the 60-month period from January 1, 2026, to December 31, 2030, during which TEAM is being tested and the TEAM participant is held accountable for spending and quality. Additionally, there was also uncertainty regarding TEAM participant status in circumstances where a hospital that previously did not satisfy the definition of TEAM participant later meets the definition criteria in the months before or during the model performance period. For example, this scenario would apply to a hospital that was previously not paid under the IPPS but then underwent a status change such that the hospital is no longer classified as a critical access hospital (CAH), as defined in section 1861(mm)(1) of the Act, or a hospital that terminated their participation in the Rural Community Health Demonstration (RCHD).[431] Further, we recognize that there may be instances where a hospital no longer satisfies the definition of TEAM

[430] TEAM participants eligible for Track 2 include safety net hospitals, rural hospitals, Medicare dependent hospitals, Sole Community Hospitals, and Essential Access Community Hospitals, all defined at § 512.505.

[431] *https://www.cms.gov/priorities/innovation/innovation-models/rural-community-hospital.*

participant during the model performance period, such as a hospital joining the RCHD or a hospital converting to a CAH.

We also note that our existing policy at § 512.550(b)(2) provides for separate TEAM reconciliation calculations for TEAM participants that experience a reorganization event, as defined at § 512.505, including any new TEAM participant that results from a reorganization event. However, this policy does not address new hospitals that open in TEAM mandatory CBSAs independently of a reorganization event.

We recognize that new hospitals that open shortly before or during the model performance period, as well as hospitals that begin to satisfy the definition of TEAM participant shortly before or during the model performance period, and that would otherwise be required to participate in TEAM based on their receipt of payment under IPPS and their geographic location, may experience multiple disadvantages relative to other TEAM participants. First, because the list of mandatory CBSAs was published as part of the FY 2025 IPPS/LTCH PPS final rule on August 1, 2024 (89 FR 69706), and a preliminary TEAM participant list was published to the TEAM public web page on September 5, 2024, the TEAM participants in existence at that time have been afforded an opportunity to prepare for TEAM prior to the beginning of the model performance period on January 1, 2026. Based on previous and current episode-based payment models like BPCI Advanced and CJR models, we recognize that hospitals may engage in a number of care redesign activities and processes in order to achieve successful model outcomes, and that new hospitals that open shortly before or during the model performance period, as well as hospitals that begin to satisfy the definition of a TEAM participant shortly before or during the model performance period, may be at a relative disadvantage by not having comparable advance notice to engage in preparatory care redesign activities or otherwise prepare for the model. Second, to accommodate the varying levels of readiness among TEAM participants at the beginning of the model performance period, we have provided participation track options which allow TEAM participants to phase in financial risk based on performance year (PY). Eligibility for Track 1, which has no downside risk, is available to all TEAM participants in PY 1 and to safety net hospitals in PYs 1 through 3. As a result, if new hospitals were to become TEAM participants during or after PY 1, they would not be afforded the same opportunity to participate in a track with no downside risk for at least 1 year prior to assuming greater levels of financial risk.

In this proposed rule, we propose to establish a cutoff date after which new hospitals and hospitals that begin to meet the definition of a TEAM participant and that are located in a mandatory CBSAs, excepting any new hospitals resulting from a reorganization event, would not be required to participate immediately in the model and would have a limited deferment period before beginning their participation in TEAM. Therefore, we are proposing that any new hospital, as identified by Medicare ID (CMS Certification Number—CCN) with an initial effective date after December 31, 2024, within the Medicare Provider Enrollment, Chain, and Ownership System (PECOS), excepting any new hospital that is created as part of a reorganization event as defined at § 512.505, would not be required to participate in TEAM immediately and would have at least one full performance year of participation deferment before being required to participate in the model. We also propose that any hospital that begins to satisfy the definition of TEAM participant after December 31, 2024, would not be required to participate in TEAM immediately and would have at least one full performance year of participation deferment before being required to participate in the model. Specifically, we propose that any new hospital located in a mandatory CBSA, and any hospital located in a mandatory CBSA that begins to meet the definition of TEAM participant after December 31, 2024, would not be required to participate in TEAM in the performance year when their Medicare ID initially became effective or when they began to meet the definition of TEAM participant, or the performance year thereafter. Rather, these hospitals would be required to participate in TEAM starting on January 1st of the subsequent performance year. For example, if a hospital opened in a mandatory CBSA with a Medicare ID initial effective date on June 1, 2026, then that hospital would not be required to begin participation in TEAM until January 1, 2028 (PY 3). Likewise, if a hospital located in a mandatory CBSA terminated their participation in the RCHD effective on August 1, 2027, then they would not be required to begin participation in TEAM until January 1, 2029 (PY 4). We believe this proposed policy would allow new hospitals and hospitals that begin to meet the definition of TEAM participant sufficient time to focus on establishing their care processes and ensuring their ability to comply with TEAM policies and requirements before being required to participate in TEAM. Specifically, the proposed cutoff date of December 31, 2024, would provide all new or newly qualifying hospitals with at least 1 year and not more than 2 years to prepare for the model, thereby establishing a level playing field with hospitals that have had the opportunity to prepare for model implementation since the publication of the preliminary TEAM participant list on the TEAM public web page on September 5, 2024.

As mentioned previously, this proposal would not affect the existing policy at § 512.550(b)(2) to conduct separate reconciliations for each hospital entity that results from a reorganization event as defined at § 512.505.

We are also proposing that a hospital that no longer satisfies the definition of TEAM participant would end TEAM participation effective the date they no longer satisfy the definition. We believe it is important to only allow hospitals that satisfy the definition of TEAM participant to participate in TEAM, otherwise it may introduce issues with pricing fairness and episode attribution. For example, since Medicare payments to CAHs and to hospitals participating in the RCHD are based on reasonable costs rather than traditional FFS, TEAM's pricing methodology may not afford these hospitals the same opportunity for savings compared to hospitals paid under FFS. Additionally, since TEAM's sampling and pricing methodologies were devised based on acute care hospitals paid under the IPPS, allowing additional hospitals that do not meet these criteria to participate in TEAM could result in changes to the TEAM sample in terms of geographic location and expected episode volume. We also propose that CMS would notify the hospital that no longer met the definition of TEAM participant within 30 days of the hospital no longer meeting the TEAM participant definition or as soon as is reasonably practicable. For example, if a TEAM participant was classified as a CAH on April 1, 2026, then their last day participating in TEAM would be March 31, 2026, and CMS would notify the hospital that they are no longer a TEAM participant by April 30, 2026, or as soon as is reasonably practicable. We recognize that this proposed policy may present an opportunity for hospitals to avoid mandatory participation in TEAM. However, we do not believe this policy would affect many hospitals

given the stringent requirements to convert to a non-IPPS hospital type, such as a CAH, or to participate in the RCHD. Irrespective of the potentially small impact, we would monitor for concerns of participation gaming.

We considered proposing that new hospitals, as identified by a Medicare ID initial effective date after December 31, 2024, within the Medicare PECOS, excepting any new hospital that is created as part of a reorganization event as defined at § 512.505, and hospitals that begin to satisfy the definition of TEAM participant after December 31, 2024, would not be required to participate in TEAM. However, we believe it important that new hospitals are exposed to value-based care early on to promote adoption of standard care practices and efficient processes.

We also considered proposing that new hospitals, as identified by a Medicare ID initial effective date after December 31, 2024, within the Medicare PECOS, excepting any new hospital that is created as part of a reorganization event as defined at § 512.505, and hospitals that begin to satisfy the definition of TEAM participant after December 31, 2024, would be required to participate in the first full performance year following their Medicare ID initial effective date or the date when they began to satisfy the TEAM participant definition. We considered allowing those hospitals to participate with no downside risk for that first performance year and then requiring them to participate in the subsequent performance year in one of the participation tracks, as applicable depending on their eligibility under the participation track requirements. However, we believe requiring the hospitals to participate in the first full performance year, even with no downside financial risk, would not provide sufficient opportunity for them to prepare for the participation requirements. That is because, while the hospitals would not have downside financial risk during the first year, they would still need to comply with other model requirements which could be challenging to meet in addition to all the Medicare conditions of participation.

We recognize that a deferred participation policy or a policy that excludes new hospitals within mandatory CBSAs could provide an opportunity for patient shifting. For example, a TEAM participant or affiliated provider could refer patients who are anticipated to need costly treatments or require extensive and potentially expensive follow-up care to a non-participating hospital. We believe that such patient shifting would run counter to the goals of the model as discussed at 89 FR 69631. We anticipate this practice would be unlikely to occur given our belief that TEAM participants would make medically appropriate decisions for beneficiaries and that the frequency of new hospitals opening during the performance period would be low. However, we recognize that the introduction of deferred participation for new hospitals in TEAM mandatory CBSAs could present an opportunity for such patient shifting. As a result, we propose to monitor specifically for the potential shifting of patients with high anticipated episode spending from TEAM participants to non-participant hospitals. We also note that, based on experience with prior models, we anticipate the opening of new hospitals within selected mandatory CBSAs during the TEAM performance period to be a relatively rare occurrence. As a result, we anticipate that the proposed policy will not affect a large number of hospitals.

We considered, but are not proposing, including as TEAM participants and requiring immediate participation from any new hospitals in TEAM mandatory CBSAs, as identified by a Medicare ID (CMS Certification Number) with an initial effective date after December 31, 2024, within PECOS and hospitals that begin to satisfy the definition of TEAM participant after December 31, 2024. As discussed previously, we believe that such hospitals would be placed at a disadvantage in terms of their performance in TEAM if they were not afforded the same opportunities to prepare for the model and phase in financial risk. We also considered, but are not proposing, alternative cutoff dates for the inclusion of hospitals as TEAM participants without a deferment period, including June 30, 2025, December 31, 2025, and December 31, 2026. While a cutoff date of June 30, 2025, would provide new or newly qualifying hospitals with at least six months to prepare for model implementation in 2025, including receipt and analysis of baseline claims and preliminary target price data from CMS, we recognize that these hospitals, especially those that open shortly before the cutoff date, could be disadvantaged relative to hospitals that have had at least one year to prepare for model implementation. We also recognize that a cutoff date at the end of 2025 could result in the same disadvantage from a lack of preparation time, and that a cutoff date at the end of 2026 could result in this same disadvantage, as well as the disadvantage of missing the opportunity to participate without downside risk in PY 1.

Lastly, we considered but are not proposing requiring new hospitals in mandatory CBSAs, as identified by Medicare ID (CMS Certification Number) with an initial effective date after December 31, 2024, within PECOS and hospitals that begin to satisfy the definition of TEAM participant after December 31, 2024, to participate in TEAM either 1 year or 2 years after their Medicare ID initial effective date or from the date they begin to satisfy the definition of TEAM participant. However, TEAM's performance years run on a calendar year basis, and a new hospital Medicare ID effective date or the date when a hospital begins to satisfy the definition of TEAM participant would not generally fall on January 1st of a calendar year, which can make including them as a TEAM participant after the performance year has started challenging. Many model requirements, like participation track decisions and submission of certain deliverables, occur prior to the beginning of each performance year and apply to the entire performance year, which may disadvantage hospitals if they started after the performance year begins.

We seek comment on our proposal at § 512.508 to require new hospitals that open in a mandatory CBSA as indicated by a Medicare ID initial effective date after December 31, 2024, and hospitals located in a mandatory CBSA that begin to satisfy the definition of TEAM participant after December 31, 2024, to participate in TEAM after one full performance year has passed from their Medicare ID initial effective date or the date when they begin to satisfy the definition of TEAM participant, respectively. We also seek comment on our proposal to monitor specifically for the potential shifting of patients with high anticipated episode spending from TEAM participants to non-participant hospitals. We also seek comment on whether or how this policy could affect the business decision of opening a new hospital even when there is patient need in the service area where the new hospital would be opened.

(3) Medicare Dependent Hospital Status

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we designated hospital types that are eligible for participation in Track 2, which offers lower levels of upside and downside financial risk relative to Track 3, for PYs 2 through 5. As stated at 89 FR 69657, we believe that certain TEAM participants may benefit from a participation option that has limited

two-sided financial risk so that their beneficiaries may receive high quality, coordinated care without imposing significant financial pressure.

The hospital types designated for Track 2 eligibility are safety net hospitals, rural hospitals, Medicare dependent hospitals (MDHs), sole community hospitals (SCHs), and essential access community hospitals. Section 1886(d)(5)(G)(iv) of the Act defines a MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in 2 of its 3 most recently settled Medicare cost reporting years). For additional information on the MDH program and proposals in this rulemaking, we refer readers to section VI.E. of the preamble of this proposed rule. The Consolidated Appropriations Act, 2024 (CAA, 2024) (Pub. L. 118–42), enacted on March 9, 2024, extended the MDH program. Specifically, section 307 of the CAA, 2024, extended the MDH program under section 1886(d)(5)(G) of the Act through December 31, 2024. Subsequently, section 3202 of the American Relief Act, 2025 (ARA, 2025) (Pub. L. 118–158), enacted on December 21, 2024, extended the MDH program for FY 2025 discharges occurring before April 1, 2025. Most recently, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4), enacted on March 15, 2025, extended the MDH program, amongst other changes, for FY 2025 discharges occurring before October 1, 2025. Because the MDH program is not authorized by statute beyond September 30, 2025, beginning October 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.

We recognize the end of the MDH program on September 30, 2025, affects Track 2 participation eligibility. However, we also acknowledge that, historically, Congress has extended the MDH program, and in some instances retroactively reinstated the program. Therefore, we are proposing that TEAM participants who are classified as MDHs would still be eligible for Track 2 participation as long as the MDH program is active at the time that participation track selections are due to CMS. As described in § 512.520(b)(2), TEAM participants must notify CMS of its Track 2 selection prior to the performance year in a form and manner and by a date specified by CMS. For example, if CMS requests participation track selections by November 15, 2026, for PY 2 and the MDH program was set to expire on December 31, 2026, then TEAM participants with a MDH classification that submit their Track 2 selection by November 15, 2026, would be eligible for Track 2 for PY 2, regardless of whether the MDH program was active in PY 2. In contrast, using the previous scenario except that the MDH program expired on June 30, 2026, no TEAM participant could use their previous MDH classification for eligibility to participate in Track 2 for PY 2 because the MDH program was not active as of the deadline by which CMS requested participation track selections. We note this proposal would not affect Track 2 eligibility for TEAM participants that meet the definition of safety net hospitals, rural hospitals, SCHs, or essential access community hospitals, as defined in § 512.505.

We believe that tying the eligibility for Track 2 participation for TEAM participants that have a MDH classification to the expiration of the MDH program allows TEAM participants to still take advantage of Track 2 participation while acknowledging that the MDH program is not indefinite. We anticipate that if the MDH program is not extended, then there would be minimal impact on Track 2 eligibility for this lower-risk participation track due to the overlap between the MDH classification as defined at § 412.108 and TEAM's rural hospital definition, as defined at § 512.505. Per § 412.108, a necessary criterion for MDH classification is location in a rural area, which means any area outside an urban area as defined at § 412.64, or, for hospitals located in a State with no rural area, satisfaction of any of the criteria for reclassification as rural as described in § 412.103(a)(1) through (3) (65 FR 47048). For the purposes of TEAM, rural hospital is defined as an IPPS hospital that meets one of the following criteria:

- Is located in a rural area as defined under § 412.64.
- Is located in a rural census tract defined under § 412.103(a)(1).

Qualification as rural under § 412.64 encompasses all hospitals not located in an urban area, meaning a Metropolitan Statistical Area or a Metropolitan Division (in the case where a Metropolitan Statistical Area is divided into Metropolitan Divisions), as defined by the Office of Management and Budget (69 FR 49242). Qualification as rural under § 412.103(a)(1) encompasses all hospitals located in a rural census tract of a Metropolitan Statistical Area as determined under the most recent version of the Goldsmith Modification,[432] 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), which is available at the web link provided in the most recent **Federal Register** notice issued by HRSA defining rural areas (65 FR 47048). For the purposes of TEAM, a hospital's qualification as rural on the basis of location in a rural census tract as defined under § 412.103(a)(1) is determined by location of the hospital's primary CCN within a rural census tract as defined under § 412.103(a)(1), regardless of whether the hospital has applied for and received rural reclassification from CMS under § 412.103.

Since these two pathways to rural hospital designation cover both hospitals located outside of an urban area and hospitals located in a rural census tract within an urban area, we anticipate that a large proportion of hospitals that would have been designated as MDHs, and thus would have been eligible for participation in Track 2 during the TEAM performance period will continue to be eligible for participation in Track 2 due to rural hospital status.

We considered, but are not proposing, continuing to classify hospitals in TEAM based on the existing MDH criteria beyond the expiration of the MDH program. While this option would maintain the list of Track 2-eligible hospitals as originally finalized in the FY 2025 IPPS/LTCH PPS final rule at § 512.520(b)(4), we do not believe that it would be appropriate for TEAM to maintain hospital designations that are no longer maintained in Medicare more broadly. We also note that § 412.108(b)(1) states that the Medicare Administrative Contractor (MAC) determines whether a hospital meets the criteria for MDH designation as specified in § 412.108(a), and that § 412.108(b) establishes classification procedures for MDH status (55 FR 15175). As a result, we do not believe that it would be appropriate for CMS to circumvent these established procedures for the purposes of TEAM.

[432] The Goldsmith Modification was originally developed and used to identify rural Census tracts in large metropolitan counties. For additional information regarding the Goldsmith Modification, we direct readers to: *https://www.ruralhealthinfo.org/pdf/improving-the-operational-definition-of-rural-areas.pdf.*

We have also considered and are seeking comment on, but not proposing, the potential for CMMI to provide support to TEAM participants that were designated as MDHs until the termination of the MDH designation, with such support including providing technical assistance in helping them determine their eligibility for other Track 2-eligible hospital designations, including rural and SCH. Such support may be necessary as the TEAM participant may not be aware of other hospital designations they may be eligible for given their potential long-standing participation in the MDH program. Table XI.A.–01 identifies the potential impact on TEAM participants if the MDH program were to expire. While we recognize that hospitals with MDH designation may qualify for other hospital designations that are eligible to participate in Track 2 for PY 2 through 5 of TEAM, we also note that provision of such assistance to TEAM participants could unfairly disadvantage non-participant hospitals that do not receive the same support from CMS.

TABLE XI.A.–01—ESTIMATED VOLUME OF HOSPITALS IMPACTED BY THE MEDICARE DEPENDENT HOSPITAL PROGRAM IN TEAM

Estimated number of TEAM participants	741
Estimated number of TEAM participants with a MDH designation	25
Estimated number of TEAM participants with a MDH designation that may also be eligible for Track 2 participation because they are a safety net hospital, rural hospital, Sole Community Hospital, or Essential Access Community Hospital, as defined at § 512.505	21
Estimated number of TEAM participants that have the MDH designation that may not be eligible for Track 2 participation if the MDH program expires	4

We seek comment on our proposal to determine MDHs' eligibility for Track 2 participation in TEAM based on the hospitals' status in the MDH program on the date CMS requires the TEAM participants to submit their track selections for the upcoming PY. We also seek comment on the potential for us to provide support to TEAM participants whose MDH designation ended as a result of the expiration of the MDH program in determining their eligibility for other hospital designations, such as rural and SCH, that are eligible for participation in Track 2 in PY 2 through 5 of TEAM.

(4) Indian Health Services/Tribal Hospitals

As indicated earlier in section XI.A.2.a.(1). of the preamble of this proposed rule, and defined at § 512.505, for a hospital to be a TEAM participant they must either—(1) initiate episodes and be paid under the IPPS with a CMS Certification Number (CCN) primary address located in one of the mandatory CBSAs selected for participation in TEAM; or (2) be a hospital that participates in either the BPCI Advanced Model or the CJR Model until the last day of the last performance period or last performance year of the respective model that voluntarily opts into TEAM and CMS approves their opt in request. We have received questions about Indian Health Service (IHS)/Tribal hospitals, as identified in section 1880 of the Act, participating in TEAM. In the FY2025 IPPS/LTCH PPS final rule, we discussed certain hospitals that would be ineligible for participation in TEAM due to not being paid under the IPPS and Outpatient Prospective Payment System (OPPS) (89 FR 69643). Specifically, hospitals located in the state of Maryland are precluded from being TEAM participants. We did not exempt IHS/Tribal hospitals from TEAM participation because IHS/Tribal hospitals are still paid under the IPPS. However, we note that IHS/Tribal hospitals are not paid under the OPPS, as described in § 419.20. While the TEAM participant definition does not explicitly state a hospital needs to be paid under the OPPS to participate in the model, we recognize that allowing hospitals to participate in TEAM that are not paid under the OPPS may create challenges when constructing target prices for episodes that initiate in the hospital outpatient department, specifically for the LEJR and spinal fusion anchor procedures.

As described in section XI.A.2.c.(1) of the preamble of this proposed rule, TEAM participants will be provided with target prices for each MS–DRG/HCPCS episode type. These target prices will be calculated using three years of baseline data, trended forward to the performance year, at the level of MS–DRG/HCPCS episode type and region, with updates to be made using the performance year data during the reconciliation process. While TEAM's target prices are constructed using regional level spending and would allow IHS/Tribal hospitals to receive a target price, including LEJR and spinal fusion target prices, there is concern on whether these target prices would accurately reflect the IHS/Tribal hospital's episode spending or allow them opportunity to achieve a reconciliation payment amount. That is because their historical spending for episodes initiated in the hospital outpatient department, specifically the hospital spending portion, would not be included in the regional spending since they are not paid under the OPPS, but rather Medicare pays them under an All-Inclusive Rate (AIR). All-inclusive rates are billed by encounter, which means the calculation of a rate accounts for all of the allowable costs of providing care. This differs from traditional fee-for-service rates, where specific services are billed at specific rates, even if more than one service is provided during an encounter.[433] Therefore, it may be possible that IHS/Tribal hospital outpatient spending could be lower (or higher) compared to other hospitals in the same region. Since the regional target prices are constructed from IPPS and OPPS hospital spending, Medicare may be at risk for setting the LEJR and spinal fusion regional target prices too high or too low for IHS/Tribal hospitals, with the latter scenario making it more challenging for them to reduce LEJR and spinal fusion spending.

Given this concern, we considered but are not proposing to exclude IHS/Tribal hospitals from initiating anchor procedures. Specifically, we considered updating § 512.525(b) to not allow IHS/Tribal hospitals that are TEAM participants to have anchor procedure episodes attributed to them. This would mean that IHS/Tribal hospitals would not be able to initiate or have episodes attributed to them for LEJR and spinal fusions in the hospital outpatient department but would be able to initiate anchor hospitalizations, including LEJR and spinal fusion anchor

[433] *https://www.cms.gov/training-education/partner-outreach-resources/american-indian-alaska-native/ltss-ta-center/information/ltss-financing/comparing-reimbursement-rates#:~:text=*%20All%2Dinclusive%20rates%20are%20billed%20by%20encounter%2C,one%20service%20is%20provided%20during%20an%20encounter.*

hospitalizations. We believe this option would mitigate some of the concern with respect to regional prices being reasonable for IHS/Tribal hospitals. While we recognize that this could open an opportunity for patient shifting, given that episodes could be initiated in the inpatient setting but not the hospital outpatient department, we believe that the generally lower AIR, relative to IPPS rates, may disincentivize such actions. Nonetheless, given the potential incentive for patient shifting if IHS/Tribal hospitals were only accountable for episode categories in one setting, we considered additional monitoring for IHS/Tribal hospitals in TEAM but believe the existing monitoring requirements, as described in § 512.590, would be sufficient given the broad scope of monitoring requirements and the ability to impose a remedial action, as described in § 512.592, if warranted.

We also considered, but are not proposing, to exclude IHS/Tribal hospitals from initiating episode categories that include both anchor hospitalizations and anchor procedures. Specifically, we considered adding a provision to § 512.525 that would exclude TEAM participants that are IHS/Tribal hospitals from the LEJR and spinal fusion episode categories. In other words, IHS/Tribal hospitals would not be eligible to initiate an anchor hospitalization or anchor procedure in the LEJR or spinal fusion episode category. This option would mitigate the potential concern for patient shifting and avoid the challenges of ensuring an accurate target price for IHS/Tribal hospitals. However, we are concerned that such an option would limit IHS/Tribal hospitals participation in the model given the volume of episodes associated with the LEJR and spinal fusion episode categories, thus reducing the number of beneficiaries that would be captured in the model.

We also considered, but are not proposing, to exclude IHS/Tribal hospitals from the model, such that they would not satisfy the definition of TEAM participant. This would be done by updating the TEAM participant definition to state that a TEAM participant must be paid under IPPS and OPPS. We recognize this consideration may not have a significant impact on the model with respect to episode volume. That is because we are aware that some IHS/Tribal hospitals may not perform the procedures tested in TEAM at their hospital but may be a part of a beneficiary's follow-up care. In those instances, the IHS/Tribal hospital would not initiate an episode in TEAM because the anchor hospitalization or anchor procedure did not initiate at the IHS/Tribal hospital. However, we are concerned that fully excluding IHS/Tribal hospitals from TEAM, particularly for those IHS/Tribal hospitals that initiate anchor hospitalizations or anchor procedures, would limit beneficiary access to the potential benefits of the model, including high-quality coordinated care, and prevent IHS/Tribal hospitals from gaining value-based care experience.

We also considered, but are not proposing, constructing IHS/Tribal hospital specific target prices for anchor procedures. This would also help to ensure that IHS/Tribal hospitals have reasonable target prices for anchor procedures. However, we recognize that creating an IHS/Tribal hospital specific target price would increase the target price calculation complexity, making it more challenging for IHS/Tribal hospitals to understand the methodology and predict their episode spending.

Lastly, we also considered, but are not proposing, to include IHS/Tribal hospitals as a hospital type eligible for Track 2 participation. However, we also believe many IHS/Tribal hospitals may already satisfy eligibility requirements for Track 2 due to being a safety net hospital or a rural hospital.

We seek comment on the alternatives we considered for IHS/Tribal hospitals. We also seek comment on alternatives that we may not have considered.

b. Quality Measures

(1) Background

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), Medicare payment policy has moved away from FFS payments that are not linked to quality of care. Through the Medicare Modernization Act and the Affordable Care Act, we have implemented specific IPPS programs like the Hospital Inpatient Quality Reporting (IQR) Program (section 1886(b)(3)(B)(viii) of the Act), the Hospital Value-Based Purchasing (VBP) Program (subsection (o) of section 1886), the Hospital-Acquired Condition (HAC) Reduction Program (subsection (q) of section 1886), and the Hospital Readmissions Reduction Program (subsection (p) of section 1886), where payment reflects the quality of care delivered to Medicare beneficiaries.

TEAM's quality measures focus on care coordination, patient safety, and patient reported outcomes (PROs) which we believe represent areas of quality that are particularly important to patients undergoing acute procedures. Wherever possible, we align TEAM quality measures with those used in ongoing models and programs to minimize participant burden, recognizing that introducing new reporting functions and requirements in a mandatory model would create additional burden. Hospitals are not required to report quality data separately to CMS for TEAM. CMS will use data already reported through existing CMS quality reporting programs, thereby avoiding duplicative reporting requirements. We aim to use quality measures in which all hospitals would have access and experience.

We finalized in the FY 2025 IPPS/LTCH PPS final rule a set of quality measures tied to payment, with these measures scored to calculate the Composite Quality Score (CQS). The CQS would be combined with the TEAM participants' reconciliation amount during the reconciliation process to tie quality performance to payment. The finalized set of TEAM quality measures have been summarized in Table XI.A.–02.

TABLE XI.A.–02—TEAM QUALITY MEASURES BY PERFORMANCE YEAR

FY 2025 IPPS/LTCH PPS Finalized TEAM Quality Measures		
Performance Year 1	All Episode Categories	Hybrid Hospital-Wide All-Cause Readmission measure (CMIT ID #356).
Performance Year 1	All Episode Categories	CMS Patient Safety and Adverse Events Composite (CMIT ID #135).
Performance Year 1	Lower Extremity Joint Replacement Episodes.	Hospital-Level Total Hip and/or Knee Arthroplasty (THA/THK) Patient Reported Outcome Based Measure (CMIT ID #1618).
Performance Year 2–5	All Episode Categories	Hospital Harm—Fall with Injury (CMIT ID #1518).
Performance Year 2–5	All Episode Categories	Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788).

TABLE XI.A.–02—TEAM QUALITY MEASURES BY PERFORMANCE YEAR—Continued

Performance Year 2–5	All Episode Categories	Thirty-Day Risk—Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Compilations Mortality Rate)) (CMIT ID #134).

For performance year 1, we proposed and finalized three quality measures (noted later in this section) due to their: (1) alignment with the goals of TEAM; (2) hospitals' familiarity with the measures due to their use in other CMS hospital quality programs, including the Hospital IQR and HAC Reduction Programs; and (3) alignment to CMS priorities, including the CMS National Quality Strategy, which has goals that support safety, outcomes, and engagement. We believe these three TEAM PY1 quality measures that link to payment reflect these goals and accurately measure hospitals' level of achievement on such goals.

These PY1 measures are:

- For all TEAM episodes: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356);
- For all TEAM episodes: CMS Patient Safety and Adverse Events Composite (CMS PSI 90) (CMIT ID #135); and
- For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618).

Additionally, we proposed and finalized inclusion of three measures that were included in the Measures Under Consideration List (known as the MUC List) that were subsequently finalized (89 FR 69540 and 89 FR 69552), starting in PY 2 (2027), and will replace the PSI 90 measure. These three measures are as follows:

- For all TEAM episodes: Hospital Harm—Falls with Injury (CMIT ID #1518) (starting in PY 2).
- For all TEAM episodes: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) (starting in PY 2).
- For all TEAM episodes: Thirty-day Risk—Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Compilations Mortality Rate) (CMIT ID #134) (starting in PY 2).

The Inpatient Surgical Complications Mortality Rate measure began mandatory reporting with the July 1, 2023–June 30, 2025, reporting period, while the other two (Hospital Harm—Falls with Injury and Hospital Harm—Postoperative Respiratory Failure) are available on the list of eCQMs from which hospitals must select to report three beginning with the CY2026 reporting period. This timeline will allow TEAM participants to have 1 year to gain experience reporting all three of these measures in the Hospital IQR program before their performance is tied to payment beginning in TEAM's second performance year (2027).

While we believe the TEAM quality measure set would provide CMS with sufficient measures to monitor quality and to calculate scoring on quality performance, we stated that we may adjust the measure set in future performance years, via rulemaking, by adding new measures or removing measures if we determine those adjustments to be appropriate at the time. In this proposed rule, we are proposing several changes to and clarifications around the TEAM quality measure set finalized in the FY 2025 IPPS/LTCH PPS final rule.

(2) Alignment of Hybrid Hospital-Wide Readmission Measure to Hospital IQR Program

As stated previously, TEAM aims to, whenever possible, align measures with existing reporting requirements so as not to introduce additional burden to participants. This includes aligning the TEAM Hybrid Hospital-Wide Readmission (HWR) Measure reporting requirements with what is required under the Hospital Inpatient Quality Reporting (IQR) Program. The Hybrid HWR measure combines claims data with electronic health record (EHR) data to risk-adjust hospital readmission rates, accounting for patient severity and illness at admission. The Hospital IQR Program initially planned that the Hybrid HWR measure would be mandatory, beginning with the July 1, 2023–June 30, 2024, reporting period. However, after public feedback on reporting difficulties, the Hospital IQR Program finalized in the CY 2025 Hospital OPPS Final Rule (89 FR 93912) the continuation of voluntary reporting of the clinical data elements for the Hybrid HWR for the July 1, 2023, through June 30, 2024, reporting period and the July 1, 2024, through June 30, 2025, reporting period. Mandatory reporting will begin the following reporting period (July 1, 2025, through June 30, 2026), impacting TEAM's PY 1. Additionally, CMS has recognized public input regarding the difficulties in reporting the clinical data elements and is proposing in section X.C. of the preamble of this proposed rule the following allowances: up to two missing laboratory results; up to two missing vital signs; the reduction of the CCDE (core clinical data elements) submission requirement to 70 percent or more of discharges, and; the reduction of the submission requirement of linking variables to 70 percent or more of discharges.

We recognize that this change means that the first year of mandatory reporting (July 1, 2025, through June 30, 2026) for the Hybrid HWR will serve as the baseline performance period for TEAM's PY1. In order to allow additional time to gain experience with the measure, we considered not aligning with the Hospital IQR Program and delaying mandatory reporting for TEAM for an additional period of time. However, since hospitals will have multiple years of voluntary reporting of the Hybrid HWR measure under the Hospital IQR Program prior to the mandatory requirement, and because the mandatory requirement contains additional allowances, we believe that TEAM participants will have sufficient time to prepare. Additionally, we believe that aligning the TEAM Hybrid HWR measure as closely as possible to the requirements under the Hospital IQR Program will be the most straightforward approach for TEAM participants.

Since TEAM aims to align with the Hospital IQR Program's requirement for the Hybrid HWR, we propose to align with the requirements set forth at 89 FR 93912, including utilizing the mandatory reporting period of July 1, 2025–June 30, 2026, as TEAM's PY1 baseline period, and including the revised submission requirements.

We seek comment on aligning with the Hospital IQR Program, specifically utilizing the first mandatory reporting period of July 1, 2025, through June 30, 2026, as the TEAM PY1 quality measure performance period for the Hybrid HWR measure. Additionally, we also seek comment on alternate considerations, including whether TEAM should not align with the Hospital IQR Program and, as during the voluntary reporting period, only use claims-based elements of the Hybrid HWR for quality measurement.

(3) Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM)

The existing quality measures finalized in TEAM were selected based on their relevance to episode categories tested in the model, while also considering the reporting burden on participants. These measures focus on key domains, including hospital readmissions, patient safety, and patient reported outcomes, which we believe represents areas of quality that are particularly important to patients undergoing acute procedures. We believe that quality measures used in TEAM should address one of these domains, given their importance to patient quality of care and relationship to episode care management.

As stated in FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we wish to incorporate more patient-reported outcome measures (PRO–PMs) into TEAM, as these measures provide valuable insights into the patient's perspective of care received. We also wish to incorporate quality measures that capture care in the outpatient setting, given the LEJR and Spinal Fusion episode categories initiate in the hospital outpatient department (HOPD) setting and all the measures finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) are measures of inpatient performance.

To identify potential quality measures for episode categories initiated in the HOPD, we reviewed quality measures from the CMS Hospital Outpatient Quality Reporting Program (Hospital OQR Program) that align with the domains emphasized in TEAM. To maintain a reasonable volume of quality measures in TEAM, we aimed to identify a single measure that would be clinically meaningful for both the LEJR and Spinal Fusion episode categories, rather than adding separate quality measures for each. We identified one quality measure, the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery, that hospitals are required to report to the Hospital OQR Program, as well as two quality measures that hospitals may voluntarily report: the Risk-Standardized PRO–PM Following Elective Primary THA and/or TKA in the HOPD Setting, and the Information Transfer PRO–PM. We evaluated the suitability of each quality measure for TEAM based on its pros and cons.

- The Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery is applicable to both the LEJR and Spinal Fusion episode categories, focuses on hospital readmissions, and could be included in TEAM for PY1 (CY 2026) given its current mandatory reporting status in the Hospital OQR program. However, it does not advance CMS's or the model's goal of increasing the number of PRO–PMs.
- The Risk-Standardized PRO–PM Following Elective Primary THA and/or TKA in the HOPD Setting aligns well with the existing THA/TKA PRO–PM for inpatient LEJR episodes and would increase the number of PRO–PMs in the model; however, it is only applicable to LEJR episodes, and mandatory reporting for the Hospital OQR Program will not begin until PY3 of TEAM (CY 2028).
- The Information Transfer PRO–PM is applicable to both the LEJR and Spinal Fusion episode categories and would increase the number of PRO–PMs in the model; however, mandatory reporting for the Hospital OQR Program will not begin until PY2 of TEAM (CY 2027).

Since our aim is to create a meaningful and efficient quality measure set, we do not believe it is necessary to include all three measures in TEAM. Given that the Risk-Standardized PRO–PM Following Elective Primary THA and/or TKA in the HOPD Setting measure is only applicable to the LEJR episode category, we do not consider it beneficial to propose this measure for use in TEAM. Of the remaining two measures, we recognize the value of the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery; however, this focuses on hospital readmissions and does not provide the patient viewpoint afforded by PRO–PMs that we are prioritizing capturing in the model. As such, we are proposing the addition of the Information Transfer PRO–PM for all episode categories initiated in the HOPD in TEAM. The Information Transfer PRO–PM can apply to all episode categories initiated in the HOPD under TEAM as it evaluates how well information is transferred to patients after outpatient procedures, particularly in HOPDs. Additionally, this measure captures patient viewpoint afforded by PRO–PMs.

To ensure alignment with the Hospital OQR Program, we propose using the following measure specifications, as detailed and updated here: *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf*. This document outlines key information related to the Information Transfer PRO–PM and highlights the need for improved patient education for post-discharge instructions. The measure was developed by Yale New Haven Services Corporation for CMS and tested across hospital outpatient departments. The goal of this measure is to enhance recovery outcomes by standardizing information transfer. We also propose to include the Information Transfer PRO–PM starting in PY3 (CY 2028) with a CY 2027 CQS baseline period and the following quality measure performance periods as displayed in Table XI.A.–03.

TABLE XI.A.–03—PROPOSED QUALITY MEASURE PERFORMANCE PERIODS BY TEAM PERFORMANCE YEAR

Measure	TEAM performance year				
	1st	2nd	3rd	4th	5th
Information Transfer PRO–PM.	Not Applicable	Not Applicable	CY 2028 (January 1, 2028–December 31, 2028).	CY 2029 (January 1, 2029–December 31, 2029).	CY 2030 (January 1, 2030–December 31, 2030).

We believe that including the Information Transfer PRO–PM in TEAM would enhance the model because it is a general measure not tied to a specific clinical diagnosis or procedure. This flexibility means it could apply to current episode categories initiated in the HOPD and any future episode categories, if proposed and finalized in future rulemaking. We also emphasize the importance of increasing the number of PRO–PMs, as they offer a direct way to incorporate patient input into quality measure performance. We further believe that delaying the inclusion of the Information Transfer PRO–PM until PY3 would allow TEAM participants to gain 1 year of mandatory reporting

experience before the measure is incorporated into TEAM, affecting their composite quality score (CQS) and ultimately their reconciliation amounts. Lastly, similar to the other two measures that we considered but did not propose (THA/TKA PRO–PM and Hospital Visits within 7 Days after Hospital Outpatient Surgery), inclusion of the Information Transfer PRO–PM aligns with those used in ongoing models and programs (this measure aligns with already existing reporting requirements for the Hospital Outpatient Quality Reporting (OQR) Program) and therefore, would not increase TEAM participant burden.

We seek comment on our proposal to include the Information Transfer PRO–PM in TEAM starting in PY 3. We also seek comment on other quality measures, including options for capturing quality of care in the outpatient setting and other PRO–PMs appropriate for TEAM quality measurement.

(4) Approach for When TEAM Participant Has No Quality Measure Performance Data

As was outlined in Table X.A.–09 of the FY 2025 IPPS/LTCH PPS final rule (89 FR 69744), TEAM quality measures will be evaluated against a measure performance period. The measure performance periods are consistent with those used in ongoing models and programs in which TEAM measures align, including the Hospital IQR Program and Hospital-Acquired Condition Reduction Program performance periods, so that there is no additional reporting burden on TEAM participants as a result of the quality measures used in TEAM. However, we recognize it is possible that some TEAM participants may not have a complete measure set during this performance period in which to measure their quality against. For example, a newly established hospital that began seeing Medicare beneficiaries in early 2025 may have no or incomplete quality measure data given the quality measure performance periods for the three quality measures used in PY 1 which rely on quality measure performance periods starting on July 1, 2023, or 2024, through June 30, 2025. Additionally, we recognize some quality measures in TEAM, specifically the Hospital Harm—Falls with Injury (CMIT ID #1518) and the Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) measures, are electronic clinical quality measure (eCQM) available for self-selection in the Hospital IQR Program. This means hospitals are not mandated to report these two measures for the Hospital IQR Program. Therefore, it's possible that a TEAM participant may not select to report those two measures to the Hospital IQR Program, which would result in having no quality measure data for those two measures in TEAM. We still believe it's important to be mindful of TEAM participant burden, and do not want to remove a TEAM participant's ability to self-select those measures. Therefore, having no or incomplete quality measure data may make calculating of the CQS, which is then used to adjust the TEAM participant's reconciliation amount, challenging. The CQS, as described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69744), is the pay-for-performance mechanism that ties quality measure performance to payment, ultimately incentivizing and rewarding cost savings in relation to the quality of episode care provided by the TEAM participant.

The CQS is constructed by converting the TEAM participant's raw quality measure score for the performance year into a scaled quality measure score. TEAM participants that have no or incomplete quality measure data would not have a raw quality measure score, making the conversion to a scaled quality measure score impossible. This would result in a CQS that is only based on the quality measures that had sufficient data to produce a scaled quality measure score or potentially a CQS that could not be calculated if all quality measures had lacked a raw quality measure score. We believe it is important for TEAM participants that may have no or incomplete quality measure data to not be penalized for a lack of quality measure data when they may in fact be providing high quality care to Medicare beneficiaries. Therefore, we propose assigning a neutral quality measure score to TEAM participants with no or an incomplete raw quality measure score for a given quality measure. Specifically, a TEAM participant that does not have a raw quality measure score for a given quality measure would be assigned a scaled quality measure score of 50, which is the midpoint on the CQS scale of 0–100. We believe this approach would not disadvantage a TEAM participant who may be providing high quality care, because this neutral quality measure score ensures providers are not unfairly penalized due to insufficient quality measure data. Once the TEAM participant reaches the threshold for sufficient data to produce raw quality measure data, it will be converted into a scaled quality measure in the subsequent performance year. We considered but are not proposing a policy under which hospitals have to meet certain criteria in order to receive a 50th performance percentile for quality measure when insufficient volume was present. For example, if a hospital had insufficient volume due to failure to report quality data, then they may receive a lower quality score, such as 25th percentile.

This approach to assign participant hospitals a 50th performance percentile of a quality measure when a low volume hospital did not have reportable quality measure values (80 FR 73364) is consistent with the CJR model. Though there is a slight policy difference since this was for CJR hospitals that had a low volume of triggered episodes, the implication of having no or minimal information of quality data is similar, and therefore, why we are proposing to utilize this approach.

We considered, but are not proposing here, a policy under which TEAM participants with no or incomplete quality measure data would receive the average scaled quality measure score across all TEAM participant hospitals for a given quality measure. While we believe this approach may result in a reasonable scaled quality measure score, we have concerns that a TEAM participant's scaled quality measure score is influenced by how well other TEAM participants perform in quality. Therefore, we believe our proposed approach of assigning a scaled quality measure score of 50 would be unbiased and easier to compute.

We seek comment on our proposal at § 512.547(b)(1)(i)(D) to assign a scaled quality measure score of 50 when the TEAM participant has no or an incomplete raw quality measure score for a given quality measure.

c. Pricing Methodology

(1) Background

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) TEAM participants will be provided with target prices for each MS–DRG/HCPCS episode type. These target prices will be calculated using 3 years of baseline data, trended forward to the performance year, at the level of MS–DRG/HCPCS episode type and region, with updates to be made using the performance year data during the reconciliation process. The regions are defined as the nine U.S. census divisions and the MS–DRG/HCPCS episode type is based on the episode categories that will be tested in the model: Coronary Artery Bypass Graft (CABG), Lower Extremity Joint Replacement (LEJR), Major Bowel

Procedure, Surgical Hip Femur Fracture Treatment (SHFFT), and Spinal Fusion.

Episode spending will be capped at the 99th percentile for each of the 29 MSDRG/HCPCS episode types and 9 regions, and the benchmark price will be calculated as the average capped and standardized spending in baseline year 3 dollars for each MS–DRG/HCPCS episode type in each region, resulting in 261 benchmark prices. Benchmark prices will be calculated using all hospitals in a region, regardless of TEAM participation status. CMS will apply a prospective trend factor and a discount factor to benchmark prices. During reconciliation, these preliminary target prices will be updated by updating the trend (subject to caps) and normalization factor (subject to caps) and by factoring in each participant's realized risk adjustment factors.

Risk adjustment factors will be calculated and made available to TEAM participants prior to the start of the performance year, so participants would be able to use them to estimate their episode-level target prices. Risk adjustment factors include age group, Hierarchical Condition Category (HCC) count, and beneficiary social risk as risk adjusters, as well as episode category-specific HCC adjusters and provider-level adjusters. The risk adjustment factors will be calculated at the MS–DRG/HCPCS level on baseline episodes, using a weighted linear regression where episodes are weighted differentially based on whether they belong to year 1, 2, or 3 of the baseline periods. Episodes from baseline year 1 will be weighted at 17 percent, baseline year 2 at 33 percent, and baseline year 3 at 50 percent. The risk adjustment factors will be held fixed and applied to performance year episodes at reconciliation based on the realized case mix of the TEAM Participant in the performance year.

After risk adjusting for the performance year case-mix, CMS will normalize the target prices to ensure that the average of the total risk-adjusted preliminary target price does not exceed the average of the total non-risk adjusted preliminary target price. The final normalization factor will be calculated as the national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type. However, it will be capped should this ratio exceed ±5 percent of the prospective normalization factor. The final target prices will include a retrospective trend factor, which will be capped at being within 3 percent of the prospective trend. The retrospective trend factor will be calculated as the average capped performance year episode spending at the MS–DRG/HCPCS episode type and region level divided by the capped mean baseline episode spending in baseline year 3 dollars at the MS–DRG/HCPCS episode type and region level (that is, national mean benchmark price). Table XI.A.–04 provides a few examples of the calculation of the retrospective trend factor for three MS–DRG/HCPCS regions in which the retrospective trend factor is capped at 3 percent below the prospective trend factor, not capped, and capped at 3 percent above the prospective trend factor, respectively.

TABLE XI.A.–04—EXAMPLE CALCULATING RETROSPECTIVE TREND FACTOR

MS–DRG	Region	Average capped baseline episode spending in BY3 dollars	Prospective trend factor	Average capped performance year episode spending	Retrospective trend factor	Capped retrospective trend factor
231	1	$80,000.00	1.05	$78,400.00	0.98	1.02
232	1	55,000.00	0.95	53,350.00	0.97	0.97
233	1	70,000.00	1.05	78,400.00	1.12	1.08

In summary, the reconciliation (final) target price will be calculated as the product of the capped mean baseline episode spending in baseline year 3 dollars, the capped retrospective trend, the risk adjustment multiplier using the performance year case-mix, and the capped final normalization factor. Table XI.A.–05 provides a few examples of reconciliation target price calculations for a fictional hospital with three MS–DRG/HCPCS and region combinations as finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986).

TABLE XI.A.–05—EXAMPLE CALCULATING RECONCILIATION TARGET PRICES PER THE FY 2025 IPPS/LTCH PPS FINAL RULE

CCN	MS–DRG	Region	Benchmark price (MS–DRG region)	Performance risk adjustment multiplier (CCN MS–DRG region)	Capped final normalization factor (MS–DRG)	Capped retrospective trend factor (MS–DRG region)	Discount factor (MS–DRG) (%)	Final target price
123456	231	1	$80,000.00	1.41	0.77	1.02	1.5	$87,048.84
123456	232	1	55,000.00	1.03	0.95	0.97	1.5	51,548.80
123456	233	1	70,000.00	1.15	0.91	1.08	1.5	77,958.94

TEAM participants will have the opportunity to achieve a reconciliation payment amount, after accounting for quality performance, if their performance year spending is below the reconciliation target price, or they may owe a repayment amount if their spending is above the reconciliation target price.

(2) Accounting for Future Changes to MS–DRGs and HCPCS

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we acknowledged comments about how we would address episode pricing when there are Medicare Severity Diagnosis Related Group (MS–DRG) or Healthcare Common Procedure Coding System (HCPCS) code modifications or other payment system changes over the course

of the model (89 FR 69719 and 69750). Specifically, we received multiple comments inquiring about this issue given the deletion of three spinal fusion MS–DRGs 453–455 and the addition of eight new spinal fusion MS–DRGs. In the final rule, we stated that we would be proposing a policy in future rulemaking for how to construct target prices when there are MS–DRG or HCPCS modifications or other payment system changes that may arise over the course of the model. In this proposed rule, we aim to clarify both our intention to incorporate these changes into the model when they occur and the specific methodology for target price construction in such a case. Failing to incorporate MS–DRG or HCPCS changes that arise between the baseline period and the performance year may lead to a significant drop in episode volume during the performance year and limit the number of beneficiaries exposed to the potential benefits of the model.

As an episode-based payment model, an important feature of TEAM is identifying the procedures or clinical conditions that would initiate an anchor hospitalization or anchor procedure. TEAM relies on MS–DRG codes to initiate an anchor hospitalization and HCPCS codes to initiate an anchor procedure. However, MS–DRG and HCPCS codes, and more specifically the assignment of HCPCS codes to Ambulatory Payment Classifications (APCs), may be modified because of changes in treatment patterns, technology, and any other factors that may change the relative use of hospital and provider resources. Typically, CMS proposes and finalizes coding changes, as applicable, through established annual payment rules, such as the FY IPPS/LTCH proposed and final rules and the CY Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) proposed and final rules. MS–DRG or HCPCS changes resulting from these rules may directly impact TEAM because they may alter which codes would initiate an anchor hospitalization and anchor procedure and subsequently may change the composition of episodes and its spending observed in the baseline period compared to the performance years for TEAM. This is significant for two reasons: (1) TEAM uses a 3-year historical baseline period to construct target prices for a given performance year, and if the codes that existed in the baseline period do not exist or were modified, then this can lead to target prices that may not appropriately reflect episode spending in the performance year; and (2) new codes established during the performance year that did not exist in the baseline period would not have a target price since TEAM's target prices are based on the MS–DRG/HCPCS episode type.

To accommodate the spinal fusion MS–DRG changes from the FY 2025 IPPS/LTCH final rule, account for any future MS–DRG or HCPCS/APC changes, and construct preliminary target prices, we are proposing a standard, three-step approach to account for MS–DRG and HCPCS/APC changes by remapping and adjusting relevant MS–DRG/HCPCS episode types during the baseline period to estimate performance year costs. Specifically, we propose that Step 1 would be to identify diagnosis or procedure codes that are being moved from one MS–DRG or HCPCS/APC to another based on the FY IPPS/LTCH or CY OPPS/ASC final rules of the relevant performance year and then map these codes to the new or revised MS–DRGs or HCPCS/APCs. In other words, baseline period episodes are reassigned to the MS–DRG or HCPCS/APC they would have received had the episode occurred in the performance year. For example, the spinal fusion MS–DRG 453 existed in the baseline period but was removed in the FY 2025 IPPS/LTCH PPS final rule. The procedure codes under MS–DRG 453 would be moved under three new MS–DRGs finalized in the FY 2025 IPPS/LTCH PPS final rule and based on the presence of specific procedure and diagnosis codes, as demonstrated in Table XI.A.–06.

TABLE XI.A.–06—EXAMPLE MS–DRG MAPPING LOGIC

Baseline MS–DRG	Mapping logic: move the anchor stay from the baseline MS–DRG to the remapped MS–DRG	Re-mapped MS–DRG
453	Presence of single anterior fusion and posterior fusion (except cervical) procedure codes without a diagnosis code on the MCC/CC list.	402
453	Presence of the following procedure code combinations with a diagnosis code on the MCC list: (i) single level anterior and multiple level posterior fusion; or (ii) single level posterior and multiple level anterior fusion; or (iii) multiple level anterior and posterior fusion; or (iv) single level anterior and posterior fusion.	426
453	Presence of cervical anterior fusion or cervical posterior fusion procedure codes with a diagnosis code on the MCC list	429

Based on the mappings for a given performance year, we propose that inpatient stays and outpatient procedures in the baseline would fall into one of three, mutually exclusive and collectively exhaustive mapping groups:

- Group 1: Existing MS–DRGs or HCPCS/APCs which would be deleted and mapped to new or existing MS–DRGs
- Group 2: Existing MS–DRGs or HCPCS/APCs which would be retained but portions of them would be mapped to new or existing MS–DRGs or HCPCS/APCs
- Group 3: MS–DRGs or HCPCS/APCs where there would be no changes occurring

For Step 2, we propose to construct episodes using the remapped MS–DRG or HCPCS/triggers. We propose that a baseline period episode would initiate an anchor hospitalization or anchor procedure based on whether the remapped MS–DRG or HCPCS, rather than the original MS–DRG or HCPCS, initiates a TEAM episode. Further, we propose that preliminary prices would then be constructed in the same manner described in § 512.540 of the FY 2025 IPPS/LTCH PPS final rule, with target prices for each MS–DRG/HCPCS episode type, inclusive of episodes initiated by anchor hospitalizations and anchor procedures that would be related to these newly incorporated diagnosis or procedure codes.

Lastly, we propose that Step 3 would adjust the standardized allowed amounts, used in target price calculations, to account for changes in fee-for-service rates between the baseline period and performance year due to changes to MS–DRG or HCPCS/APC weights (which account for relative intensity of hospital resource use). To do this, we propose to use a scaling factor, which we propose to define at § 512.505 to mean the ratio of the remapped MS–DRG or HCPCS/APC relative weight in the performance year, as applicable to the original MS–DRG or HCPCS/APC relative weight in the baseline period. The scaling factor adjusts the standardized allowed amount to account for differences in the

relative weights of the original and re-mapped MS–DRGs. This adjustment would replicate the payment the anchor hospitalization or anchor procedure would have received if the MS–DRG or HCPCS/APC assignments had been the same as they are in the performance year. Calculating the scaling factor as the ratio of the re-mapped MS–DRG relative weight in the performance year to the original MS–DRG relative weight in the baseline year also ensures the cost remains in baseline year dollars. Table XI.A.-07 provides an example of the scaling factor calculation for each of the three possible MS–DRG groups.

TABLE XI.A.–07—EXAMPLE CALCULATING THE SCALING FACTOR

Group	Baseline period fiscal year	Baseline MS–DRG	Performance year fiscal year	Remapped MS–DRG	Original MS–DRG relative weight	Remapped MS–DRG relative weight	Scaling factor
Group 1	2021	453	2025	402	9.1936	3.9292	0.427384
Group 2	2020	469	2023	521	3.1399	3.0192	0.961559
Group 2	2020	469	2023	469	3.1399	3.2314	1.02914
Group 3	2021	329	2023	329	4.8503	4.6233	0.953199

After calculating the scaling factor, we propose that the standardized allowed amount of the MS–DRG portion of the anchor hospitalization, or the HCPCS/APC portion of the anchor procedure, from the baseline year would be multiplied by the corresponding scaling factor to calculate the standardized allowed amount for the performance year. Table XI.A.–08 demonstrates application of the scaling factor for anchor hospitalizations while Table XI.A.–09 demonstrates application of the scaling factor for anchor procedures.

TABLE XI.A.–08—EXAMPLE APPYLING THE SCALING FACTOR TO ANCHOR HOSPITALIZATIONS

Baseline year (BY)	Baseline MS–DRG	Re-mapped PY MS–DRG	Performance year (PY)	Standardized (std) allowed amount in BY	Std allowed amount for MS–DRG	Scaling factor	Scaled std allowed amount for MS-DRG	Total adjusted cost (std dollars)
2021	453	402	2024	$20,000	$20,000	0.427384	$8,547.69	$8,547.69
2021	453	402	2024	22,500	20,000	0.427384	8,547.69	11,047.69
2021	453	402	2024	15,000	15,000	0.427384	6,410.76	6,410.76

TABLE XI.A.–09—EXAMPLE APPYLING THE SCALING FACTOR TO ANCHOR PROCEDURES

Baseline CY	Baseline HCPCS	Baseline APC	PY	Remapped PY APC	Baseline APC weight	PY APC weight	Scaling factor	Baseline episode cost	Total adjusted cost (std. dollars)
2021	27702	5115	2024	5116	148.7344	203.203	1.366214	$12,000	$16,394.57
2021	22612	5115	2024	5116	148.7344	203.203	1.366214	15,000	20,493.21

We believe this three-step approach allows the construction of preliminary target prices when there are MS–DRG or HCPCS/APC changes while ensuring anchor hospitalizations and anchor procedures maintain a consistent composition of patient cohorts. Further, it creates a standard process to address Medicare payment rate changes across time by identifying MS–DRG and HCPCS codes that initiate an anchor hospitalization or anchor procedure in the baseline period and how it would be billed under current Medicare payment rates and rules. Lastly, we believe this three-step approach for TEAM adequately captures the majority of year-to-year variation in Medicare spending and avoids unnecessary complexity by focusing on anchor hospitalization and anchor procedure costs. TEAM's pricing methodology includes a retrospective trend factor that can help capture Medicare FFS rate changes for non-anchor hospitalization and anchor procedure costs, which makes capturing additional Medicare spending variation outside of the anchor hospitalization or anchor procedure unnecessary and less transparent to TEAM participants.

We considered an alternative approach to make different adjustments to claims in the post-discharge or post-procedure period. This approach would have incorporated a fourth step, similar to the method used in the BPCI Advanced model, to further adjust the mapped, performance year MS–DRG and HCPCS/APC using setting-specific update factors. Although this methodology more accurately captures the changes in episode spending related to shifts in MS–DRG HCPCS/APC composition and Medicare FFS rate updates, there are more steps involved which can increase the complexity and require a high level of effort to implement. We also considered an even more simplistic approach in which we would replace the standardized MS–DRG or APC allowed amount from the baseline year with the standardized allowed amount from the performance year. However, doing so would not account for other changes in pricing from year to year. Using a ratio of the relative weights better preserves these pricing changes. We seek comment on these alternatives.

We note that TEAM constructs preliminary target prices based on a performance year, which aligns with a calendar year timeframe, and would be shared with TEAM participants prior to each performance year. Typically, MS–DRG changes are aligned to a fiscal year and HCPCS/APC changes align to a calendar year. This means that the proposed three-step approach may not address MS–DRG changes that are implemented in the last quarter of a performance year. We considered, but are not proposing, updating preliminary target prices for Medicare payment rule fiscal year updates, similar to how the BPCI Advanced model updates prices and how the early years of the Comprehensive Care for Joint Replacement (CJR) model updated prices. However, that would create two

preliminary target prices for a given performance year, rather than one preliminary target price as currently finalized. Having to manage two different preliminary target prices in a given performance year can increase participant burden and pricing methodology complexity. Further, updating the preliminary target price during the middle of the performance year can increase target price instability, even though it may produce more accurate target prices. We seek comment on whether we should update preliminary target prices during the performance year to account for any fiscal year or calendar year Medicare payment rule changes that occur after preliminary target prices are released to TEAM participants.

We seek comment on our proposal at § 512.505 to define scaling and at § 512.540(a)(2)(i) through (iii) to account for MS–DRG and HCPCS/APC changes between the baseline period and the performance year that arise from Medicare payment rule changes.

(3) U.S. Territories and Census Division 9

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we noted that hospitals in the five U.S. territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands) will be grouped alongside Census Division 9 (that is, the Pacific region) for the purposes of construction of regional prices (89 FR 69751). In response to public inquiries asking which specific Census Division U.S. territories would be categorized into since it was not reflected in regulatory text, we are proposing to revise the definition for region at § 512.505 to more clearly reflect this policy. Therefore, we propose that hospitals located in one of the five U.S. territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the U.S. Virgin Islands) will be grouped alongside Census Division 9. Specifically, we propose to revise the definition for region at § 512.505 to mean one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9. We believe grouping the U.S. territories to Census Division 9 is the most appropriate given the majority of U.S. territories captured in this group are located in the Pacific region. Mean episode spending for hospitals within the five U.S. territories is lower than hospitals in Census Division 9 for most episode types, and episode counts are significantly smaller. Therefore, including hospitals within the five U.S. territories as part of Census Division 9 will not disadvantage them since the benchmarks are expected to be higher. Moreover, any differences in spending that are due to patient case-mix between these regions should be accounted for through risk adjustment, ensuring providers are not penalized within the five U.S. territories.

Further, this approach is similar to how the BPCI Advanced model grouped the U.S. territories for the Census Division peer group characteristic. This policy would address the one CBSA in Puerto Rico (10380: Aguadilla, PR) selected for participation in TEAM. TEAM participants in this CBSA would use regional target prices calculated for Census Division 9.

We considered but are not proposing grouping hospitals in a U.S. territory into a separate group not based on Census Division but believe that doing so would create unnecessary complexity and reduce uniformity in how target prices are constructed in TEAM.

We seek comment on our proposal at proposed § 512.505 to include U.S. territories in Census Division 9.

(4) Calculation and Application of Normalization Factors

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we finalized using a normalization factor in our calculation of preliminary and reconciliation target prices. The normalization factor is the ratio of the average benchmark price divided by the average risk-adjusted benchmark price. We will multiply the risk-adjusted benchmark prices by the normalization factor to ensure the average benchmark price after risk adjustment does not exceed the average benchmark price prior to risk adjustment. If the average benchmark price is higher than the average risk-adjusted benchmark price, then the normalization factor will be greater than 1, and its application will increase the risk-adjusted benchmark prices. If the average benchmark price is lower than the average risk-adjusted benchmark price, then the normalization factor will be less than 1, and its application will decrease the risk-adjusted benchmark prices.

In the FY 2025 IPPS/LTCH PPS final rule, we finalized a policy to calculate a prospective normalization factor during the creation of preliminary target prices, which we would then modify (by no more than ±5 percent) for the final normalization factor when constructing reconciliation target prices. Under our current policy, the prospective normalization factor will be calculated as the ratio of the average total risk-adjusted preliminary target price to the average total non-risk adjusted preliminary target price for each MS–DRG/HCPCS episode type. We also finalized the final normalization factor, which will be calculated as the national mean of the benchmark price for each MS–DRG/HCPCS episode type divided by the national mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type.

To ensure consistency in our approach to calculating the prospective normalization factor(s) and the final normalization factor(s), we are proposing to update the language at § 512.505 to clarify that the prospective normalization factor will be calculated using the benchmark prices (that is, the average non-risk adjusted preliminary benchmark price divided by the average risk adjusted preliminary benchmark price) rather than using preliminary target prices. Specifically, we are proposing to revise the definition for prospective normalization factor to mean the multiplier incorporated into the preliminary target price to ensure that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, calculated as set forth in § 512.540(b)(6). We are similarly proposing to revise the definition for final normalization factor at § 512.505 to mean the benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region. Benchmark prices are calculated prior to incorporating the trend factor and discount factor. Therefore, using benchmark prices rather than target prices for calculating the prospective normalization factor would preserve the effect of the trend and discount factors and would prevent the prospective normalization factor from being influenced by the trend and discount factors. This proposed policy would ensure consistency in the construction of the prospective and final normalization factors. We seek comment on our proposals at § 512.505 to construct the prospective normalization factor using benchmark prices and to construct the final normalization factor to be based on MS–DRG/HCPCS episode type and region.

Additionally, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we finalized a policy to calculate normalization factors at the MS–DRG/HCPCS level—that is, to calculate normalization factors as the average national non-risk adjusted benchmark price divided by the average national risk-adjusted preliminary benchmark

price for each MS–DRG/HCPCS episode type. To further ensure consistency in our approach to calculating target prices, we are proposing to calculate normalization factors at the MS–DRG/HCPCS region level. We propose to calculate normalization factors as the average regional non-risk adjusted benchmark price divided by the average regional risk-adjusted preliminary benchmark price for each MS–DRG/HCPCS episode type. This will produce a unique normalization factor for each region and MS–DRG/HCPCS episode type for a total of 261 normalization factors (as opposed to just 29 normalization factors, as previously proposed). We believe this approach is preferable because it will ensure that the regional average MS–DRG/HCPCS target price is equal to the regional average MS–DRG/HCPCS benchmark price. We seek comment on our proposal at §§ 512.540(b)(6) and 512.545(e)(1)(i) to construct the normalization factors for each MS–DRG/HCPCS at the region level.

Table XI.A.–10 provides a few examples of the proposed calculation of the prospective and final normalization factors for three MS–DRG/HCPCS regions in which the final normalization factor is capped at 5 percent below the prospective normalization factor, not capped, and capped at 5 percent above the prospective normalization factor, respectively.

TABLE XI.A.–10—EXAMPLE CALCULATING NORMALIZATION FACTOR

DRG	Region	National mean benchmark price	National mean baseline risk adjusted benchmark	Prospective normalization factor	National mean performance risk adjusted benchmark	Final normalization factor	Capped final normalization factor
231	1	$80,000.00	$96,000.00	0.83	$104,000.00	0.77	0.79
232	1	55,000.00	55,550.00	0.99	57,750.00	0.95	0.95
233	1	70,000.00	84,000.00	0.83	77,000.00	0.91	0.88

Lastly, we wish to clarify how normalization factors will be applied in the calculation of preliminary target prices and how preliminary target prices will be provided to TEAM participants. We previously finalized a policy to provide each TEAM participant within a region with the same preliminary target price for an MS–DRG/HCPCS episode type. We also stated that prospective normalize factors would be incorporated into this preliminary target price and that risk adjustment factors would be calculated and separately be made available to TEAM participants prior to the start of the performance year, so participants would be able to use them to estimate their episode-level target prices. In this proposed rule, we are proposing that two separate preliminary target prices will be made available to all participants: (1) the regional average target price for each MS–DRG/HCPCS episode type, before application of the risk adjustment factors or normalization factors; and (2) a TEAM participant-specific preliminary target price, including the TEAM participant's average risk adjustment factors (calculated based on the TEAM participant's case mix in the baseline period) and the regional MS–DRG/HCPCS normalization factors. We believe that these two target prices will provide TEAM participants with the most complete information to both anticipate their final reconciliation target prices and understand their performance as compared to other participants within the same region. We seek comment on our proposal at § 512.540(b)(8) to communicate and share preliminary target prices that are region specific and TEAM participant specific.

(5) Calculation of the Prospective Trend Factor

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we finalized a pricing methodology using a 3 percent capped retrospective trend factor. Under this methodology, reconciliation target prices are based on average regional MS–DRG spending in the contemporaneous performance year. The retrospective approach ensures that reconciliation target prices accurately account for unpredictable year-to-year fluctuations in spending, including the introduction of new technologies and medical advancements and unexpected increases or decreases to health care utilization (for example, the COVID–19 public health emergency). However, as stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69745), we believe that providing TEAM participants with preliminary target prices before each performance year—and ensuring the accuracy and reliability of preliminary target prices—is essential to participants' success. Accurate target prices enable participants to prepare and undertake appropriate care transformation. We also believe the methodology for setting prospective target prices should be sufficiently simple that it is transparent to participants. With our methodology, we aimed to find the balance between simplicity and predictive accuracy.

The methodology finalized in the FY 2025 IPPS/LTCH PPS final rule calculates preliminary target prices by applying a trend factor to average regional MS–DRG spending in the final year of the baseline period. This trend factor is calculated as the 2-year percentage change from baseline year 1 (BY1) to baseline year 3 (BY3)—specifically average regional MSDRG spending in BY3 divided by average regional MS–DRG spending in BY1. We proposed and finalized the use of a 2-year trend because of the 2-year lag between each performance year and spending data availability from prior years. For example, preliminary target prices for performance year 1, 2026, will be shared with participants during 2025, when the last available complete year of data will be from 2024. Therefore, there is a need to convert 2024 spending into 2026 prices. We believed the simplicity of this approach would ensure transparency in our methodology.

However, further review of our methodology and testing using simulated reconciliation results, which relied on using baseline period data from 2019 and 2021 and a 2023 performance year, demonstrated potential shortcomings of this methodology. Specifically, the specification for the calculation of the 2-year trend factor used only spending data from BY1 and BY3, omitting data from BY2. Given expected variability in year-to-year spending, BY2 is a potentially valuable data point to include in our trend predictions. Furthermore, its omission has the potential to produce year-to-year fluctuations in preliminary target prices which may not accurately reflect trends in the baseline period data.

Therefore, we are proposing to update our preliminary target price calculation methodology to one which more fully incorporates available data and would more accurately represent year-to-year

trends. First, we are proposing to change the calculation of the prospective trend factor from a percentage change based between BY1 and BY3 to an annual percentage change calculated using a linear regression model. Specifically, we are proposing to use a log-linear model which would fit the model to logarithmically transformed values of average regional MS–DRG spending for each of the baseline years. Logarithmic transformation of the spending variables serves two purposes. First, it reduces the effect of outliers on our coefficient estimates. Second, it allows for interpretation of the coefficients as an annual percentage change rather than an absolute change. The coefficient estimates would be interpretable as the anticipated one-year percentage point change in the preliminary target price. For example, a coefficient of 0.03 reflects a 3 percent year-over-year increase in the average regional MS–DRG spending of the hospital. Conversely, a coefficient of −0.03 reflects a 3 percent year-over-year decrease in the average regional MS–DRG spending of the hospital. As there is a 2-year lag between the last baseline year and the performance year, we would square the exponentiated value of the coefficient estimate to calculate the 2-year prospective trend factor to predict the performance year spending. An exponentiated coefficient estimate of 1.03 would produce a 2-year prospective trend factor of: 1.03^2 = ~1.061, meaning that average regional MS–DRG spending is expected to increase by 6.1 percent between the last baseline year and performance year. An exponentiated coefficient of 0.97 would produce a trend factor of 0.97^2 = ~0.941, meaning that average regional MS–DRG spending is expected to decrease by 5.9 percent between the last baseline year and performance year. The 2-year trend factor will then proportionally adjust the benchmark price for each MS–DRG/HCPCS region preliminary target price based on the expected percentage increase or decrease in spending between the last baseline year and performance year.

Second, we are proposing to use 2 additional years of episode spending data in our calculation of the prospective trend factor. We propose these 2 years be the 2 years immediately prior to the 3-year baseline period. Therefore, we propose to define trend year at § 512.505 to mean either of the 2 years immediately prior to the 3-year baseline period used in combination with the baseline period to calculate the prospective trend factor. For example, for performance year 1 (2026), the 3-year baseline period is 2022 through 2024. Therefore, the trend years for performance year 1 would be 2020 (trend year 1) and 2021 (trend year 2). We believe using 2 additional trend years to calculate the trend factor and estimate preliminary target prices would produce more accurate projections of future FFS costs and, therefore, more reliable preliminary target prices for TEAM participants. We are proposing the use of trend years to only be applicable to construction of the prospective trend factor used in preliminary target price calculations. We would continue to use the 3-year baseline period previously finalized in the FY 2025 IPPS/LTCH PPS final rule for all other purposes related to TEAM, including but not limited to: excluded services, safety net hospital determinations, and risk adjustment. We also propose that trend years would roll forward on an annual basis in the same manner as the 3-year baseline period. We believe rolling the trend years forward annually with the baseline period is consistent with our previously finalized methodology, as well as with other CMMI models, and ensures a uniform approach to calculating prospective trends factors and preliminary target prices in each performance year. Lastly, we are proposing to use a blend of regional and national trend factors in the calculation of preliminary target prices. In the FY 2025 IPPS/LTCH PPS rule we proposed and finalized a policy to calculate individual trend factors for each regional MS–DRG (89 FR 69756). While we believe that preservation of potential variation in regional trends is an important element of our pricing methodology, we are concerned that a short baseline period—even when adding 2 trend years to the period used to make projections—may amplify short-term regional trends and unpredictable year-to year fluctuations that are not an accurate representation of longer-term cost trends for TEAM participants and are not likely to produce reliable preliminary target prices. Therefore, we propose for each regional MS–DRG in each performance year to calculate the prospective trend factor as the average (arithmetic mean) of the regional trend factor (calculated as proposed previously in this rulemaking) and a national trend factor. The national MS–DRG trend factor would be calculated in the same manner as regional MS–DRG trend factors using a linear regression of logarithmically transformed national average MS–DRG spending.

Lastly, we are proposing an additional change to how we calculate and apply the high-cost outlier cap finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69745). Currently, the high-cost outlier cap is an episode spending cap applied to the 99th percentile of regional spending for a given MS–DRG/HCPCS episode type in a given region across all 3 years of the baseline period. That is, the 99th percentile of regional spending for a given MS–DRG/HCPCS episode type is calculated for all episodes within the 3-year baseline period, rather than for each baseline year individually. As a result, episodes from different baseline years are not equally likely to be capped. For example, if per episode spending increases year-to-year within the baseline period, episodes in more recent years will be more likely to be subject to the high-cost outlier cap than episodes in earlier years. Conversely, if the per episode spending decreases year-to-year within the baseline period, episodes in earlier years will be more likely to be capped. To ensure that the trend factor—as well as the benchmark price—are calculated in a way that treats all 3 baseline years equally, with respect to the high-cost outlier cap, we are proposing to calculate the 99th percentile for a given MS–DRG/HCPCS episode type in a given region individually in each of the baseline and trend years. Although trend years are not used in calculation of the benchmark price, we propose to apply the high-cost outlier cap to episodes in the trend years as well to ensure consistency in the calculation of our trend factor. Therefore, we propose to revise the definition for high-cost outlier cap at § 512.505 to mean the 99th percentile of regional spending for a given MS–DRG/HCPCS episode type, region, and baseline year, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending. We believe this approach would improve the accuracy of our benchmark prices and trend factors and, ultimately, of target prices.

In proposing this revised methodology for calculating TEAM participants' preliminary target prices, we considered multiple alternatives for each proposed change. As alternatives to the proposed regression-based approach to calculating an annual prospective trend factor, we considered retaining the approach finalized in the FY 2025 IPPS/LTCH PPS rule as well as two similar approaches. The first alternative approach we considered would calculate the 2-year trend factor

as double the average of the 1-year trend from BY1 to BY2 (that is, average regional MS–DRG episode spending in BY2 divided by average regional MS–DRG episode spending in BY1) and from BY2 to BY3. This approach would have the benefit of retaining the simplicity of the methodology previously finalized while also incorporating all 3 years of available baseline data. We also considered an approach that would use 4 years of data (3-year baseline plus 1 trend year, defined as the year prior to the start of the baseline period) to calculate the 2-year trend factor as the average of the 2-year trend from BY1 to BY3 and trend year 1 to BY2 (for example, for performance year 1, 2026, the average of the 2-year trend factor from 2022 [BY1] to 2024 [BY3] and the 2-year trend factor from 2021 [trend year 1] to 2023 [BY2]). We intend to conduct further analysis to evaluate the reliability of both of these approaches, as compared to the proposed approach, for historical episode spending as part of simulated reconciliation. We request comment from stakeholders on whether either of these approaches would produce more accurate prospective trend factor estimates or meaningfully simplify our pricing methodology such that it would be easier for TEAM participants to replicate preliminary target price calculations and identify potential opportunities for spending efficiencies.

Additionally, we considered proposing the use of weights for different baseline and trend years for the regression-based approach. Specifically, we considered two alternatives to our proposed approach. In the first alternative, we would weight each of the 3 baseline years at 0.25 and each of the 2 trends years at 0.125. In the second, we considered weights of: BY3 = 0.3, BY2 = 0.25, and BY1 and both trend years = 0.15. We request comment on whether weighting more recent years used in the calculation of prospective tend factors and projection of preliminary target prices would improve the accuracy of target price calculations.

Lastly, we considered alternatives to our proposal to use the average of the regional and national trend factors. Specifically, we considered using just the regional trend factor, as proposed and finalized in the FY 2025 IPPS/LTCH PPS, as well as the use of different weights on the regional and national trend factors, for example, a weight of 0.67 for the regional trend factor and 0.33 for the national trend factor. We intend to conduct further analysis on whether alternative weights would provide better estimates of real FFS spending.

We believe our proposed revisions to our methodology for the calculation of the prospective trend factor would produce more accurate and reliable preliminary target prices for TEAM participants and reduce adjustments to reconciliation target prices that are calculated during reconciliation. We will maintain the ±3 percent cap on the retrospective trend factor adjustment. However, we believe that by improving the accuracy of prospective trend factor construction used in preliminary target prices, the methodological changes proposed previously will reduce the frequency with which that 3 percent cap need be applied.

We seek comment on our proposals at § 512.540(b)(7) to reconstruct the prospective trend factor and at § 512.540(b)(4) to calculate the high-cost outlier cap for each baseline year in the baseline period.

(6) Standardizing Area Deprivation Index (ADI)

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we finalized a social need risk adjustment factor for beneficiary-level risk adjustment in the construction of our preliminary and reconciliation target prices. We finalized this variable as a single binary variable with a value of yes = 1 if the beneficiary—(1) was eligible for full Medicaid benefits (referred to as a dual eligible beneficiary eligible to receive both full Medicare and Medicaid benefits); (2) was eligible for the Medicare Part D Low Income Subsidy (LIS); or (3) resided in a census block group with an Area Deprivation Index (ADI) above the 80th percentile of either national ranking or 8th decile of the state-level ranking. We noted that we believed that accounting for multiple potential markers of beneficiary social risk would be most appropriate to ensure accurate representation of the additional resources required to treat beneficiaries with greater levels of social vulnerability and need. In the FY 2025 IPPS/LTCH PPS final rule, we also acknowledged concerns that the lack of standardization of ADI variables may make the ADI primarily a function of a subset of variables (namely income and home values) included in its calculation. Further, we further stated that we would continue to explore whether standardization of the ADI variables would be appropriate for the purposes of TEAM's risk adjustment approach and would propose any such changes in future rulemaking.

As part of our preparation for TEAM and the calculation of preliminary target prices, we constructed episodes using a 2019 through 2021 baseline period to reassess the value of the social need risk adjustment factor. We calculated cross-tabulations of dual eligibility, LIS, and ADI status of episodes and beneficiaries identified as triggering a TEAM episode. We found that 99.9 percent of dual eligible beneficiaries who triggered an episode in TEAM (as well as 99.9 percent of episodes associated with a dual eligible beneficiary) were also qualified for LIS. This is consistent with the fact that LIS has more lenient asset and income requirements than Medicaid and that dual eligible beneficiaries automatically qualify for LIS without having to apply.

As previously suggested by commenters in response to the FY 2025 IPPS/LTCH PPS proposed rule, we explored options for the standardization of the ADI that would better measure deprivation in urban areas. The CMS Innovation Center's Accountable Care Organization REACH (ACO REACH) model includes an adjustment that is a blend of one-third National ADI scores, one-third State ADI scores, and one-third Dual-Eligibility or Low-Income Subsidy status. In performance year 2025, CMS will remove the National/State blended ADI from ACO REACH and replace it with an area-level deprivation measure that uses standardized variables. This will better identify deprived areas of the nation, particularly for populations in high housing cost areas where housing costs do not correlate with the other included economic variables.

Specifically, ACO REACH intends to use a slightly modified census block group deprivation index, known as the Community Deprivation Index (CDI), which updates and standardizes the variables used in the construction of the ADI. Standardization refers to the process making the individual indicators that comprise the ADI unit to be neutral by subtracting the mean and dividing by the standard deviation before combining them to form a composite measure. Standardization prevents those variables with high nominal values, namely income and home values, from predominating the calculation of the metric. Given the extensive work the ACO REACH model has conducted to standardize the ADI, we believe it is important to use a similar approach to more accurately measure areas of deprivation and create alignment across CMS Innovation Center models with similar adjustments.

Based on our further research and analysis, we are proposing a few changes to the construction of the social need risk adjustment factor for beneficiary-level risk adjustment in TEAM.

First, we are proposing to rename the social needs risk adjustment factor to be the beneficiary economic risk adjustment factor and replace the use of the ADI in the construction of our beneficiary economic risk adjustment variable, with a similar but slightly modified census block group deprivation index, the Community Deprivation Index (CDI). We propose to use the same construction methodology as the ACO REACH model. Specifically, the CDI would be a factor-weighted composite measure of 18 variables collected from the Census Bureau. We propose the deprivation scores would be percentile ranked relative to the Nation such that the resulting index would range from a score of 1, indicating the lowest level of relative deprivation, to 100, indicating the highest level of relative deprivation. We also propose maintaining the use of the 80th percentile threshold for the CDI. For example, the TEAM beneficiary would be assigned a value of yes = 1 on the beneficiary economic risk adjustment factor if the TEAM beneficiary's CDI was above the 80th percentile. We believe the updated variable name better represents what the variable is risk adjusting for. We also believe the use of the CDI instead of the ADI will better represent beneficiary-level deprivation in urban areas due to the standardization of variables prior to the construction of the composite measure.

Second, we are proposing to use only national-level CDI rankings in the construction of our beneficiary economic risk adjustment factor. In our initial proposal in the FY25 IPPS/LTCH PPS proposed rule (89 FR 36450), we stated that the use of national- and state-level ADIs would help mitigate potential concerns about the validity of the ADI as a measure of economic risk given its close correlation with home values. We believed that using a relative measure of deprivation within states, in addition to a national measure, would better identify high deprivation census block groups and beneficiaries in states with high incomes and home values. We believe that the standardization of variables in the CDI will adequately address the influence of these two variables in the aggregate measure, negating the need for the use of both national and state rankings.

Furthermore, we believe that the inclusion of too many measures of beneficiary deprivation will dilute risk adjustment for TEAM participants with beneficiaries with the highest levels of economic vulnerability. Although in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69772) we confirmed that we would only make upward risk adjustments to target prices, target price increases through risk adjustment must be offset by across-the-board target price reduction with the application of the normalization factor in our target price methodology. Therefore, the more beneficiaries receive risk-adjusted target prices, the smaller those adjustments must necessarily be.

As an alternative to our proposed changes to the construction of the economic risk factor for beneficiary-level risk adjustment, we considered retaining the use of the ADI, including both the national- and state-level rankings, and dual eligibility status. As previously stated, we believe that the use of the CDI as a standardized alternative to the ADI provides a more reliable measure of economic risk and negates the need for used of the state-level rankings. We further believe that minimizing the number of variables used to identify economic risk both keeps the methodology simpler and reduces the extent to which positive risk adjustments must be offset by normalization, therefore ensuring that beneficiaries with the highest levels of deprivation receive adequate risk adjustment. We also gave further consideration to additional alternatives to the ADI, including the Centers for Disease Control and Prevention's (CDC) Social Vulnerability Index (SVI). However, as stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69799), we continue to believe that it would not have been appropriate to use the SVI in place of the ADI or CDI, given that SVI is not as granular as the ADI (SVI uses census tracts as opposed to census block groups), and given the limitations and timing of this source data, the American Community Survey (ACS) 5-year estimates. For these reasons, we are not proposing the SVI as a potential risk adjustor in TEAM.

We seek comment on our proposal at § 512.545(a) to rename the risk adjustment variable. We also seek comment on our proposal at § 512.545(a)(3)(i) to use the CDI and remove a measurement of deprivation at the State level.

Finally, we considered but are not proposing at this time to omit the dual eligibility (receiving both full Medicare and Medicaid benefits) variable from our construction of the single, binary economic risk adjustment factor. While we continue to believe that dual eligibility is an important indicator of economic vulnerability, we believe the near complete overlap between dual eligibility and LIS status makes the use of dual eligibility status redundant. Removing the dual eligibility variable would simplify the construction of the economic risk adjustment factor without sacrificing the identification of beneficiaries with high economic risk. Furthermore, LIS also provides a nationally consistent measure of economic risk, as LIS eligibility is set at the national level, unlike Medicare-Medicaid dual eligibility. Lastly, the use of only LIS status, as opposed to both LIS and dual eligibility, is consistent with the specification used by CMS Innovation Center models, such as the Making Care Primary (MCP) Model.

While we are not proposing any change at this time to the inclusion of the dual eligibility variable in our construction of the economic risk adjustment factor, we are seeking comment on whether the removal of this variable to streamline construction of the economic risk adjustment factor would be preferable.

(7) Hierarchical Condition Categories (HCC) in Risk Adjustment

(a) Lookback Period

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we recognized the need to account for beneficiary acuity in setting target prices for episode categories tested in TEAM. We finalized the use of beneficiary level variables that are episode category specific. These beneficiary level variables are drawn from the HCCs used in the CMS–HCC risk adjustment model that informs the Medicare Advantage (MA) capitation rates and Part C and Part D Payment Policies. While the specific HCCs were finalized for each episode category in TEAM, we did not finalize the lookback period duration to capture the HCCs. Specifically, we did not specify how far back from the episode start date CMS would look to capture HCC data to determine the total count of HCCs and the episode-specific HCC variables.

In the early years of BPCI Advanced, we used a 90-day lookback for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure. We would use the beneficiary's Medicare Fee-For-Service (FFS) claims from that 90-day lookback period to determine which HCC flags the beneficiary is assigned and create a count of those HCC flags. During the COVID–19 public health emergency (PHE), BPCI Advanced participants urged CMS to reconsider the 90-day lookback period because beneficiaries were hesitant to interface with providers during this time, which directly affected the risk adjustment and target price methodology. Given those concerns, BPCI Advanced began using a 180-day lookback period.

Since the COVID–19 PHE has ended and utilization is now once again similar to pre-PHE levels, we proposed in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 35934) that we would conduct a 90-day lookback for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure. We would use the beneficiary's Medicare FFS claims from that 90-day lookback period to determine which HCC flags the beneficiary is assigned and create a count of those HCC flags. This methodology would have been consistent with the earlier years of BPCI Advanced and would represent a more uniform way of measuring clinical complexity across beneficiaries. It would also reduce the incentive for increased coding intensity at the time of the initiating procedure. However, following feedback from public comments, we held off on finalizing a lookback period to take more time to consider alternatives, such as a longer lookback period.

We now propose to conduct a 180-day lookback for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure. We propose to use the beneficiary's Medicare FFS claims from that 180-day lookback period to determine which HCC variables (or flags) the beneficiary is assigned and determine the HCC episode specific flags as well as the TEAM HCC count flag. We also propose that the TEAM beneficiary would need to meet beneficiary inclusion criteria, as described in § 512.535, during the entire 180-day lookback period. We believe a 180-day lookback period would sufficiently capture beneficiary acuity and ultimately improve the risk adjustment methodology to better reflect the level of spending outside of the hospital's control. This methodology would be consistent with the current BPCI Advanced methodology and would continue to represent a more uniform way of measuring clinical complexity across beneficiaries. In past internal analyses, CMS has found that a 180-day lookback period may improve model fit in a risk adjustment model but may reduce episode volume. Internal analysis demonstrated that using a 180-day lookback period in BPCI Advanced reduced total episodes from 12,473,202 to 12,451,784 when looking at a period from October 1, 2015, through September 30, 2019. Our analysis further found that extending the lookback period from 90 days to 180 days resulted in an average increase in regional MS–DRG benchmark prices of just 0.04 percent. The average change in regional MS–DRG benchmark prices was just ± 0.2 percent and only 16 of the 261 benchmark prices changed by more than ± 0.5 percent. Use of 270-day and 365-day lookback periods produced only marginally different results.

However, because of the importance of accurate and complete data when risk-adjusting for TEAM, we believe 180-days is the most appropriate duration as opposed to lookback periods longer than 180 days. The 180-day lookback period allows for improvements in model fit and modest adjustments in target price accuracy, relative to a 90-day lookback period, without a large drop in episode volume in the lookback period. Additionally, we believe a 180-day lookback period would address public commenters' concerns that the 90-day lookback period did not adequately account for past spending associated with beneficiary health status. It would also reduce the incentive for increased coding intensity at the time of the initiating procedure. Using a lookback period, rather than including diagnoses from the episode initiating admission/procedure, will minimize the opportunities for participants to change coding intensity among their patients relative to non-participants.

We recognize other CMS initiatives may use different lookback periods. For example, the Enhancing Oncology Model uses HCCs from the previous calendar year, and some of the episode-based cost measures in the Merit-based Incentive Payment Systems that align with similar episode categories tested in TEAM use a 120-day lookback period. Therefore, we considered, but are not proposing here, a 90-day, 120-day, 270-day, or 365-day lookback period to determine which HCC flags the beneficiary is assigned. We have not considered lookback periods longer than 1 year as we believe that it would capture beneficiary acuity that may be unrelated to their episodic care in TEAM, and thus arbitrarily adjusting target prices. There is limited research into the most appropriate lookback period duration for risk adjustment, however there are some findings that suggest that incorporating clinical information beyond 1 year does not improve risk adjustment. Although we are not proposing this alternative, we seek comment on whether these alternative lookback periods would be appropriate for TEAM or if there are other lookback period options we should consider.

We seek comment on our proposal at proposed § 512.545(a) to use a 180-day lookback period to determine which HCC flags the beneficiary is assigned.

(b) HCC Version

In the FY 2025 IPPS/LTCH PPS final rule we finalized TEAM's approach to risk adjustment for target prices, which included episode category risk adjusters linked to specific HCCs that aimed to improve target price accuracy by accounting for beneficiary-driven episode expenditure variation (89 FR 69763). As indicated in the final rule, a Lasso regression analysis with additional input from a Technical Expert Panel (TEP) of clinicians was performed to identify the finalized risk adjusters, including the specific HCCs. The analysis used HCCs from version 22 (v22) of the CMS–HCC risk adjustment model as this version is the version used in the BPCI Advanced model which TEAM predicated its risk adjustment approach on. However, we are aware that v22 is not the most updated version used in the CMS–HCC risk adjustment model. Currently, version 28 (v28), as finalized in the Risk Adjustment Data Validation (RADV) final rule (88 FR 6643), is used in Medicare Part C and other CMS initiatives. Given there is a more recent HCC version and its adoption across CMS and its initiatives, we believe it is important for TEAM to use a more recent HCC version that relies on ICD–10 diagnosis codes, rather than previous versions that include ICD–9 diagnosis codes, leading to more granular HCCs.

Given HCC v28 results in more granular HCCs, there is not a one-to-one mapping of the HCCs used in v22 to v28. As there is not a one-to-one match between HCCs in v22 and v28, a Lasso regression analysis with additional clinician input was repeated to identify the specific HCCs in v28 that would be used to risk adjust target prices in TEAM. Lasso regression analysis is a statistical modeling method used to identify a subset of risk adjusters which are most relevant for prediction of the natural log difference between clinical episode spending and the benchmark price. The objective of Lasso regression is to find the risk adjusters that minimize the residual sum of squares. In other words, the Lasso regression analysis identifies the risk adjusters that minimize the difference between the predicted and the actual values. Clinician input helps to identify risk adjusters relevant to clinical practice and predicting target prices. Clinician input was informed by a literature review of perioperative comorbidities that would affect outcome and Lasso covariate estimates to support their recommendations.

Based on the Lasso analysis and clinician input, we are proposing to use

HCC v28 to identify the episode category specific HCC risk adjusters used in TEAM's risk adjustment methodology. Specifically, we are proposing to replace the HCC episode category specific risk adjusters finalized in FY 2025 IPPS/LTCH PPS final rule with the following HCC episode category specific risk adjusters as demonstrated in Table XI.A.–011.

TABLE XI.A.–011—PROPOSED HCC V28 EPISODE CATEGORY SPECIFIC RISK ADJUSTERS

Episode category	Finalized HCC v22 risk adjusters	Proposed HCC v28 risk adjusters
CABG	• HCC 18: Diabetes with Chronic Complications. • HCC 46: Severe Hematological Disorders. • HCC 58: Major Depressive, Bipolar, and Paranoid Disorders. • HCC 84: Cardio-Respiratory Failure and Shock. • HCC 85: Congestive Heart Failure. • HCC 86: Acute Myocardial Infarction. • HCC 96: Specified Heart Arrhythmias. • HCC 103: Hemiplegia/Hemiparesis. • HCC 111: Chronic Obstructive Pulmonary Disease. • HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders. • HCC 134: Dialysis Status.	• HCC 37: Diabetes with Chronic Complications. • HCC 48: Morbid Obesity. • HCC 125: Dementia, Severe. • HCC 126: Dementia, Moderate. • HCC 127: Dementia, Mild or Unspecified. • HCC 155: Major Depression, Moderate or Severe, without Psychosis. • HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia. • HCC 213: Cardio-Respiratory Failure and Shock. • HCC 224: Acute on Chronic Heart Failure. • HCC 226: Heart Failure, Except End-Stage and Acute. • HCC 228: Acute Myocardial Infarction. • HCC 229: Unstable Angina and Other Acute Ischemic Heart Disease. • HCC 238: Specified Heart Arrhythmias. • HCC 249: Ischemic or Unspecified Stroke. • HCC 253: Hemiplegia/Hemiparesis. • HCC 263: Atherosclerosis of Arteries of the Extremities with Ulceration or Gangrene. • HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders. • HCC 298: Severe Diabetic Eye Disease, Retinal Vein Occlusion, and Vitreous Hemorrhage. • HCC 326: Chronic Kidney Disease, Stage 5. • HCC 327: Chronic Kidney Disease, Severe (Stage 4). • HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle. • HCC 409: Amputation Status, Lower Limb/Amputation Complications.
LEJR	• HCC 8: Metastatic Cancer and Acute Leukemia. • HCC 18: Diabetes with Chronic Complications. • HCC 22: Morbid Obesity. • HCC 58: Major Depressive, Bipolar, and Paranoid Disorders. • HCC 78: Parkinson's and Huntington's Diseases. • HCC 85: Congestive Heart Failure. • HCC 86: Acute Myocardial Infarction. • HCC 103: Hemiplegia/Hemiparesis. • HCC 111: Chronic Obstructive Pulmonary Disease. • HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders. • HCC 134: Dialysis Status. • HCC 170: Hip Fracture/Dislocation.	• HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic. • HCC 36: Diabetes with Severe Acute Complications. • HCC 37: Diabetes with Chronic Complications. • HCC 48: Morbid Obesity. • HCC 125: Dementia, Severe. • HCC 126: Dementia, Moderate. • HCC 127: Dementia, Mild or Unspecified. • HCC 151: Schizophrenia. • HCC 155: Major Depression, Moderate or Severe, without Psychosis. • HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia. • HCC 224: Acute on Chronic Heart Failure. • HCC 225: Acute Heart Failure (Excludes Acute on Chronic). • HCC 226: Heart Failure, Except End-Stage and Acute. • HCC 238: Specified Heart Arrhythmias. • HCC 253: Hemiplegia/Hemiparesis. • HCC 267: Deep Vein Thrombosis and Pulmonary Embolism. • HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders. • HCC 326: Chronic Kidney Disease, Stage 5. • HCC 327: Chronic Kidney Disease, Severe (Stage 4). • HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle. • HCC402: Hip Fracture/Dislocation.
Major Bowel Procedure.	• HCC 11: Colorectal, Bladder, and Other Cancers. • HCC 18: Diabetes with Chronic Complications. • HCC 21: Protein-Calorie Malnutrition. • HCC 33: Intestinal Obstruction/Perforation. • HCC 82: Respirator Dependence/Tracheostomy Status. • HCC 85: Congestive Heart Failure. • HCC 86: Acute Myocardial Infarction. • HCC 103: Hemiplegia/Hemiparesis. • HCC 111: Chronic Obstructive Pulmonary Disease. • HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders. • HCC 134: Dialysis Status. • HCC 188: Artificial Openings for Feeding or Elimination.	• HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic. • HCC 22: Bladder, Colorectal, and Other Cancers. • HCC 37: Diabetes with Chronic Complications. • HCC 48: Morbid Obesity. • HCC 78: Intestinal Obstruction/Perforation. • HCC 125: Dementia, Severe. • HCC 126: Dementia, Moderate. • HCC 127: Dementia, Mild or Unspecified. • HCC 151: Schizophrenia. • HCC 155: Major Depression, Moderate or Severe, without Psychosis. • HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia. • HCC 201: Seizure Disorders and Convulsions. • HCC 211: Respirator Dependence/Tracheostomy Status/Complications. • HCC 213: Cardio-Respiratory Failure and Shock. • HCC 224: Acute on Chronic Heart Failure. • HCC 226: Heart Failure, Except End-Stage and Acute. • HCC 238: Specified Heart Arrhythmias. • HCC 253: Hemiplegia/Hemiparesis. • HCC 267: Deep Vein Thrombosis and Pulmonary Embolism. • HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders. • HCC 326: Chronic Kidney Disease, Stage 5. • HCC 327: Chronic Kidney Disease, Severe (Stage 4). • HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

TABLE XI.A.–011—PROPOSED HCC V28 EPISODE CATEGORY SPECIFIC RISK ADJUSTERS—Continued

Episode category	Finalized HCC v22 risk adjusters	Proposed HCC v28 risk adjusters
SHFFT	• HCC 18: Diabetes with Chronic Complications. • HCC 22: Morbid Obesity. • HCC 82: Respirator Dependence/Tracheostomy Status. • HCC 83: Respiratory Arrest. • HCC 84: Cardio-Respiratory Failure and Shock. • HCC 85: Congestive Heart Failure. • HCC 86: Acute Myocardial Infarction. • HCC 96: Specified Heart Arrhythmias. • HCC 103: Hemiplegia/Hemiparesis. • HCC 111: Chronic Obstructive Pulmonary Disease. • HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders. • HCC 134: Dialysis Status. • HCC 157: Pressure Ulcer of Skin with Necrosis Through to Muscle, Tendon, or Bone. • HCC 158: Pressure Ulcer of Skin with Full Thickness Skin Loss. • HCC 161: Chronic Ulcer of Skin, Except Pressure. • HCC 170: Hip Fracture/Dislocation.	• HCC 463: Artificial Openings for Feeding or Elimination. • HCC 36: Diabetes with Severe Acute Complications. • HCC 37: Diabetes with Chronic Complications. • HCC 38: Diabetes with Glycemic, Unspecified, or No Complications. • HCC 48: Morbid Obesity. • HCC 63: Chronic Liver Failure/End-Stage Liver Disorders. • HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders. • HCC 109: Acquired Hemolytic, Aplastic, and Sideroblastic Anemias. • HCC 125: Dementia, Severe. • HCC 126: Dementia, Moderate. • HCC 127: Dementia, Mild or Unspecified. • HCC 180: Quadriplegia. • HCC 181: Paraplegia. • HCC 191: Quadriplegic Cerebral Palsy. • HCC 198: Multiple Sclerosis. • HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia. • HCC 211: Respirator Dependence/Tracheostomy Status/Complications. • HCC 213: Cardio-Respiratory Failure and Shock. • HCC 226: Heart Failure, Except End-Stage and Acute. • HCC 238: Specified Heart Arrhythmias. • HCC 249: Ischemic or Unspecified Stroke. • HCC 253: Hemiplegia/Hemiparesis. • HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders. • HCC 326: Chronic Kidney Disease, Stage 5. • HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle. • HCC 402: Hip Fracture/Dislocation.
Spinal Fusion	• HCC 8: Metastatic Cancer and Acute Leukemia. • HCC 18: Diabetes with Chronic Complications. • HCC 22: Morbid Obesity. • HCC 40: Rheumatoid Arthritis and Inflammatory Connective Tissue Disease. • HCC 58: Major Depressive, Bipolar, and Paranoid Disorders. • HCC 85: Congestive Heart Failure. • HCC 86: Acute Myocardial Infarction. • HCC 96: Specified Heart Arrhythmias. • HCC 103: Hemiplegia/Hemiparesis. • HCC 111: Chronic Obstructive Pulmonary Disease. • HCC 112: Fibrosis of Lung and Other Chronic Lung Disorders. • HCC 134: Dialysis Status.	• HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic. • HCC 18: Cancer Metastatic to Bone, Other and Unspecified Metastatic Cancer; Acute Leukemia Except Myeloid. • HCC 37: Diabetes with Chronic Complications. • HCC 48: Morbid Obesity. • HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders. • HCC 125: Dementia, Severe. • HCC 126: Dementia, Moderate. • HCC 127: Dementia, Mild or Unspecified. • HCC 155: Major Depression, Moderate or Severe, without Psychosis. • HCC 180: Quadriplegia. • HCC 181: Paraplegia. • HCC 182: Spinal Cord Disorders/Injuries. • HCC 192: Cerebral Palsy, Except Quadriplegic. • HCC 193: Chronic Inflammatory Demyelinating Polyneuritis and Multifocal Motor Neuropathy. • HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia. • HCC 224: Acute on Chronic Heart Failure. • HCC 226: Heart Failure, Except End-Stage and Acute. • HCC 238: Specified Heart Arrhythmias. • HCC 249: Ischemic or Unspecified Stroke. • HCC 253: Hemiplegia/Hemiparesis. • HCC 254: Monoplegia, Other Paralytic Syndromes. • HCC 267: Deep Vein Thrombosis and Pulmonary Embolism. • HCC 326: Chronic Kidney Disease, Stage 5. • HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle. • HCC 401: Vertebral Fractures without Spinal Cord Injury.

We recognize that our proposed list of episode category specific HCCs is greater in number compared to what we finalized in the FY 2025 IPPS/LTCH PPS final rule. There are approximately 25 risk adjusters per episode category, inclusive of non-HCC risk adjusters, that were finalized in the FY 2025 IPPS/LTCH PPS final rule as compared to the approximately 30 risk adjusters that would result from incorporating the proposed v28 HCCs. We believe this increase in HCCs is comparable given the HCC volume increased from v28 to v22. We also believe that the proposed list of episode category specific HCCs maintains our goal of a simplified risk adjustment methodology that aims to capture spending accurately, while aligning with the most recent HCC version.

We note that there are other episode category specific risk adjusters that were finalized in the FY 2025 IPPS/LTCH PPS final rule which are not HCCs. We are not proposing to replace the non-HCC episode category specific risk adjusters. Nor are we proposing to replace the beneficiary level risk adjusters applicable to all episode categories, such as HCC count and age bracket, or the provider-level risk adjusters, such as hospital bed size and safety net status. All of these risk adjusters were included in the Lasso regression analysis and clinical review and deemed appropriate for continued use in TEAM's risk adjustment methodology. However, we are proposing to update the social need risk adjustment factor, as described in section XI.A.2.c.(6). of the preamble of this proposed rule.

We seek comment on our proposal at § 512.545(a)(6)(i) through (v) to use HCC

v28 to construct our episode category specific HCC risk adjusters.

(8) Low Volume Hospitals

In both CJR and BPCI Advanced, we recognized that hospitals that perform a number of episodes below a certain volume threshold may have challenges taking on two-sided financial risk. As noted in the Episode-Based Payment Model Request for Information (88 FR 45872), episode volume is an important feature in an episode-based payment model because episode categories with sufficient volume help to reduce pricing volatility and spread financial risk. In the 2015 CJR final rule (80 FR 73285), we acknowledged that such hospitals might not find it in their financial interests to make systemic care redesigns or engage in an active way with the CJR model. At 80 FR 73292, we acknowledged commenter concerns about low volume providers, including but not limited to observations that low volume providers could be: less proficient in taking care of LEJR patients in an efficient and cost-effective manner, more financially vulnerable with fewer resources to respond to the financial incentives of the model, and disproportionately impacted by high-cost outlier cases. In spite of these potential challenges, we stated that the inclusion of low volume hospitals in CJR was consistent with the goal of evaluating the impact of bundled payment and care redesign across a broad spectrum of hospitals with varying levels of infrastructure, care redesign experience, market position, and other considerations and circumstances (80 FR 73292).

In CJR, we set the low volume threshold as fewer than 20 CJR episodes across the 3-year baseline years of 2012 through 2014. Low volume hospitals received target prices based on 100 percent regional data, rather than a blended target price that incorporated their participant-specific data, because a target price based on limited data is less likely to be accurate and reliable. These hospitals were also subject to the lower stop-loss limits that we offered to rural hospitals, in recognition of the fact that they might be less prepared to take on downside risk than hospitals with higher episode volume. In the CJR 2017 final rule that reduced the number of mandatory MSAs, low volume hospitals were among the types of hospitals that were required to opt in if they wanted to remain in the model (82 FR 57072). In the CJR 2020 final rule, we removed the remaining low volume hospitals from the CJR extension when we limited the CJR participant hospital definition to those hospitals that had been mandatory participants throughout the model (86 FR 23497).

In BPCI Advanced, our low volume threshold policy was to not provide a target price for a given clinical episode category if performed at a hospital that did not meet the 41 clinical episode minimum volume threshold during the 4-year baseline period. This meant that no BPCI Advanced episodes would be triggered for that particular clinical episode category during the applicable performance period at that hospital. However, participants could continue to trigger other clinical episode categories for which they had enrolled and for which there was sufficient baseline volume. Additionally, clinical episodes that occurred at the hospital during the performance period, though not triggering a BPCI Advanced episode, would count toward the low volume threshold when that year became part of a subsequent baseline period. Therefore, as the baseline shifted forward each year, bringing a more recent year into the baseline and dropping the oldest year, a hospital could potentially meet the volume threshold and receive a target price for the clinical episode category for a subsequent performance period.

Last year, in the FY 2025 IPPS/LTCH PPS proposed rule (89 FR 35934) that established TEAM, we proposed that TEAM would include a low volume threshold. We proposed that if a TEAM Participant did not meet the proposed low volume threshold of at least 31 total episodes across all episode categories in the baseline period for PY1, CMS would still reconcile their episodes, but the TEAM participant would be subject to the Track 1 stop-loss and stop-gain limits for PY1. If a TEAM Participant did not meet the proposed low volume threshold of at least 31 total episodes in the applicable 3-year baseline periods for PYs 2 through 5, the TEAM Participant would be subject to the Track 2 stop-loss and stop-gain limits for PY 2 through 5. However, after many comments that this policy was insufficient for low volume hospitals, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), we determined we would not finalize a policy for low volume hospitals and instead would propose a new policy in future notice and comment rulemaking.

In this rulemaking, rather than offering a specific proposal, we are proposing to maintain our current policy of having no low volume episode policy, given that Track 1 of the model has no downside risk and we expect most TEAM participants to select Track 1 for the first performance year. Rather, we are seeking comment on several potential policies to address prior commenters' concerns about low volume providers participating in TEAM.

First, we are considering, but not proposing, that a low volume threshold would apply to specific episode categories in the baseline period for a given PY, similar to BPCI Advanced. If a TEAM participant did not meet the considered low volume threshold of at least 31 episodes in a given baseline period for a given episode category, CMS would still reconcile their episodes, but the TEAM participant would not be held accountable for any performance year episode spending that exceeded the reconciliation target price for each of the MS–DRG/HCPCS episode types in that given episode category during the applicable performance year. This policy would effectively waive downside financial risk for the TEAM participant for episode categories in which they did not meet the considered low volume threshold. For example, in PY1, if a TEAM participant only initiated 30 episodes in the baseline period for the major bowel procedure episode category, and initiated 31 or more episodes in the baseline period for each of the other episode categories tested in TEAM, then the TEAM participant would not be held accountable for performance year episode spending that exceeded the reconciliation target price for the major bowel procedure episode category but would be accountable for performance year episode spending that exceeded the reconciliation target price for all the other episode categories for PY1. We note that the baseline period for a given performance year in TEAM rolls forward each year. Therefore, it is possible for a TEAM participant to not meet the low volume threshold for a given episode category in one performance year and then meet the low volume threshold the next performance year because the baseline period rolled forward and captured a different volume of baseline period episodes. We do not anticipate there would be a significant number of hospitals meeting the threshold one performance year and not the next (and vice versa), because procedure volumes tend to remain consistent across performance years.

This considered policy may addresses commenters' concerns, by placing the low volume threshold at the episode category level rather than across all episode categories and acknowledge commenters' concerns regarding the level of financial risk that is tolerable for low volume hospitals, especially hospitals that are safety net hospitals or rural hospitals. TEAM participants with

low volume may not have enough episode volume to spread the risk or create efficient care pathways sufficient for downside risk. Further, and as compared to the BPCI Advanced model, this considered policy would allow TEAM participants to still initiate episodes and earn a reconciliation payment amount if they can reduce spending and provide quality care. However, we are concerned that waiving downside risk for low volume hospitals may affect potential TEAM savings for CMS. Additionally, the 31-episode category threshold may not be the optimal threshold to ensure a low volume policy adequately addresses the concerns of TEAM participants and stakeholders affected by a potential low volume policy. A 31-episode is a similar approach to capturing the per baseline year threshold in BPCI Advanced, but this threshold could theoretically be too low to capture all TEAM participant hardship caused by episode volatility. It could also be too high and exclude too many episodes from the model and thus deprive TEAM participants an opportunity to enhance patient quality of care or provider efficiency and earn associated reconciliation payments.

We also considered, but are not proposing, different low volume thresholds for the above considered policy in the baseline period for a given episode category, including 91, 61, 51, 41, 21, and 11 episodes. In an internal analysis of hospitals that were potentially eligible for TEAM using claims data from calendar year 2023, we found that 30 percent of acute care hospital (ACH)-clinical episode category (CEC) combinations had 10 or fewer episodes and were not flagged as a low volume hospital using the baseline period methodology of fewer than 31 episodes in a given CEC. Presumably, these could be seen as false negative results for low volume status or indications that the fewer than 31-episode threshold was set too high. Among these ACH–CEC combinations, the average episode count was seven. Additionally, 14 percent of these ACH–CEC combinations had five episodes or fewer. It could be the case that the 31 or fewer episode threshold could include hospitals that are not truly so low volume as to justify waiving downside risk. Alternatively, hospitals may just barely cross the 31 or fewer episode threshold and thus be subject to downside risk and may still be fundamentally similar to identified low volume TEAM participants experiencing hardship from the natural volatility involved in having fewer qualifying episodes. Though this is true of any threshold, the likelihood of this increases at lower thresholds than larger thresholds. Therefore, we are considering alternative thresholds such as fewer than 91 episodes (approximately 3 times the fewer than 31 episode threshold), fewer than 61 episodes (approximately 2 times the fewer than 31 episode threshold), fewer than 51 episodes (the fewer than 31 episode threshold plus 3 times the average count of episodes for ACH–CEC combinations in our mock reconciliation not cited as low volume), fewer than 41 episodes (the fewer than 31 episode threshold plus one-third the threshold), fewer than 21 episodes (3 times the average count of episodes for ACH–CEC combinations in our mock reconciliation not cited as low volume), and fewer than 11 episodes (a threshold that should only flag ACH–CEC combinations at the lowest threshold found in our analysis).

We considered, but are not proposing, limiting the scope of a potential low volume policy to safety net and rural hospitals only, since these hospital types are more likely to initiate lower volumes of episodes. However, we are concerned that this restriction would unfairly hinder other low-volume providers (which are not safety net or rural) from gaining efficiency in care coordination, since they would still bear the same financial risk as higher volume hospitals. In an internal analysis, approximately 343 acute care hospitals are not designated as safety net hospitals or rural hospitals. Of these hospitals, approximately 109 acute care hospitals would have at least one episode category that had fewer than 31 episodes in the baseline period and would meet the definition of low volume if safety net hospital status or rural hospital status was not required for a low volume qualification. Excluding non-safety net hospitals and non-rural hospitals from a low volume status could unfairly hinder nearly one-third of non-safety net hospitals or non-rural hospitals.

We also considered, but are not proposing, including alternative approaches to a low episode volume threshold in TEAM, including an approach similar to BPCI Advanced, where if a TEAM participant did not meet the 31 episode low volume threshold for a given episode category in the baseline period, the TEAM participant would not be held accountable for that episode category for the performance year that aligned with the baseline period. In other words, they would not be eligible to initiate episodes in that episode category during the performance year and would be not eligible to earn any reconciliation payment amount or repayment amount for that given episode category during the performance year. However, we are concerned that imposing a minimum volume threshold that removes TEAM participant accountability may restrict the number of hospitals eligible to participate in TEAM and limit beneficiary access to the benefits of value-based, coordinated care.

We also considered allowing low-volume episode types to be subject to a stop-loss/stop-gain limit of 5 percent, similar to Track 2, or a lower stop-loss/stop-gain limit of 3 percent, 2 percent, and 1 percent, such that TEAM participants are subject to a lower level of financial risk and gain, but still held accountable for the care provided under these episode categories. Under this approach, after creating the quality-adjusted reconciliation amount based on the TEAM participant's track selection, CMS would calculate the proportion of the quality-adjusted reconciliation amount that each episode category contributes to based on the PY episode weight. For example, Table XI.A.–012 demonstrates a TEAM participant, assuming Track 3 participation, meeting the low-volume threshold for the LEJR episode category but not for the SHFFT episode category.

TABLE XI.A.–012—EXAMPLE LOW-VOLUME THRESHOLD AT EPISODE CATEGORY LEVEL

Episode category	Meets low-volume threshold	Performance year (PY) episode count	Quality-adjusted reconciliation amount	Episode-level quality adjusted reconciliation amount
LEJR	Y	15	$50,000	$16,666.67
SHFFT	N	30		33,333.33

Table XI.A.–013 continues the example by showing the stop-loss/stop-gain cap would then be applied to each episode category where the low-volume episode-type is subject to a 5 percent stop-loss/stop-gain cap while any other non-low volume episode types are subject to the stop-loss/stop-gain cap based on the TEAM participant's Track 3 selection.

TABLE XI.A.–13—EXAMPLE LOW-VOLUME THRESHOLD APPLICATION AFFECTING STOP-LOSS/STOP-GAIN LIMITS

Episode category	Meets low-volume threshold	Stop-loss/ stop-gain limit (%)	Episode-level quality adjusted reconciliation amount	Target amount	Volume weighted target amount based on stop-loss/ stop-gain limit	Stop-loss/ stop-gain limit applied	Episode-level NPRA	Hospital-level NPRA
LEJR	Y	5	$16,666.67	$100,000	$5,000	Y	$5,000	$38,333.33
SHFFT	N	20	33,333.33	200,000	40,000	N	33,333.33	

However, as demonstrated by Tables XI.A.–12 and XI.A.–13, we are concerned that this approach adds complexity to the reconciliation calculations by adding additional steps. Further, we are also concerned that lower stop-loss/stop-gain limits would still not sufficiently protect low-volume episode TEAM participants from undue financial risk in the model.

We also considered implementing low episode volume thresholds during the performance year. Specifically, we considered not holding TEAM participants accountable for a given episode category if they initiated less than 11 or 6 episodes in a given episode category or less than 31 or 21 total episodes across episode categories in a performance year. However, we are concerned that including minimum episode volume thresholds during the performance year may introduce program integrity issues.

We seek comment on our considered policies. We also seek comment on low volume policy alternatives we have not considered.

(9) Aligning Date Range in the Baseline and Performance Years and Timing of Reconciliation

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we finalized the policy that we would calculate preliminary target prices using a 3-year rolling baseline period as described in § 512.540(b)(2). For example, for PY 1, covering the period from January 1, 2026, to December 31, 2026, we would use a baseline period from January 1, 2022, to December 31, 2024. We noted that we would attribute episodes to the baseline period based on the episode start date. An episode with an anchor hospitalization beginning in December 2022 and an anchor hospitalization discharge date in January 2023 would have an episode start date in 2022 and would be included in the baseline for PY 1 but not for PY 2, for which the baseline period is January 1, 2023, to December 31, 2025.

However, as indicated in § 512.540(a)(3), we finalized our proposal to attribute episodes to performance years based on the date of discharge from the anchor hospitalization or the date of the anchor procedure for the purpose of assigning target prices. We further clarified this approach in section X.A.3.d.(3).(d) of the FY 2025 IPPS/LTCH PPS final rule and gave the following example: If an episode has an anchor hospitalization or anchor procedure end date in December 2026 but an episode end date in January 2027, the episode is assigned to PY 1 and will have the PY 1 target price applied to it. However, if the episode starts in 2026 but both the anchor hospitalization discharge and episode end dates are in 2027, the episode is assigned to PY 2 and will have the PY 2 target price applied to it.

To better align our episode attribution and pricing methodologies across the baseline and performance periods, we are proposing to modify our approach to attribution of episodes to baseline years for the purposes of calculating preliminary target prices. Specifically, we propose to adopt the same approach that we finalized for attribution of performance year episodes, as described previously. Therefore, we are proposing that an episode with an anchor hospitalization beginning in a given baseline year and an anchor hospitalization discharge date in the subsequent baseline year would be attributed to the baseline year when the anchor hospitalization discharge date occurred. For example, an episode with an anchor hospitalization beginning in December 2022 with an anchor hospitalization discharge date in January 2023 would be included in the baseline for both PY 1 (as baseline year 2 of a baseline period from January 1, 2022, to December 31, 2024) and PY 2 (as baseline year 1 of a baseline period from January 1, 2023, to December 31, 2025). This modification does not make any change to the methodology for attribution of episodes to the performance year. We believe this approach simplifies the construction of baseline and performance year episodes and maintains consistent application of episode assignment between baseline and performance years.

We also indicated in FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that for episodes that begin in one performance year and end in a subsequent performance year we would reconcile episodes based on the episode end date. However, we recognize that reconciling an episode based on the episode's end date may unnecessarily increase operational burden when trying to manage when an episode would be reconciled, especially when comparing the target price to the performance year. For example, if an episode starts in one performance year and ends in a subsequent performance year, then a TEAM participant would have to wait an additional year before that episode would be reconciled even though its target price was aligned with the performance year of the anchor hospitalization discharge date. Table XI.A.–14 demonstrates how episodes starting in a one performance year and ending in a subsequent performance year are reconciled.

TABLE XI.A.–14—EXAMPLE OF WHEN EPISODES WOULD BE RECONCILED BASED ON EPISODE END DATE

Anchor hospitalization/procedure start date	Anchor hospitalization/procedure discharge date	Episode end date	Performance year (PY) for target price	Reconciliation time period
November 1, 2026	November 15, 2026	December 15, 2026	PY 1	Fall 2027.
November 1, 2026	December 15, 2026	January 15, 2027	PY 1	Fall 2028.
January 5, 2027	January 10, 2027	February 10, 2027	PY 2	Fall 2028.

Therefore, we propose to reconcile an episode based on the episode's anchor hospitalization or anchor procedure discharge date. We believe this approach would simplify tracking episodes and their reconciliation timing for TEAM participants. Additionally, it would keep all episodes aligned to a given performance year based on target price construction to the same reconciliation time period. Table XI.A.-15 demonstrates the proposed approach to reconciling episodes based on anchor hospitalization or anchor procedure discharge date.

TABLE XI.A.–15—EXAMPLE OF WHEN EPISODES WOULD BE RECONCILED BASED ON ANCHOR HOSPITALIZATION/ANCHOR PROCEDURE DISCHARGE DATE

Anchor hospitalization/procedure start date	Anchor hospitalization/procedure discharge date	Episode end date	Performance year (PY) for target price	Reconciliation time period
November 1, 2026	November 15, 2026	December 15, 2026	PY 1	Fall 2027.
November 1, 2026	December 15, 2026	January 15, 2027	PY 1	Fall 2027.
January 5, 2027	January 10, 2027	February 10, 2027	PY 2	Fall 2028.

We seek comment on our proposal at proposed § 512.540(b)(2)(i) through (v) to construct baseline year episodes based on the anchor hospitalization or anchor procedure discharge date. We also seek comment on our proposal at proposed § 512.540(a)(3) to reconcile episodes based on anchor hospitalization or anchor procedure discharge date.

(10) Converting Standardized Dollars to Real Dollars

(a) Converting Target Prices and Reconciliation Amounts to Real Dollars

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we finalized the methodology for constructing regional target prices and, ultimately, determining performance year spending and reconciliation amounts. Spending and reconciliation amounts are based on Medicare allowed amounts (also referred to as ''allowed amounts''), which include the amount Medicare reimburses providers as well as any beneficiary liability (that is, beneficiary deductibles and coinsurance) and payment from other payers. Specifically, we finalized an approach for using standardized dollar amounts (as also referred to as ''standardized dollars'') as opposed to the actual, nominal dollar amounts reflected on claims (also referred to as ''real dollars'') in the calculation of performance year spending and reconciliation amounts. Standardization of Medicare allowed amounts removes adjustments to payment amounts including but not limited to those from Medicare incentive programs (for example, the HVBP Program, the HAC Reduction Program, and the HIQR Program) and geographic or policy-driven payment system adjustments, such as hospital wage index or indirect medical education adjustments, from TEAM's target prices. Standardization of allowed amounts allows for meaningful comparison of resource use for services covered by CMS across provider types and geographic areas. When comparing standardized allowed amounts, cost differences primarily result from differences in practice patterns and health care delivery choices (for example, about the setting, provider type, or number of services provided). Not standardizing allowed amounts by removing adjustments and incentive payments would unduly penalize hospitals receiving additional payments for compliance and undermine the incentives of CMS reporting or quality programs. Without payment standardization, high-quality or reporting compliant hospitals may appear to have high episode payments under TEAM. Conversely, lower quality or non-reporting compliant hospitals that incur payment reduction penalties may appear to have low episode payments under TEAM. Additionally, removal of geographic adjustments is important given variation in episode payments across hospitals resulting from wage index adjustments. We want to avoid having the wage level or other adjustments for one hospital arbitrarily influence target prices for another hospital with a different wage level or adjustments, as this would introduce unintended pricing distortions not based on utilization pattern differences. Thus, we believe it is important to use standardized allowed amounts as the foundation for constructing target prices and determining performance year spending and reconciliation amounts (reconciliation payment amounts or repayment amounts) to ensure a TEAM participant's actual performance is not artificially improved or worsened because of adjustments or incentive payments.

However, we acknowledge that when target prices and reconciliation amounts are denominated in standardized dollars, they may not reflect relative differences in costs faced by TEAM participants. We expect that TEAM participants will use their reconciliation payment amounts to invest in care redesign, coordination, and delivery infrastructure, and we expect that the costs for such investments would vary by geography and by the type of hospital, such as due to differences in local wages or whether the hospital is a teaching hospital. For example, we expect that hiring a care coordinator would cost a TEAM participant more in San Francisco than in a rural part of Idaho. Therefore, we considered approaches to converting standardized target prices and reconciliation amounts back to real dollars as other CMMI models have done. For example, the BPCI Advanced model converted back

to real dollars using a ratio of the sum of real clinical episode spending to standardized allowed amount spending at the episode initiator-clinical episode category level. In another approach, the CJR model used a wage factor derived from the IPPS wage index (aligned with the fiscal year and based on the episode start date) to account for differences in real costs between model participants.

We believe that all these approaches have limitations that may unduly negatively impact TEAM participants. For example, if we used an approach similar to the BPCI Advanced model, TEAM participants that receive add-on payments unrelated to the direct costs associated with providing services (for example, low-volume volume payment adjustment payments and indirect medical payment adjustments) would have a higher real-to-standardized ratio than comparable participants that do not receive these payments. In the case where such a TEAM participant has a negative reconciliation amount (that is, owes a repayment amount to CMS), converting the reconciliation amount to real dollars would increase this repayment amount. We are worried that such an increase may unduly burden TEAM participants with already limited resources. Furthermore, specific approaches have unique limitations. For example, we believe the approach used in the CJR model of converting standard dollars back to real dollars using a wage factor ignores two key considerations. First, there may be significant differences in relative wages between the IPPS setting in which the episode is triggered and other claims settings in the post-discharge period. Therefore, applying the IPPS-derived wage factor to the entire episode (that is, all claims grouped to it, including those in the post-discharge period) may not accurately reflect differences in real costs across participants and settings of care. Second, using only the wage factor fails to take into account non-wage differences in Medicare payment amounts such as outlier payments and provider-specific adjustments from other Medicare initiatives.

Given all of these considerations, we are not proposing any methodology for converting standardized target prices and reconciliation amounts to real dollars at this time. Instead, we are keeping target prices and reconciliation amounts in standardized dollars, while requesting comment on whether we should convert to real dollars and the preferred methodology for doing so, including but not limited to all the approaches discussed herein.

(b) Converting Post-Episode Spending Amounts to Real Dollars

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) that established TEAM, we noted that some hospitals may have an incentive to withhold or delay medically necessary care until after an episode ends to reduce their actual episode payments. In order to identify and address such inappropriate shifting of care, we finalized a post-episode spending calculation methodology. In this approach, we would identify whether the average 30-day post-episode spending for a TEAM participant in any given performance year is greater than 3 standard deviations above the regional average 30-day post-episode spending, based on the 30-day post-episode spending for episodes attributed to all TEAM regional hospitals in the same region as the TEAM participant. We finalized that beginning with PY 1 for Track 3 TEAM participants, and PY 2 for Track 2 TEAM participants, if the TEAM participant's average post-episode spending exceeds this threshold, the amount above the threshold would be subtracted from the reconciliation amount or added to the repayment amount for that performance year.

We recognize it is important to remain consistent across our calculations when converting to real dollars. Therefore, we are also seeking comment on whether and how to convert the post-episode spending amounts from standardized dollars to real dollars. Specifically, we are requesting comment on whether, if a TEAM participant's average post-episode spending in the MS–DRG/HCPCS episode type exceeds the region's threshold in that MS–DRG/HCPCS episode type, the amount above the threshold should be converted from standardized to real dollars using a hospital-level real-to-standardized spending ratio.

Additionally, we considered that the post-episode spending amounts would be determined at a MS–DRG-hospital level rather than an episode level like our target price and reconciliation amount consideration because—

- Average post-episode spending is more representative of consistent patterns in the delay of medically necessary services in the post discharge period by a hospital; and
- Hospitals do not have the same incentives to not exceed the expected post-episode spending that they have with in-episode spending. Hence, TEAM participants may be subject to higher penalties if the post-episode calculation is at an episode level compared to an aggregate hospital-level.

Therefore, were we to propose to convert from standardized dollars to real dollars, we would propose to do so at the hospital level to align with the hospital-level post-episode spending amounts. The hospital level real-to-standardized ratios would be determined as the ratio of sum of total post-episode spending in real dollars to sum of total post-episode spending in standardized dollars using the set of reconciled episodes in the corresponding MS–DRG/HCPCS episode type.

We seek comment on our consideration to determine post-episode spending amounts at the MS–DRG-hospital level rather than an episode level. We also seek comment on whether and how to convert target prices, reconciliation amounts, and post-episode spending amounts from standardized dollars to real dollars in a consistent manner.

d. Health Data Reporting

As described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69800), we finalized voluntary reporting of three elements that aims to address reducing health disparities for TEAM beneficiaries. The elements include health equity plans, demographic data, and health related social needs data. We continue to believe that it is important to understand and address health needs of all TEAM beneficiaries so that they can benefit from the care redesign interventions implemented by TEAM participants. However, due to the new Administration's priorities and concern over placing additional burdens on TEAM participants in a mandatory model, we recognize the need to remove the voluntary health equity plan and the health-related social needs data to reduce burden on TEAM participants. We recognize that asking TEAM participants to submit health equity plans or report health related social needs data, even on a voluntary basis, could add an additional burden that CMS does not intend to add in the model. Even if TEAM participants choose to not voluntarily submit a health equity plan or report health related social needs data, we believe it would be a better use of TEAM participant resources to focus on care redesign activities that would help improve their performance in the model and improve the quality of care and care experience for the beneficiary, rather than spend resources on collecting and reporting health equity plan information or health related social needs data. Therefore, we are proposing to completely remove the health equity plan and health related social needs

data policies from TEAM, including all references to health equity plans. Though currently there is no replacement for these policies, CMS will consider adding elements that are consistent with the new Administration's focus on making America healthy again. We believe there is opportunity through TEAM to encourage healthy habits among TEAM beneficiaries to drive improvements in overall health. Changes to TEAM that would incorporate the Administration's focus on prevention and healthy living would be proposed in future notice and comment rulemaking.

Given our desire to remove health equity plans, we also propose to remove the ''Health equity reporting'' title to § 512.563 and replace it with ''Health data reporting''. Lastly, we also propose removing the definition for ''Health equity goal'', ''Health equity plan'', ''Health equity plan intervention strategy'', ''Health equity plan performance measure'', and ''Underserved community'' from the definitions at § 512.505.

Additionally, we propose to remove the voluntary collection of health-related social needs screening and reporting. This includes removing voluntary reporting of the Screening for Social Drivers of Health measure, adopted at § 512.563(b); and the Screen Positive Rate for Social Drivers of Health measure, adopted § 512.563(b).

We also continue to believe voluntarily collecting demographic data is important to better understand TEAM beneficiaries. Therefore, we are not proposing any changes to this element. We note that we did discuss in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69802) potential demographic data variables that CMS would voluntarily collect from TEAM participants such as race, ethnicity, language, disability, sexual orientation, gender identity, sex characteristics, and other demographics. While we have not specified the exact variables TEAM participants will report and will notify TEAM participants through sub-regulatory guidance of the demographic variables we wish to collect, as indicated in the final rule (89 FR 69804), we can clarify that we will not be collecting variables such as sexual orientation, race, ethnicity, or gender identity to align with the Administration's priorities and to reduce reporting burden on TEAM participants.

Finally, to align with the Administration's executive order to identify an individual's immutable biological classification as either male or female, we propose to update the name of a beneficiary-identifiable data variable, that is not used for pricing or payment purposes, that we would share with TEAM participants, pursuant to a data request and executed TEAM data sharing agreement.[434] Specifically, we propose the ''gender'' variable identified at § 512.562(c)(3) to be renamed ''sex''. We believe sex better represents the binary variable that we would be sharing with TEAM participants and allows for consistent interpretation of the term across Federal programs and initiatives.

We seek comment on our proposal at § 512.505 to remove from the definitions section health equity goal, health equity plan, health equity plan intervention strategy, health equity plan performance measure, and underserved community. We seek comment on our proposal at § 512.563 to retitle the header and remove the health equity plan and health related social needs data elements. We also seek comment on our proposal at § 512.562(c)(3) to rename the ''gender'' variable to ''sex''.

e. Referral to Primary Care Services

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69850) we finalized the referral to primary care services requirement. To comply with this requirement, TEAM participants must (1) include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure and (2) follow beneficiary freedom of choice requirements, as indicated in § 512.582(a). Since a TEAM episode only lasts 30 days after the TEAM beneficiary is discharged from the hospital, the goal of this policy is to integrate care during the transition from an acute event—an episode—back to longitudinal care relationships, such as primary care.

We continue to believe there is value in maintaining this requirement in TEAM so that the TEAM beneficiary has continuity of care after the episode ends. Therefore, we propose no change to the current policy. However, we are aware that the current policy does not take into consideration the TEAM beneficiary's relationship with existing suppliers of primary care services. In other words, the TEAM participant may refer the TEAM beneficiary to a supplier of primary care services that is different from the supplier of primary care services that the TEAM beneficiary has an established relationship with, as documented through previous encounters via claims data, as long as it complies with beneficiary freedom of choice requirements. As such, the TEAM participant may be incentivized to refer to their own suppliers of primary care services with whom they have a contractual relationship, even when complying with beneficiary freedom of choice requirements. While we anticipate most TEAM participants would refer TEAM beneficiaries back to suppliers with whom they have an existing relationship with, we seek comment on whether not specifically requiring that beneficiaries be referred back to suppliers with whom they have an existing relationship could disrupt fair competition as well as limit access to high-value care.

We considered, but are not proposing, including in the referral to primary care services the requirement that TEAM participants refer the TEAM beneficiary back to the supplier of primary care services with whom they have an established relationship. As part of the alternative, we considered identifying an established relationship by the TEAM beneficiary's interaction with a supplier of primary care services within the 2 previous years before the initiation of the episode and TEAM participants would still need to comply with beneficiary freedom of choice requirements. However, we are concerned that this consideration, namely requiring the TEAM participant to refer the TEAM participant back to a supplier of primary care services with whom they have an existing relationship, would increase TEAM participant administrative burden by having them review claims data for an existing relationship and may be challenging to operationalize given the window of time when the beneficiary is admitted to the hospital or hospital outpatient department and when they are required to submit the referral—before the TEAM beneficiary is discharged from the hospital or hospital outpatient department. As such, we considered extending the timeframe of when the referral to primary care services would occur. For example, we considered requiring the referral to primary care services occur any time before the episode ends, rather than by the time the TEAM beneficiary is discharged from the hospital or hospital outpatient department. Given the administrative burden, we considered only requiring the referral for TEAM beneficiaries who do not have any relationship with a supplier of primary

[434] Defending Women from Gender Ideology Extremism and Restoring Biological Truth to the Federal Government: *https://www.whitehouse.gov/presidential-actions/2025/01/defending-women-from-gender-ideology-extremism-and-restoring-biological-truth-to-the-federal-government/.*

care services within the two previous years before the initiation of the episode as long as beneficiary freedom of choice requirements would be met, which would reduce burden since evidence from the BPCI Advanced model suggests most beneficiaries have some existing relationship. However, we recognize burden would not be diminished because it would still require the TEAM participant to identify through claims data whether the beneficiary had an established relationship or not.

We also considered, but are not proposing, that a TEAM participant could refer the beneficiary to a supplier of primary care services other than their existing supplier, including referral to a TEAM participant's supplier of primary care services, as long as beneficiary freedom of choice requirements would be met, and the TEAM participant documented the TEAM beneficiary's preference. We recognize such a policy would increase administrative burden on TEAM participants to document a TEAM beneficiary's preference to be referred to a supplier of primary care services other than the supplier with whom they have an established relationship. However, we believe this additional documentation would help to ensure referrals are not influenced by a TEAM participant's financial or contractual relationships with certain suppliers of primary care services.

An internal analysis for the BPCI Advanced model demonstrated that approximately 94 percent of beneficiaries that initiated an episode, medical or surgical, had some primary care visit, as demonstrated through at least one evaluation & management (E&M), care management services, care planning, or wellness visit in 2 years prior to their episode. Additionally, among the small group that did not have a primary care visit in those 2 years before the episode, the BPCI Advanced model increased the share of beneficiaries getting a primary care visit within the 90-day post-discharge period by 9 percent for medical episodes. This suggests that the majority of BPCI Advanced beneficiaries have interfaced with primary care prior to their episode of care and that they may have an existing relationship with a supplier of primary care services. However, the benefit to requiring referral to primary care may be more practical for medical episodes rather than surgical episodes. This may be because the surgeon specialist has the expertise to manage the clinical follow-up, whereas a medical episode is generally an acute exacerbation of a chronic condition that primary care may typically manage. Given TEAM's current set episodes are all surgical, we recognize the primary care service referral may not be as impactful to driving primary care connections. We therefore considered, but are not proposing, removing the referral to primary care services requirement from TEAM. This means that a TEAM participant would not be required to submit a referral to primary care services for any TEAM beneficiary. In addition to the internal analysis findings, we believe many TEAM participants already have the mechanisms in place to refer the TEAM beneficiary back to their preferred supplier of primary care services, thus making the requirement inconsequential. Further, TEAM's testing of surgical episodes may also be contrary to a goal of the model. Meaning, referring back to a supplier of primary care services could result in unnecessary spending if the supplier of primary care services does not effectively manage the TEAM beneficiary's care. For example, a supplier of primary care services has the TEAM beneficiary go to the emergency department for surgical wound assessment, whereas the surgeon specialist may have informed the TEAM beneficiary the wound was healing as expected. Despite the consideration to removing the referral to primary care services requirement, we still believe it is an important policy because it provides additional assurances the TEAM participant will connect the TEAM beneficiary to primary care services for ongoing care and follow-up that may help to reduce avoidable readmissions and promote better longer-term outcomes.

We seek comment on our proposal to maintain the current policy as well as the alternative approaches for the referral to primary care services requirement as described previously. We also seek comment on alternatives that we may not have considered.

f. Waivers of Medicare Program Requirements—3-Day SNF Rule

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69833), we finalized the 3-Day SNF Rule Waiver that waives the requirement for a 3-day inpatient hospital stay prior to a Medicare-covered, post-hospital, extended-care service for eligible beneficiaries if certain conditions are met. As finalized, the 3-Day SNF Rule Waiver allows TEAM participants to send eligible TEAM beneficiaries to qualified SNFs, as described in § 512.580(b), which does not include hospitals which swing bed arrangements. We sought comment in the FY 2025 IPPS/LTCH PPS proposed rule on the potential to allow TEAM participants to use the SNF 3-day rule waiver for hospitals and Critical Access Hospitals (CAHs), as designated in § 485.606, providing post-acute care (PAC) under swing bed arrangements (89 FR 36468). We considered including swing bed arrangements under the TEAM SNF 3-day rule waiver, but did not propose to do so at the time, citing concerns about the inability to ensure the quality of swing bed arrangements for post-acute care following an early hospital discharge. We received stakeholder feedback recommending that we allow TEAM participants to use the TEAM SNF 3-day rule waiver for PAC provided under swing bed arrangements on the grounds that the inclusion of swing beds would increase access to PAC services for beneficiaries in rural areas or areas with health care shortages (89 FR 69834). However, we did not alter our proposal and finalized the TEAM SNF 3-day rule waiver without including swing beds. In the final rule, we noted that greater risks may be present for patients following early inpatient hospital discharge, and that the SNF quality rating requirement for use of the SNF 3-day rule waiver, which requires SNFs to have a CMS Five-Star Quality Rating System rating of at least 3 stars in 7 of the past 12 months, offers an additional level of protection to beneficiaries following an early discharge by ensuring that all TEAM beneficiaries discharged to a SNF after a hospital stay of fewer than 3 days are admitted to a SNF that has demonstrated that it can provide quality care to patients with significant unresolved post-surgical symptoms and problems. Without a corresponding metric in place for swing bed arrangements, we declined to include swing beds under the TEAM SNF 3-day rule waiver.

To address stakeholder concerns surrounding PAC access in rural and underserved areas, we are now proposing to allow TEAM participants to use the TEAM SNF 3-day rule waiver for TEAM beneficiaries discharged to hospitals and CAHs providing PAC under swing bed arrangements.

In order to furnish SNF services under a swing bed agreement, hospitals must be substantially in compliance with the SNF participation requirements specified at § 482.58(b), whereas CAHs must be substantially in compliance with the SNF participation requirements specified at § 485.645(d). However, per current TEAM regulations, TEAM participants are not permitted to use the TEAM 3-day SNF waiver for SNF services furnished under a swing bed agreement because: (1) The SNF 3-day rule waiver under the TEAM regulations

at § 512.580(b)(1) waives the requirement for a 3-day prior inpatient hospitalization only with respect to otherwise covered SNF services furnished by an eligible SNF and does not extend to otherwise covered post-hospital extended care services furnished by a provider under a swing bed agreement; and (2) CAHs and other rural hospitals furnishing SNF services under swing bed agreements are not included in the CMS Five-Star Quality Rating System and, therefore, cannot meet the requirement at § 512.580(b)(3) that, to be qualified for Medicare coverage of SNF services provided to a TEAM beneficiary discharged from the hospital with a stay of less than 3 days under the TEAM SNF 3-day rule waiver, the SNF must have an overall rating of 3 or higher under the CMS Five-Star Quality Rating System for 7 of the previous 12 months.

For the reasons described in stakeholder comments on the FY 2025 IPPS/LTCH PPS proposed rule as well as recent research on PAC access in rural areas, we believe it is necessary to offer hospitals participating under episode-based payment models and thereby assuming financial responsibility for their beneficiaries' PAC—especially hospitals operating in areas where PAC access may be limited and SNF services specifically may only be available in non-traditional SNF settings—additional tools and flexibility to manage and coordinate care for their beneficiaries. We agree with stakeholders that there are fewer SNFs in rural areas. Therefore, we agree with stakeholders that risk-bearing hospitals in rural areas would be better able to coordinate and manage care, and thus to control unnecessary costs, if the SNF 3-day rule waiver extended to otherwise covered SNF services provided by a hospital or CAH under a swing bed agreement. We believe this proposal would primarily benefit hospitals located in rural areas because most CAHs and hospitals that are approved to furnish post-acute SNF-level care via a swing bed agreement are located in rural areas. Consistent with this proposal, and in line with the Medicare Shared Savings Program regulations at § 425.612(a)(1) introductory text and (a)(1)(iii)(A), we also propose to revise the regulations governing the SNF 3-day rule waiver at § 512.580(b)(1) to indicate that, for purposes of determining SNF qualification for the SNF 3-day rule waiver, SNFs include providers furnishing SNF services under swing bed arrangements. We believe it's important to align the SNF 3-day rule waiver with other CMS programs and initiatives, where appropriate, to create more uniform policies and hopefully increase waiver utilization. In addition, we propose to revise § 512.580(b)(3) to specify that the minimum 3-star rating requirement for 7 of the past 12 months applies only if the provider furnishing SNF services is eligible to be included in the CMS Five-Star Quality Rating System. We do not have a comparable data element to the CMS Five-Star Quality Rating System for hospitals and CAHs under swing bed agreements; however, under §§ 512.590 and 512.586(a), we reserve the right to monitor and audit the use of payment waivers. We will continue to monitor the use of the SNF 3-day rule waiver to ensure TEAM participants are not compromising beneficiary protections at § 512.582(a) and reserve the right to perform remedial action under § 512.592 if the waiver is used inappropriately or beneficiaries are not receiving appropriate care.

Additionally, we note the possibility that a beneficiary could be admitted to a hospital, have an inpatient stay of less than 3 days, and then be admitted to the same hospital under its swing bed agreement. As previously discussed, we believe hospitals that bear a degree of financial risk have a stronger incentive not to overutilize services and have an incentive to recommend a beneficiary for admission to a SNF only when it is medically appropriate. We also note this scenario could occur when a beneficiary meets the generally applicable 3-day stay requirement. Thus, we do not believe extending the SNF 3-day rule waiver to include services furnished by a hospital under a swing bed agreement would create a new gaming opportunity.

We considered, but are not proposing, including only swing bed arrangements at CAHs under the expanded TEAM SNF 3-day rule waiver. While stakeholder feedback received on the 2025 IPPS/LTCH PPS proposed rule focused on swing bed arrangements at CAHs, we believe that the inclusion of swing bed arrangements at other hospitals is better aligned with the swing bed eligibility requirements detailed in § 482.58.

We seek comment on our proposal at § 512.580(b)(3) to allow TEAM participants to use the TEAM SNF 3-day rule waiver for TEAM beneficiaries discharged to hospitals and CAHs providing post-acute care (PAC) under swing bed arrangements.

g. Decarbonization and Resilience Initiative

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69859) we finalized the Decarbonization and Resilience Initiative (DRI). This initiative was designed to address threats posed by climate change to the Nation's health and health care system by collecting, monitoring, and assessing hospital carbon emissions and their effects on health outcomes, costs, and quality. The initiative includes two primary elements—

- Emissions reporting in four priority areas: organizational, building energy, anesthetic gas, and transportation; and
- Technical assistance on reducing emissions.

While the DRI is a voluntary initiative for TEAM participants and their hospital corporate affiliates, we recognize it does not align with the Administration's priorities. We note that it is not uncommon to reevaluate policies and programs, and that doing so is within an agency's discretion, especially after a change in Administration, to implement changes through rulemaking. Additionally, since TEAM is a mandatory model, we want to reduce the reporting burden and reduce administrative costs on TEAM participants as much as possible, so eliminating this initiative will reduce the amount of data TEAM participants may report and reduce the costs to set up the reporting infrastructure. The Episode Payment Models and the Cardiac Rehabilitation (CR) Incentive Payment Model were cancelled because, at that time, those models were not in the best interest of the Agency or the providers affected by them (82 FR 57066), and we similarly believe that retaining the DRI in TEAM is not in the best interest of the Agency or providers who already a part of a mandatory model. We believe removing this initiative from TEAM will allow TEAM participants to focus on the requirements of the model, rather than a voluntary initiative. We also believe that cancelling the DRI from TEAM will offer CMS flexibility to design and test other initiatives in the future that align with the Administration's goals. We note that TEAM participants are not precluded from continuing their own efforts to reduce greenhouse gas emissions and are encouraged to engage in other areas that may help improve patient quality of care and reduce hospital spending and operating costs. Therefore, we propose to remove the DRI from TEAM.

We seek comment on our proposal to remove the DRI from TEAM and remove the corresponding regulations at § 512.598.

XII. MedPAC Recommendations and Publicly Available Files

A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2025 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this proposed rule. MedPAC recommendations for the IPPS for FY 2026 are addressed in Appendix B to this proposed rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov*.

B. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2022 Medicare cost reports used to create the proposed FY 2026 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4. of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2007 through FY 2026 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2022 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.C.4 of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2026 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2026 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Periods Available: FY 2005 through FY 2026.

5. FY 2026 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2026 proposed rule home page or the FY 2026 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2026 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: internet at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year*.

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text*.

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2026.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-*

for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2026 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY-1994-through-Present*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2026 IPPS Update.

11. AOR/BOR File

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR file are ''Before Outliers Removed'' and the AOR file is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2026 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2026 proposed rule home page or the FY 2026 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2026 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2026 proposed rule home page or the FY 2026 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2026 IPPS Update.

14. Hospital Readmissions Reduction Program Supplemental File

The Hospital Readmissions Reduction Program Supplemental File is only available and updated for the final rule, when the most recent data is available. Therefore, we refer readers to the FY 2025 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2026 IPPS/LTCH PPS proposed rule supplemental file.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2026 proposed rule home page or the FY 2026 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2026 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for DSH-eligible hospitals as well as the supplemental payments for eligible IHS and Tribal hospitals and hospitals located in Puerto Rico for FY 2026. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments, estimated per-claim uncompensated care payment amounts, and if applicable, supplemental payment amounts. The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2026 proposed rule home page or the FY 2026 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2026 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of the preamble of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.) Two versions of this file are created each year to support rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS/Index.html (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html.*

Periods Available: FY 2025 through FY 2027 applications.

XIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. To fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

In this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The following ICRs are listed in the order of appearance within the preamble (see sections II. through XI. of the preamble of this proposed rule).

B. Collection of Information Requirements

1. ICRs for the Hospital Readmissions Reduction Program

In section VI.K. of the preamble of this proposed rule, we discuss our proposed updates to the Hospital Readmissions Reduction Program. Specifically, in this proposed rule, we propose to (1) modify the six readmission measures in the program to include Medicare Advantage (MA) beneficiaries into the patient cohorts, and (2) modify the applicable performance period from a 3-year period to a 2-year period. All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures, therefore this proposal would not impact information collection burden. We believe that continuing to use these claims-based measures would not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes under OMB control number 0938–1197 (expiration date October 31, 2027).

2. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section VI.L. of the preamble of this proposed rule, we discuss our proposed updates to the Hospital VBP Program. Specifically, we propose to modify the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty/Total Knee Arthroplasty (THA/TKA) measure in alignment with the Hospital IQR Program, beginning with the April 1, 2029–March 31, 2031, performance period/FY 2033 payment determination. The proposed modifications would include adding Medicare Advantage (MA) beneficiaries into the patient cohorts and modifying the applicable performance period from a 3-year period to a 2-year period.

The Hospital-Level RSCR Following Elective Primary THA/TKA measure currently uses data that are collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes; therefore, there is no additional information collection burden associated with this measure regarding the modification of the applicable performance period. We also do not anticipate any change in burden associated with the proposed modification to add MA beneficiaries into the patient cohorts. As proposed, the measure would use MA encounter data already collected by CMS to determine cohort inclusion criteria, complications outcomes, and present on admission (POA) comorbidities. We discuss the burden associated with the similar proposal to modify the Hospital-Level RSCR Following Elective Primary THA/TKA measure under the Hospital IQR Program in section X.C.3.b of the preamble of this proposed rule.

We also propose to remove the Health Equity Adjustment (HEA) that rewards top performing hospitals that serve higher proportions of patients with dual eligibility status. Because the HEA affects the scoring methodology and does not require hospitals to submit any additional information, we do not anticipate any change in burden associated with the proposal.

3. ICRs for the Hospital-Acquired Condition (HAC) Reduction Program

OMB has currently approved 28,840 hours of burden and approximately $1.5 million under OMB control number 0938–1352 (expiration date November 30, 2025), accounting for information collection burden experienced by 400 subsection (d) hospitals selected for validation each year in the HAC Reduction Program.

In section VI.M. of the preamble of this proposed rule, we discuss our proposed updates to the HAC Reduction Program. Specifically, we propose to update the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) Hospital-Acquired Infection (HAI) chart-abstracted measures to a more recent baseline year to better reflect current HAI diagnostic practices to improve patient safety outcomes and quality of care. This proposed update does not affect the amount of data hospitals are required to submit for these measures, therefore we do not anticipate any change in information collection burden. Information collection burden associated with collection of data for these measures is accounted for by CDC under OMB control number 0920–0666 (expiration date December 31, 2027).

4. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

Data collections for the Hospital IQR Program are associated with OMB control number 0938–1022 (expiration date January 31, 2026), under which OMB has currently approved 2,283,878 hours of burden at a cost of approximately $92.1 million, accounting for information collection burden experienced by approximately 3,050 IPPS hospitals and 1,500 non-IPPS hospitals for the FY 2027 payment determination. In this proposed rule, we describe the burden changes regarding collection of information, under OMB control number 0938–1022.

For more detailed information on our proposals for the Hospital IQR Program, we refer readers to sections X.C.3., X.C.4., and X.C.7. of the preamble of this proposed rule. We proposed modifications to two measures: (1) the Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure (herein after referred to as the COMP–HIP–KNEE measure) beginning with the FY 2027 payment determination, associated with the April 1, 2023–March 31, 2025 performance period; (2) the Hospital 30-Day, All-

Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization (hereinafter referred to as the MORT–30–STK) measure, beginning with the FY 2027 payment determination, associated with a July 1, 2023–June 30, 2025 performance period. We also proposed to modify the reporting requirements of the Hybrid Hospital-Wide Readmission (HWR) measure beginning with the FY 2028 payment determination, associated with a July 1, 2025–June 30, 2026, performance period; and the Hybrid Hospital-Wide Mortality (HWM) measure beginning with the FY 2028 payment determination, associated with a July 1, 2025–June 30, 2026, performance period. We do not anticipate any of these proposals will affect information collection burden.

We also proposed to remove four measures beginning with the CY 2024 reporting period/FY 2026 payment determination: (1) the Hospital Commitment to Health Equity measure; (2) the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure; (3) the Screening for Social Drivers of Health measure; and (4) the Screen Positive Rate for Social Drivers of Health Measure. We discuss the impacts on information collection burden associated with these proposals later in this section.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2023 National Occupational Employment and Wage Estimates (OEWS), we propose to use the mean hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.69.[435] We believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of this proposed rule for the Hospital IQR Program. If BLS releases updated wage rates after this proposed rule is published and before the final rule is published, we will maintain the wage rates used in this proposed rule.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69894), our burden estimates were based on an assumption of approximately 3,050 IPPS hospitals. For this proposed rule, based on data from the FY 2025 Hospital IQR Program payment determination, we are maintaining that assumption and estimate that approximately 3,050 IPPS hospitals will report data to the Hospital IQR Program for the CY 2026 reporting period.

b. Information Collection Burden Estimate for the Proposed Modifications to the Hospital-Level, RSCR Following Elective Primary THA/TKA Measure and Hospital 30-Day, All-Cause, RSMR Following Acute Ischemic Stroke Hospitalization Measure Beginning With the FY 2027 Payment Determination

In sections X.C.3.a. and X.C.3.b. of the preamble of this proposed rule, we discuss the proposals to modify the COMP–HIP–KNEE measure beginning with the FY 2027 payment determination, associated with the April 1, 2023—March 31, 2025 performance period and the MORT–30–STK measure beginning with the FY 2027 payment determination, associated with the July 1, 2023–June 30, 2025 performance period. These proposed modifications would include adding MA patients to the current cohort of patients and shortening the performance period from 3 years to 2 years. Because these measures would be calculated using MA encounter data and Medicare FFS claims that are already reported to the Medicare program for payment purposes, modifying these measures would not result in a change in burden associated with OMB control number 0938–1022.

c. Information Collection Burden Estimate for the Proposed Modification of the Hybrid HWR and HWM Measures Beginning With the FY 2028 Payment Determination

In section X.C.7.c. of the preamble of this proposed rule, we propose to modify the Hybrid HWR and HWM measure reporting requirements beginning with the FY 2028 payment determination, associated with a July 1, 2025–June 30, 2026, performance period. This modification would lower the submission thresholds for both the Hybrid HWR and HWM measures to allow for up to two missing laboratory results and up to two missing vital signs, reduce the core clinical data elements (CCDEs) submission requirement to 70 percent or more of discharges, and reduce the submission requirement of linking variables to 70 percent or more of discharges.

In the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499), we finalized that submission of CCDEs and linking variables associated with the Hybrid HWR and Hybrid HWM measures will remain voluntary. In the FY 2020 IPPS/LTCH PPS and FY 2022 IPPS/LTCH PPS final rules, respectively, we estimated the burden for voluntary reporting for the Hybrid HWR (84 FR 42603 and 42604) and Hybrid HWM measures (86 FR 45508) and stated that we encourage all hospitals to submit data for the Hybrid HWR and Hybrid HWM measures during the voluntary reporting period. As a result, our previously finalized reporting burden estimates assume that all hospitals will participate in order to not underestimate the burden on participating hospitals and account for the submission of CCDEs and linking variables. Therefore, while the proposed modifications are designed to reduce the administrative burden associated with reporting these measures, they would not affect information collection burden as neither the amount of data collected nor frequency of data submission are impacted.

d. Information Collection Burden Estimate for the Proposed Removal of the Hospital Commitment to Health Equity Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section X.C.4.a. of the preamble of this proposed rule, we propose to remove the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2024 reporting period/FY 2026 payment determination. Reporting on the HCHE measure involves each hospital being required to provide responses and attest ''yes'' or ''no'' in response to as many as five questions one time per year for a given reporting period through CMS' HQR System. We estimate each hospital would require 10 minutes (0.167 hours) annually to report this measure.

The current burden estimate approved under OMB control number 0938–1022 is 509 hours annually across all 3,050 IPPS hospitals (0.167 hours × 3,050 IPPS hospitals). Therefore, we estimated the removal of this measure would decrease the burden for all 3,050 IPPS hospitals

[435] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed November 27, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

by 509 hours annually at a savings of $28,188 (509 hours × $55.38).

e. Information Collection Burden Estimate for the Proposed Removal of the COVID–19 Vaccination Coverage Among HCP Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section X.C.4.b. of the preamble of this proposed rule, we propose to remove the COVID–19 Vaccination Coverage among HCP measure beginning with the CY 2024 reporting period/FY 2026 payment determination. This measure was previously finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45374 through 45382), and the associated information collection is approved under OMB control number 0920–1317 [436] (expiration date January 31, 2028).

Hospitals have the option to manually enter data directly into the Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) web-based application or by uploading a CSV file. CDC estimates that each hospital requires between 40 minutes (0.67 hours) to upload a CSV file and 45 minutes (0.75 hours) monthly to enter the data manually. CDC assumes that manual data entry would be completed by a Microbiologist with a wage rate of $58.60/hour and uploading of a CSV file would be completed by an Information Technologist with a wage rate of $56.50/hour. Therefore, we estimate that this proposal will result in a decrease in burden of between 24,400 hours (0.67 hours × 12 months × 3,050 IPPS hospitals) at a cost of $1,378,600 (24,400 hours × $56.50) and 27,450 hours (0.75 hours × 12 months × 3,050 IPPS hospitals) at a cost of $1,608,570 (27,450 hours × $58.60) annually across all 3,050 IPPS hospitals under OMB control number 0920–1317.

f. Information Collection Burden Estimate for the Proposed Removal of the Social Drivers of Health Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section X.C.4.c. of the preamble of this proposed rule, we propose to remove the Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. There are two components to this measure: patient screening for five health related social needs domains and hospital submission of aggregated hospital-level measure data. We estimate each patient requires 2 minutes (0.033 hours) to complete the screening and each hospital requires 10 minutes (0.167 hours) annually to report this measure.

With regard to patient screening, the currently approved burden estimate under OMB control number 0938–1022 is 625,500 hours annually for 18,765,000 patients (0.033 hours × 18,765,000 patients). With regard to measure reporting, the currently approved burden estimate is 509 hours annually across all 3,050 IPPS hospitals (0.167 hours × 3,050 IPPS hospitals).

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $25.63/hour based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[437] To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of $1,192 is divided by 40 hours to calculate an hourly pre-tax wage rate of $29.80/hour.[438] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[439] resulting in the post-tax hourly wage rate of $25.63/hour. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs because the individuals' activities, if any, will occur outside the scope of their employment.

Therefore, we estimate the removal of this measure would decrease the burden for all 3,050 IPPS hospitals by 626,009 hours (625,500 + 509) annually at a savings of $16,059,753 (625,500 hours × $25.63 + 509 hours × $55.38).

g. Information Collection Burden Estimate for the Proposed Removal of the Screen Positive Rate for Social Drivers of Health Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section X.C.4.c. of the preamble of this proposed rule, we propose to remove the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. For this measure, hospitals are required to report on an annual basis the number of patients who screen positive for one or more of the five Social Drivers of Health domains divided by the total number of patients screened (reported as five separate rates). We estimate each hospital requires 10 minutes (0.167 hours) annually to report this measure.

The current burden estimate approved under OMB control number 0938–1022 is 509 hours annually across all 3,050 IPPS hospitals (0.167 hours × 3,050 IPPS hospitals). Therefore, we estimated the removal of this measure would decrease the burden for all 3,050 IPPS hospitals by 509 hours annually at a savings of $28,188 (509 hours × $55.38/hour).

We invite public comments on the proposed information collection requirements and whether our estimated burden reduction of 0.033 hours per patient and an annual decrease of 509 hours in burden per hospitals at admission is an accurate estimate.

h. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022 (expiration date January 31, 2026), we estimate that the policies promulgated in this proposed rule would result in a decrease in information collection burden of 627,027 hours at a savings of $16,116,129. We also estimate that the policies promulgated in this proposed rule would result in a decrease in information collection burden of between 24,400 hours at a savings of $1,378,600 and 27,450 hours at a savings of $1,608,570 under OMB control number 0920–1317. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1022. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory

[436] Available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202501-0920-003*. Accessed February 26, 2025.

[437] Office of the Assistant Secretary for Planning an Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-departmenthealth-human-services-regulatory-impact-analysesconceptual-framework*.

[438] Bureau of Labor and Statistics, Usual Weekly Earnings of Wage and Salary Workers, First Quarter 2024. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf*. Accessed March 3, 2025.

[439] U.S. Census Bureau, Income in the United States: 2023, p. 43, September 2024. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf*.

Impact Analysis (section I.K. of Appendix A of this proposed rule).

TABLE XIII.B–01—SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938–1022 for the CY 2024 Reporting Period								
Removal of HCHE Measure	−0.167	1	3,050	1	-0.167	0	509	−509
Removal of Social Drivers of Health Measure (Patient Screening)	−0.033	1	18,765,000	1	−.033	0	625,500	−625,500
Removal of Social Drivers of Health Measure (Measure Reporting)	−0.167	1	3,050	1	−0.167	0	509	−509
Removal of Screen Positive for Social Drivers of Health Measure	−0.167	1	3,050	1	−0.167	0	509	−509
Total Change in Information Collection Burden Hours: −627,027.								
Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (−627,027) = −$16,116,129.								

TABLE XIII.B–02—SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

Activity	Estimated time per record (minutes)	Number reporting periods per year	Number of respondents reporting	Average number records per respondent per period	Annual burden (hours) per respondent	Proposed annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920–1317 for the CY 2024 Reporting Period								
Removal of COVID–19 Vaccination Coverage Among HCP Measure	*−0.75	12	3,050	1	−9	0	27,450	−27,450
Total Change in Information Collection Burden Hours: −27,450.								
Total Cost Estimate: Updated Hourly Wage ($58.60) × Change in Burden Hours (−27,450) = −$1,608,570.								

*For purposes of this table, we state the maximum possible burden across all IPPS hospitals.

5. ICRs for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

OMB has currently approved 109 hours of burden at a cost of $2,844 under OMB control number 0938–1175 (expiration date November 30, 2027), accounting for the annual information collection requirements for 11 PCHs for the PCHQR Program. In this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1175 for PCHs.

For more detailed information on our proposals for the PCHQR Program, we refer readers to section X.D. of the preamble of this proposed rule. We propose to remove three measures beginning with the FY 2026 program year: (1) the Hospital Commitment to Health Equity measure; (2) the Screening for Social Drivers of Health measure; and (3) the Screen Positive Rate for Social Drivers of Health Measure. We discuss the impacts on information collection burden associated with these proposals later in this section.

We also propose to modify the public reporting requirements to allow for public reporting of the PCHQR Program on the Care Compare tool on Medicare.gov or a successor website in addition to current publication in the Provider Data Catalog. This proposal would not affect information collection burden as neither the amount of data collected nor frequency of data submission are impacted.

Using the most recent data from the BLS for medical records specialists (SOC 29–2072), entitled, the May 2023 National Occupational Employment and Wage Estimates (OEWS), we propose to use the mean hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.69. We believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of this proposed rule for the PCHQR Program. If BLS releases updated wage rates after this proposed rule is published and before the final rule is published, we will maintain the wage rates used in this proposed rule.

b. Information Collection Burden Estimate for the Proposed Removal of the Hospital Commitment to Health Equity Measure Beginning With the FY 2026 Program Year

In section X.D.2.a. of the preamble of this proposed rule, we propose to remove the Hospital Commitment to Health Equity (HCHE) measure beginning with the FY 2026 program year. Reporting on the HCHE measure involves each PCH being required to provide responses and attest ''yes'' or ''no'' in response to as many as five questions one time per year for a given program year through CMS' HQR System.

The current burden estimate approved under OMB control number 0938–1175 is 2 hours annually across all 11 PCHs (0.167 hours × 11 PCHs). Therefore, we estimated the removal of this measure would decrease the burden for all 11 PCHs by 2 hours annually at a savings of $111 (2 hours × $55.38).

c. Information Collection Burden Estimate for the Proposed Removal of the Screening for Social Drivers of Health Measure Beginning With the FY 2026 Program Year

In section X.D.2.b. of this proposed rule, we propose to remove the Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. There are two components to this measure: patient screening for five health related social needs domains and PCH submission of aggregated PCH-level measure data. In the FY 2024 IPPS/LTCH PPS final rule, the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures were adopted with voluntary reporting in the FY 2026 program year followed by mandatory reporting on an annual basis beginning with the FY 2027 program year (88 FR 59317 and 59318). We estimate each patient requires 2 minutes (0.033 hours) to complete the screening and each PCH requires 10 minutes (0.167 hours) annually to report this measure.

With regard to patient screening, the currently approved burden estimate under OMB control number 0938–1175 is 28 hours for 828 patients (0.033 hours × 828 patients) for the FY 2026 program year and 101 hours annually for 3,025 patients (0.033 hours × 3,025 patients) beginning with the FY 2027 program year. With regard to measure reporting, the currently approved burden estimate is 1 hour (0.167 hours × 6 PCHs) for the FY 2026 program year and 2 hours annually (0.167 hours × 11 PCHs) beginning with the FY 2027 program year. We invite public comments on the proposed information collection requirements and whether our estimated burden reduction of 0.033 hours per patient and an annual decrease of 2 hours in burden per PCH at admission is an accurate estimate.

We determine the cost for patients (or their representative) undertaking administrative and other tasks, such as filling out a survey or intake form, using a post-tax wage of $25.63/hour based on the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies the approach for valuing time when individuals undertake activities on their own time.[440] To derive the costs for patients (or their representatives), a measurement of the usual weekly earnings of wage and salary workers of $1,192 is divided by 40 hours to calculate an hourly pre-tax wage rate of $29.80/hour.[441] This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 14 percent calculated by comparing pre- and post-tax income,[442] resulting in the post-tax hourly wage rate of $25.63/hour. Unlike our state and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs because the individuals' activities, if any, will occur outside the scope of their employment.

Therefore, we estimate the removal of this measure would decrease the burden by 29 hours (1 hour + 28 hours) at a savings of $773 (28 hours × $25.63 + 1 hour × $55.38) for 6 PCHs for the FY 2026 program year and 103 hours (2 hour + 101 hours) at a savings of $2,699 (101 hours × $25.63/hour + 2 hours × $55.38/hour) for 11 PCHs for the FY 2027 program year.

d. Information Collection Burden Estimate for the Proposed Removal of the Screen Positive Rate for Social Drivers of Health Measure Beginning With the FY 2026 Program Year

In section X.D.2.b. of the preamble of this proposed rule, we propose to remove the Screen Positive Rate for Social Drivers of Health measure beginning with the FY 2026 program year. For this measure, PCHs are required to report on an annual basis the number of patients who screen positive for one or more of the five Social Drivers of Health domains divided by the total number of patients screened (reported as five separate rates). We estimate each PCH requires 10 minutes (0.167 hours) annually to report this measure.

The current burden estimate approved under OMB control number 0938–1175 is 1 hour (0.167 hours × 6 PCHs) for the FY 2026 program year and 2 hours annually (0.167 hours × 11 PCHs) beginning with the FY 2027 program year. Therefore, we estimated the removal of this measure would decrease the burden by 1 hours at a savings of $55 (1 hour × $55.38) for the FY 2026 program year and 2 hours at a savings of $111 (2 hours × $55.38) beginning with the FY 2027 program year.

e. Summary of Information Collection Burden Estimates for the PCHQR Program

In summary, under OMB control number 0938–1175 (expiration November 30, 2027), we estimate that the policies promulgated in this proposed rule would result in a decrease in burden of 107 hours and $2,921. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1175. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.L. of Appendix A of this proposed rule).

[440] Office of the Assistant Secretary for Planning an Evaluation, Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices, September 17, 2017. Available at *https://aspe.hhs.gov/reports/valuing-time-us-departmenthealth-human-services-regulatory-impact-analysesconceptual-framework*.

[441] Bureau of Labor and Statistics, Usual Weekly Earnings of Wage and Salary Workers, First Quarter 2024. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf*. Accessed March 3, 2025.

[442] U.S. Census Bureau, Income in the United States: 2023, p. 43, September 2024. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf*.

TABLE XIII.B–03—SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2026 PROGRAM YEAR

Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed annual burden (hours) across PCHs	Previously finalized annual burden (hours) across PCHs	Net difference in annual burden hours
Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938–1175 for the FY 2026 Program Year								
Removal of HCHE Measure	−0.167	1	11	1	−0.167	0	2	−2
Removal of Social Drivers of Health Measure (Patient Screening)	−0.033	1	828	1	−.033	0	28	−28
Removal of Social Drivers of Health Measure (Measure Reporting)	−0.167	1	6	1	−0.167	0	1	−1
Removal of Screen Positive for Social Drivers of Health Measure	−0.167	1	6	1	−0.167	0	1	−1
Total Change in Information Collection Burden Hours: −32.								
Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (−32) = −$939.								

TABLE XIII.B–04—SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2027 PROGRAM YEAR

Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Proposed annual burden (hours) across PCHs	Previously finalized annual burden (hours) across PCHs	Net difference in annual burden hours
Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938–1175 for the FY 2027 Program Year								
Removal of HCHE Measure	−0.167	1	11	1	−0.167	0	2	−2
Removal of Social Drivers of Health Measure (Patient Screening)	−0.033	1	3,025	1	−.033	0	101	−101
Removal of Social Drivers of Health Measure (Measure Reporting)	−0.167	1	11	1	−0.167	0	2	−2
Removal of Screen Positive for Social Drivers of Health Measure	−0.167	1	11	1	−0.167	0	2	−2
Total Change in Information Collection Burden Hours: −107.								
Total Cost Estimate: Updated Hourly Wage (Varies) × Change in Burden Hours (−107) = −$2,921.								

6. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

As required by section 1886(m)(5)(A)(i) of the Act, an LTCH that does not meet the requirements of the LTCH QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual update for that fiscal year. We estimate that the burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. In section X.E.4 of the preamble of this proposed rule, we are proposing to amend the LTCH QRP reconsideration request policy and process. As we noted in the FY2016 IPPS/LTCH PPS Final rule (80 FR 49755), we believe the reconsideration requirements, and the associated burden would be incurred subsequent to an administrative action. In accordance with the implementing regulations for the PRA (5 CFR 1320.4(a)(2) and (c)), the burden associated with any information collected subsequent to the administrative action is exempt from the requirements of the PRA. However, we have provided detailed cost burden estimates in section I.M. of Appendix A of this proposed rule. We welcome public comments on the accuracy of the cost estimate assigned to this administrative burden.

a. Information Collection Burden Estimate for the Proposed Modification of Reporting Requirements for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2028 LTCH QRP

In section X.E.3. of the preamble of this proposed rule, we propose to modify reporting requirements for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure to exclude patients who have expired in the LTCH beginning with the FY 2028 LTCH QRP. Version 5.1 of the LCDS, which includes the Patient/Resident COVID–19 Vaccine item (O0350) for purposes of reporting the Patient/Resident COVID–19 Vaccine measure, has been approved under OMB control number 0938–1163 (Expiration date: 12/31/2027). To implement the proposed modification to this measure, we also propose to remove the related Patient/Resident COVID–19 Vaccine Status item (O0350) from the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) form used for patients who have expired. The remaining LCDS forms used for Planned Discharge and Unplanned Discharge would continue to include the Patient/Resident COVID–19 Vaccine Status item (O0350) for purposes of collecting and reporting data on the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. The following is a discussion of this information collection.

If our proposal in section X.E.3. is finalized, LTCHs would no longer be required to collect information and report the Patient COVID–19 Vaccination Status item on the LCDS form used for patients who have expired in the LTCH. This would result in a decrease of 0.005 hours (0.3 minutes/60

minutes) of clinical staff time on the LCDS form used for expired patients. We identified the staff type based on past LTCH burden calculations, and our assumptions are based on the staff type generally necessary to perform an assessment.

Using data collected for FY 2024, we estimate 130,050 total admissions and 6,503 expired assessments from 330 LTCHs annually. This equates to a decrease of 33 hours for all LTCHs (6,503 × 0.005 hour) and 0.10 hours per LTCH.

We estimate that the item on the LCDS would be completed equally by a Registered Nurse (RN) and a Licensed Practical and Licensed Vocational Nurse (LPN/LVN). However, LTCHs determine the staffing resources necessary. For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates. To account for other indirect costs and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table XIII.B–05. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of $70.10/hour was calculated by weighting each adjusted hourly wage equally (that is, 50 percent) [($82.76 × 0.5) + ($57.44 × 0.5) = $70.10].

TABLE XIII.B–05—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2023 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hour)	Overhead and fringe benefit ($/hour)	Adjusted hourly wage ($/hour)
Registered Nurse (RN)	29–1141	$41.38	$41.38	$82.76
Licensed Practical Nurse/Licensed Vocational Nurse (LPN/LVN)	29–2061	28.72	28.72	57.44

We estimate that the burden and cost for LTCHs for complying with data collection and reporting requirements for the FY 2028 LTCH QRP would decrease under this proposal. Using FY 2024 data, we estimate a total of 6,503 expired assessments from 330 LTCHs annually for a decrease of 33 hours for all LTCHs (6,503 × 0.005 hour) and 0.10 hours per LTCH. Given 33 hours at $70.10 per hour, we estimate the total cost will be decreased by $2,313.30 (33 hours × $70.10 per hour) for all LTCHs annually, or $7.01 per LTCH (2,279.13 ÷ 330 LTCHs) annually.

b. Information Collection Burden Estimate for the Proposed Removal of Four Standardized Patient Assessment Data Elements Beginning With the FY 2028 LTCH QRP

In section X.E.4 of the preamble of this proposed rule, we propose to remove four standardized patient assessment data elements from the LCDS, with respect to admission, effective October 1, 2026.

We identified the staff type based on past LTCH burden calculations, and our assumptions are based on the categories generally necessary to perform an assessment. We believe that the items would be completed equally by a Registered Nurse (RN) and a Licensed Practical and Licensed Vocational Nurse (LPN/LVN). However, LTCHs determine the staffing resources necessary.

For the purposes of calculating the costs associated with the collection of information requirements, we obtained median hourly wages for these staff from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates.[443] To account for other indirect costs and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table XIII.B–06. We established a composite cost estimate using our adjusted wage estimates. The composite estimate of $70.10/hr was calculated by weighting each adjusted hourly wage equally (that is, 50 percent) [($82.76 × 0.5) + ($57.44 × 0.5) = $70.10].

TABLE XIII.B–06—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2023 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hour)	Overhead and fringe benefit ($/hour)	Adjusted hourly wage ($/hour)
Registered Nurse (RN)	29–1141	$41.38	$41.38	$82.76
Licensed Practical Nurse/Licensed Vocational Nurse (LPN/LVN)	29–2061	28.72	28.72	57.44

We estimate that the burden and cost for LTCHs for complying with requirements of the FY 2028 LTCH QRP would decrease under this proposal. We estimate that the removal of these four standardized patient assessment data elements will result in a decrease of 1.2 minutes (0.3 minutes × 4), or 0.02 hours (1.2 ÷ 60). Using FY 2024 data, we estimate a total of 130,050 admissions from 330 LTCHs annually for a decrease of 2,601 hours in burden for all LTCHs (130,050 × 0.02 hour), or a decrease of 7.88 hours per LTCH (2,601 ÷ 330 LTCHs). Given 7.88 hours at $70.10 per hour, we estimate the total cost will be decreased by $552.39 (7.88 × $70.10)

[443] U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates. *https://www.bls.gov/oes/current/oes_nat.htm.*

annually, or $182,330.100 ($552.39 × 330 LTCHs) for all LTCHs annually.

c. Summary of Information Collection Burden Estimates for the LTCH QRP Program

As described in Table XIII.B–07, under OMB control number 0938–1163, we estimate that our proposals set forth in this proposed rule for the LTCH QRP, if finalized, would result in an overall decrease of 7.98 hours per LTCH, or 2,633.51 hours annually for 330 LTCHs. The total cost decrease related to this information collection is estimated at approximately −$180,016.80, or $545.51 per LTCH. The decrease in burden would be accounted for in a revised information collection request under OMB control number 0938–1163.

TABLE XIII.B–07—ESTIMATED LTCH QRP PROGRAM IMPACTS FOR FY 2028

Requirement	Per LTCH		All LTCHs	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Estimated change in burden associated with removal of one item collected on expired assessment beginning with the FY 2028 LTCH QRP	−0.10	−$7.01	−33	−$2,313.30
Estimated change in burden associated with removal of four items collected on admission assessment beginning with the FY 2028 LTCH QRP	−7.88	−552.52	−2,601	−182,330.10
Total estimated change in burden for the FY 2028 LTCH QRP	−7.98	−545.51	−2,633.51	−180,016.80

We invite public comments on the proposed modification to information collection requirements for LTCH QRP beginning with the FY 2028 LTCH QRP.

7. ICRs for the Medicare Promoting Interoperability Program

a. Background

OMB has currently approved 30,151 hours of burden at a cost of $1,571,474 under OMB control number 0938–1278 (expiration date April 30, 2027), accounting for information collection burden experienced by approximately 3,150 eligible hospitals and 1,400 CAHs for the electronic health record (EHR) reporting period in CY 2025. The collection of information burden analysis in this proposed rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and report the objectives and measures, and report electronic Clinical Quality Measures (eCQMs), under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2026 through CY 2027.

For more detailed information on our proposals for the Hospital IQR Program, we refer readers to section X.C. of the preamble of this proposed rule. For the Medicare Promoting Interoperability Program, we proposed to adopt a new optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange with a public health agency (PHA) that occurs using the Trusted Exchange Framework and Common Agreement (TEFCA), and where the eligible hospital or CAH meets certain additional requirements, beginning with the EHR reporting period in CY 2026. We also proposed to modify two measures: (1) the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guides measure, which we proposed to modify by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using the SAFER Guides published in January 2025 beginning with the EHR reporting period in CY 2026; and (2) the Security Risk Analysis measure, which we proposed to modify to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required under the HIPAA Security Rule beginning with the EHR reporting period in CY 2026. We also proposed to define the EHR reporting period in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that CY for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

Using the most recent data, the May 2023 National Occupational Employment and Wage Estimates (OEWS) from the BLS, we propose to use the mean hourly wage for medical records specialists (SOC 29–2072) for the industry, ''general medical and surgical hospitals,'' which is $27.69.[444] We believe the industry of ''general medical and surgical hospitals'' is more specific to this program compared to other industries under medical records specialists, such as ''office of physicians'' or ''nursing care facilities.'' We calculated the cost of overhead, including fringe benefits, at 100 percent of the mean hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($27.69 × 2 = $55.38) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we calculate the cost burden to eligible hospitals and CAHs using a wage plus benefits estimate of $55.38 per hour throughout the discussion in this section of the preamble of this proposed rule for the Medicare Promoting Interoperability Program. If BLS releases updated wage rates after this proposed rule appears in the **Federal Register** and before the final rule appears in the **Federal Register**, we will maintain the wage rates used in this proposed rule.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69903), our burden estimates were based on an assumption of 4,550 eligible hospitals and CAHs. For this FY 2026 proposed rule, based on data from the EHR reporting period in CY 2023, we continue to estimate approximately 3,150 eligible hospitals and 1,400 CAHs will report data to the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2026, for a total number of 4,550 respondents.

[444] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed November 27, 2024. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

b. Information Collection Burden for the Proposed Adoption of a New Optional Bonus Measure Under the Public Health and Clinical Data Exchange Objective Beginning With the EHR Reporting Period in CY 2026

In section X.F.5. of the preamble of this proposed rule, we are proposing to adopt a new optional bonus measure under the Public Health and Clinical Data Exchange objective for reporting data to a PHA using TEFCA, and where the eligible hospital or CAH meets certain additional requirements, beginning with the EHR reporting period in CY 2026.

As part of the Public Health and Clinical Data Exchange objective, eligible hospitals and CAHs can receive credit for attesting to up to one optional bonus measure. While eligible hospitals and CAHs can attest to more than one optional bonus measure, we assumed they will not attest to more than one because they cannot receive any additional credit for doing so. Under OMB control number 0938–1278, our currently approved burden estimates include 0.5 minutes for eligible hospitals and CAHs to attest to one of the previously finalized optional bonus measures (the Public Health Registry measure and the Clinical Data Registry Reporting measure) under this objective. As a result, we estimate no additional burden for eligible hospitals and CAHs that elect to instead attest to this new optional bonus measure.

c. Information Collection Burden for the Proposed Modification of the SAFER Guides measure Beginning With the EHR Reporting Period in CY 2026

In section X.F.4. of the preamble of this proposed rule, we are proposing to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using the SAFER Guides published in January 2025 beginning with the EHR reporting period in CY 2026.

In the FY 2022 IPPS/LTCH PPS final rule, we adopted the SAFER Guides measure and required eligible hospitals and CAHs to attest ''yes'' or ''no'' as to whether they completed an annual self-assessment on each of the nine SAFER Guides at any point during the CY in which their EHR reporting period occurs (86 FR 45479 through 45481). In the FY 2024 IPPS/LTCH PPS final rule, we finalized a requirement for eligible hospitals and CAHs to attest ''yes'' to fulfill the measure and discussed the associated costs for eligible hospitals and CAHs to conduct a SAFER Guides self-assessment (88 FR 59262 through 59265; 59432 and 59433). In this proposed rule, because we are not proposing an additional attestation, but instead propose to modify one that was previously finalized, this proposal would not result in any changes to the information collection burden currently approved under OMB control number 0938–1278.

d. Information Collection Burden for the Proposed Modification of the Security Risk Analysis Measure Beginning With the EHR Reporting Period in CY 2026

In section X.F.3. of the preamble of this proposed rule, we are proposing to modify the Security Risk Analysis measure by adding a requirement for eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(B) beginning with the EHR reporting period in CY 2026.

The currently approved burden estimate under OMB control number 0938–1278 for eligible hospitals and CAHs to conduct or review a security risk analysis, including addressing the security (to include encryption) of data created or maintained by CEHRT, implementing security updates as necessary, and correcting identified security deficiencies as part of the eligible hospital's or CAH's risk management process is approximately 6 hours annually as currently approved under OMB control number 0938–1278. Given the negligible additional effort associated with this proposal compared to the currently approved burden estimate, we propose that the currently approved burden estimate is sufficient to include the proposed attestation and do not propose any changes to the information collection burden currently approved under OMB control number 0938–1278.

e. Information Collection Burden for the Proposal to Define the EHR Reporting Period in CY 2026 and Subsequent Years as a Minimum of Any Continuous 180-Day Period Within That CY

In section X.F.2. of the preamble of this proposed rule, we are proposing to define the EHR reporting period in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that CY for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program. As this is the current requirement for the EHR reporting period in CY 2025 as finalized in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59259 through 59260), this proposal would not result in any changes to the information collection burden currently approved under OMB control number 0938–1278.

f. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date April 30, 2027), we estimate that the policies in this proposed rule would not result in a change in information collection burden. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.N. of Appendix A of this proposed rule).

8. ICRs for the Transforming Episode Accountability Model

In section XI.A. of the preamble of this proposed rule, we discuss testing the Transforming Episode Accountability Model (TEAM), finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), and propose updates to the model under the authority of the CMS Innovation Center. Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in section 1115A(d)(3) of the Act, chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models under section 1115A of the Act. As a result, the information collection requirements contained in this proposed rule for TEAM need not be reviewed by the Office of Management and Budget.

XIV. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

Stephanie Carlton, Acting Administrator of the Centers for Medicare & Medicaid Services, approved this document on April 8, 2025.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 512

Administrative practice and procedure, Health care, Health facilities, Health insurance, Intergovernmental relations, Medicare, Penalties, Reporting and recordkeeping requirements.

For the reasons set out in the preamble, 42 CFR parts 412, 413, 495, and 512 are proposed to be amended as follows:

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 1. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Section 412.24 is amended by revising paragraphs (e) and (f) to read as follows:

§ 412.24 Requirements under the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program.

* * * * *

(e) *Extraordinary circumstances exceptions (ECEs)*—(1) *General rule.* CMS may grant an ECE with respect to the reporting requirements under this section in the event of extraordinary circumstances beyond the control of the PCH. For purposes of this paragraph (e), an extraordinary circumstance is an event beyond the control of a PCH (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the PCH to comply with one or more applicable reporting requirements with respect to a fiscal year.

(2) *Process for requesting an ECE.* (i) A PCH may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the PCH of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the PCH, the written decision specifies whether the PCH is exempted from one or more reporting requirements or whether CMS has granted the PCH an extension of time to comply with one or more reporting requirements.

(3) *Authority to Grant an ECE.* (i) CMS may grant an ECE to one or more PCHs that have not requested an ECE if CMS determines that—

(A) A systemic problem with a CMS data collection system directly impacted the ability of the PCH to comply with a quality data reporting requirement; or

(B) An extraordinary circumstance has affected an entire region or locale.

(ii) Any ECE granted under this paragraph (e)(3) specifies whether the affected PCHs are exempted from one or more reporting requirements or whether CMS has granted the PCHs an extension of time to comply with one or more reporting requirements.

(f) *Public reporting of PCHQR Program data.* CMS makes data submitted by PCHs under the PCHQR Program available to the public on CMS websites. Prior to making any such data submitted by a PCH available to the public, CMS gives the PCH an opportunity to review the data via the Hospital Quality Reporting (HQR) system and announces the timeline for review on the QualityNet website and applicable listservs.

■ 3. Section 412.85 is amended by revising the section heading and paragraphs (b) and (c) to read as follows:

§ 412.85 Payment adjustment for certain immunotherapy cases.

* * * * *

(b) *Discharges subject to payment adjustment.* Payment is adjusted in accordance with paragraph (c) of this section for discharges assigned to MS–DRG 018 involving expanded access use of immunotherapy or that are part of an applicable clinical trial as determined by CMS based on the reporting of a diagnosis code indicating the encounter is part of a clinical research program on the claim for the discharge or, for discharges occurring on or after October 1, 2025, other cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost.

(c) *Adjustment.* The DRG weighting factor determined under § 412.60(b) is adjusted by a factor that reflects the average cost for cases assigned to MS–DRG 018 that involve expanded access use of immunotherapy, are part of an applicable clinical trial, or where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, to the average cost for all other cases assigned to MS–DRG 018.

§ 412.90 [Amended]

■ 4. Section 412.90 is amended in paragraph (j) by removing the date ''January 1, 2025'' and adding in its place the date ''October 1, 2025''.

§ 412.101 [Amended]

■ 5. Section 412.101 is amended by—

■ a. In paragraph (b)(2)(i), removing the phrase ''FY 2010, the portion of FY 2025 beginning on January 1, 2025 and subsequent fiscal years,'' and adding in its place the phrase ''FY 2010 and FY 2026 and subsequent years,'';

■ b. In paragraph (b)(2)(iii), removing the phrase ''FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024,'' and adding in its place the phrase ''FY 2025,'';

■ c. In paragraph (c)(1), removing the phrase ''FY 2010, the portion of FY 2025 beginning on January 1, 2025, and subsequent fiscal years,'' and adding in its place the phrase '' FY 2010 and FY 2026 and subsequent years,''; and

■ d. In paragraph (c)(3) introductory text, removing the phrase ''FY 2024 and the portion of FY 2025 beginning on October 1, 2024, and ending on December 31, 2024,'' and adding in its place ''FY 2025,''.

§ 412.108 [Amended]

■ 6. Section 412.108 is amended by—

■ a. In paragraph (a)(1) introductory text, removing the date ''January 1, 2025'' and adding in its place the date ''October 1, 2025''; and

■ b. In paragraph (c)(2)(iii) introductory text, removing the date ''January 1, 2025'' and adding in its place the date ''October 1, 2025''.

■ 7. Section 412.140 is amended by revising paragraph (c)(2) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(c) * * *

(2) *Extraordinary circumstance exception (ECE)*—(i) *General rule.* CMS may grant an ECE with respect to the reporting requirements under this section in the event of extraordinary circumstances beyond the control of the hospital. For purposes of this paragraph (c)(2), an extraordinary circumstance is an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

(ii) *Process for requesting an ECE.* (A) A hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(B) CMS notifies the hospital of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision specifies whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

(iii) *Authority to Grant an ECE.* CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that—

(A) A systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement; or

(B) An extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (c)(2)(iii) specifies whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

* * * * *

■ 8. Section 412.152 is amended by—

■ a. In the definition of ''Applicable period''—

■ i. Revising the introductory text;

■ ii. Removing the word ''and'' at the end of paragraph (1);

■ iii. Removing the period at the end of paragraph (2) and adding in its place ''; and''; and

■ iv. Adding paragraph (3); and

■ b. In the definition of ''Applicable period for dual eligibility,'' removing the phrase ''3-year data period'' and adding in its place the phrase ''2-year or 3-year data period''.

The revision and addition read as follows:

§ 412.152 Definitions for the Hospital Readmissions Reduction Program.

* * * * *

Applicable period is, with respect to a fiscal year, the 2-year or 3-year period (specified by the Secretary) from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(3) Beginning with the FY 2027 program year, the applicable period is the 2-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission ratios and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary.

* * * * *

■ 9. Section 412.154 is amended by adding paragraph (d) to read as follows:

§ 412.154 Payment adjustments under the Hospital Readmissions Reduction Program.

* * * * *

(d) *Extraordinary circumstance exception (ECE)*—(1) *General rule.* CMS may grant an ECE with respect to the reporting requirements under this section in the event of extraordinary circumstances beyond the control of the hospital. For purposes of this paragraph (d), an extraordinary circumstance is an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

(2) *Process for requesting an ECE.* (i) A hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the hospital of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision specifies whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

(3) *Authority to Grant an ECE.* CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement, or that an extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (d)(3) specifies whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

* * * * *

§ 412.160 [Amended]

■ 10. Section 412.160 is amended by removing the definition of ''Health equity adjustment bonus points.''

■ 11. Section 412.165 is amended by—

■ a. Removing paragraph (b)(5);

■ b. Redesginating paragraph (b)(6) as paragraph (b)(5);

■ c. Revising newly redesignated paragraph (b)(5) and paragraph (c).

The revisions read as follows:

§ 412.165 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(b) * * *

(5) The hospital's Total Performance Score for the fiscal year is the sum of the weighted domain scores up to a maximum score of 100.

(c) *Extraordinary circumstance exception (ECE)*—(1) *General rule.* CMS may grant an ECE with respect to the reporting requirements under this section in the event of extraordinary circumstances beyond the control of the hospital. For purposes of this paragraph (c), an extraordinary circumstance is an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

(2) *Process for requesting an ECE.* (i) A hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the hospital of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision will specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

(3) *Authority to Grant an ECE.* CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement or that an extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (c)(3) specifies whether the affected hospitals are exempted from one or more reporting requirements or whether CMS has granted the hospitals an extension of time to comply with one or more reporting requirements.

■ 12. Section 412.172 is amended by adding paragraph (c) to read as follows:

§ 412.172 Payment adjustments under the Hospital-Acquired Condition Reduction Program.

* * * * *

(c) *Extraordinary circumstance exception (ECE)*—(1) *General rule.* CMS may grant an ECE with respect to the reporting requirements under this section in the event of extraordinary circumstances beyond the control of the hospital. For purposes of this paragraph (c), an extraordinary circumstance is an event beyond the control of a hospital (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the hospital to comply with one or more applicable reporting requirements with respect to a fiscal year.

(2) *Process for requesting an ECE.* (i) A hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the hospital of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision specifies whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

(3) *Authority to grant an ECE.* CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that a systemic problem with a CMS data collection system directly impacted the ability of the hospital to comply with a quality data reporting requirement, or that an extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (c)(3) will specify whether the affected PCHs are exempted from one or more reporting requirements or whether CMS has granted the PCHs an extension of time to comply with one or more reporting requirements.

* * * * *

■ 13. Section 412.273 is amended by—

■ a. Revising the section heading, the definitions of ''Termination'' and ''Withdrawal'' in paragraph (a), and paragraphs (c)(1), (d), and (e)(2); and

■ b. Adding paragraph (e)(3).

The revisions and addition read as follows:

§ 412.273 Withdrawing an application, terminating an approved 3-year reclassification, or reinstating a previous termination.

(a) * * *

Termination refers to the termination of an approved 3-year MGCRB reclassification. A termination is effective only for the full fiscal year(s) remaining in the 3-year period at the time the request is received. Requests for terminations for part of a fiscal year are not considered.

Withdrawal refers to the withdrawal of a 3-year MGCRB reclassification where the MGCRB has not yet issued a decision on the application.

* * * * *

(c) * * *

(1) A request for withdrawal must be received by the MGCRB at any time before the MGCRB issues a decision on the application.

* * * * *

(d) *Reapplication within the approved 3-year period, reinstatement of terminations, and prohibition on overlapping reclassification approvals*—(1) *Reinstatement of terminations.* Subject to the provisions of this section, a hospital (or group of hospitals) may cancel a termination, effective for the subsequent year, and request the MGCRB to reinstate the wage index reclassification for the remaining fiscal year(s) of the 3-year period.

(2) *Timing and process of reinstatement request.* Reinstatement requests must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB no later than the deadline for submitting reclassification applications for the following fiscal year, as specified in § 412.256(a)(2).

(3) *Reapplications.* A hospital may apply for reclassification to a different area (that is, an area different from the one to which it was originally reclassified for the 3-year period). If the application is approved, the reclassification will be effective for 3 years. Once a 3-year reclassification becomes effective, a hospital may no longer reinstate a termination of another 3-year reclassification, regardless of whether the termination request is made within 3 years from the date of the withdrawal or termination.

(4) *Termination of existing 3-year reclassification.* In a case in which a hospital with an existing 3-year wage index reclassification applies to be reclassified to another area, its existing 3-year reclassification will be terminated when a second 3-year wage index reclassification goes into effect for payments for discharges on or after the following October 1. The terminated reclassification in such a case is not eligible for reinstatement.

(e) * * *

(2) A request to terminate or reinstate an approved individual reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB.

(3) A request to terminate or reinstate an approved group reclassification must be submitted in writing to the MGCRB according to the method prescribed by the MGCRB.

(i) A request to terminate or reinstate an approved group reclassification that has not yet gone into effect must include all hospitals party to the reclassification.

(ii) Termination requests for group reclassification for the second or third year of the 3-year wage index reclassification and reinstatement requests for a group reclassification effective for the third year of the 3-year wage index reclassification may be submitted by an individual hospital that is party to the reclassification.

* * * * *

■ 14. Section 412.312 is amended by revising paragraph (f) to read as follows:

§ 412.312 Payment based on the Federal rate.

* * * * *

(f) *Payment adjustment for certain immunotherapy cases.* For discharges occurring on or after October 1, 2020, in determining the payment amount under this section for certain clinical trial or expanded access use immunotherapy cases, or, for discharges occurring on or after October 1, 2025, other cases where the immunotherapy product is not purchased in the usual manner, such as provided at no cost, as described in § 412.85(b), the DRG weighting factor described in paragraph (b)(1) of this section is adjusted as described in § 412.85(c).

■ 15. Section 412.560 is amended by—

■ a. Revising paragraph (d)(3); and

■ b. Adding paragraphs (d)(4) and (5).

The revision and additions read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

* * * * *

(d) * * *

(3) *CMS decision on reconsideration request.* (i) CMS notifies the LTCH, in writing, of its final decision regarding any reconsideration request through at least one of the following methods:

(A) CMS designated data submission system.

(B) The United States Postal Service.

(C) Via email from the CMS Medicare Administrative Contractor (MAC).

(ii) CMS grants a timely request for reconsideration, and reverses an initial finding of non-compliance, only if CMS determines that the long-term care hospital was in full compliance with the

LTCH QRP requirements for the applicable program year.

(4) *Request for an extension to file a reconsideration of noncompliance request.* A long-term care hospital may request, and CMS may grant, an extension to file a reconsideration request if, during the period to request a reconsideration as set forth in paragraph (d)(2) of this section, the long-term care hospital was affected by an extraordinary circumstance beyond the control of the LTCH (for example, a natural or man-made disaster).

(i) The long-term care hospital must submit its request for an extension to file a reconsideration request no later than 30 calendar days from the date of the written notification of noncompliance.

(ii) The long-term care hospital must submit its request for an extension to CMS via email to *LTCHQRPReconsiderations@cms.hhs.gov*, and it must contain the following information:

(A) The CCN for the long-term care hospital.

(B) The business name of the long-term care hospital.

(C) The business address of the long-term care hospital.

(D) Contact information for the long-term care hospital's chief executive officer or designated personnel, including the name, telephone number, title, email address, and physical mailing address, which may not be a post office box.

(E) A statement of the reason for the request for the extension.

(F) Evidence of the impact of the extraordinary circumstances, including, for example, photographs, newspaper articles, and other media.

(5) *CMS decision on extension to file a reconsideration of noncompliance request.* CMS notifies the long-term care hospital in writing of its final decision regarding its request for an extension to file a reconsideration of noncompliance request via an email from CMS.

* * * * *

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

■ 16. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

■ 17. Section 413.85 is amended by revising paragraphs (d)(2)(i) and (ii) to read as follows:

§ 413.85 Cost of approved nursing and allied health education activities.

* * * * *

(d) * * *

(2) * * *

(i) Subject to the provisions of paragraphs (d)(2)(ii) and (iii) of this section, the net cost of approved educational activities is determined based on all of the following:

(A) Determine allowable direct costs incurred by the provider for trainee stipends and compensation of teachers employed by the provider.

(B) Subtract from allowable direct costs the revenues the provider receives from students or on behalf of students enrolled in the program, such as, but not limited to, tuition, student fees, or textbooks purchased for resale.

(C) Add indirect costs of the activities as determined under the Medicare cost-finding principles in § 413.24 but limited to indirect costs that the provider itself incurs as a consequence of operating the approved educational activities.

(ii) The direct and indirect allowable costs of educational activities do not include patient care costs, costs incurred by a related organization, or costs that constitute a redistribution of costs from an educational institution to a provider or costs that have been or are currently being provided through community support.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 18. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 19. Section 495.4 is amended in the definition of ''EHR reporting period for a payment adjustment year'' by adding paragraphs (2)(x) and (3)(x) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(x) For an eligible hospital in CY 2026 and subsequent years, the EHR reporting period is any continuous 180-day period within that calendar year and applies for the fiscal year payment adjustment year that is 2 years after the calendar year of the EHR reporting period.

(3) * * *

(x) For a CAH in CY 2026 and subsequent years, the EHR reporting period is any continuous 180-day period within that calendar year and applies for the fiscal year payment adjustment year for the calendar year of the EHR reporting period.

* * * * *

PART 512—STANDARD PROVISIONS FOR MANDATORY INNOVATION CENTER MODELS AND SPECIFIC PROVISIONS FOR CERTAIN MODELS

■ 20. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 21. The heading for part 512 is revised to read as set forth above.

■ 22. Section 512.505 is amended by—

■ a. Removing the definition for ''ADI'';

■ b. Adding definitions for ''APC'' and ''CDI'' in alphabetical order;

■ c. Revising the definition for ''Final normalization factor'';

■ d. Removing the definitions for ''Health equity goal'', ''Health equity plan'', ''Health equity plan intervention strategy'', and ''Health equity plan performance measure'';

■ e. Revising the definition for ''High-cost outlier cap'';

■ f. Adding definitions for ''Medicare ID'' and ''PECOS'' in alphabetical order;

■ g. Revising the definitions for ''Prospective normalization factor'' and ''Region'';

■ h. Adding definitions for ''Scaling factor'' and ''Trend year'' in alphabetical order; and

■ i. Removing the definition for ''Underserved community''.

The additions and revisions read as follows:

§ 512.505 Definitions.

* * * * *

APC stands for Ambulatory Payment Classification.

* * * * *

CDI stands for the Community Deprivation Index.

* * * * *

Final normalization factor refers to the mean of the benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean of the risk-adjusted benchmark price for the same MS–DRG/HCPCS episode type and region.

* * * * *

High-cost outlier cap refers to the 99th percentile of regional spending for a given MS–DRG/HCPCS episode type, region, and baseline year, which is the amount at which episode spending would be capped for purposes of determining baseline and performance year episode spending.

* * * * *

Medicare ID means the hospital CCN in the PECOS.

* * * * *

PECOS stands for the Provider Enrollment, Chain, and Ownership System.

* * * * *

Prospective normalization factor refers to the multiplier incorporated into the preliminary target price to ensure that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, calculated as set forth in § 512.540(b)(6).

* * * * *

Region means one of the nine U.S. census divisions, as defined by the U.S. Census Bureau, with the U.S. territories included in Census Division 9.

* * * * *

Scaling factor means the ratio of the remapped MS–DRG or HCPCS/APC relative weight in the performance year, as applicable, to the original MS–DRG or HCPCS/APC relative weight in the baseline period.

* * * * *

Trend year means either of the 2 years immediately prior to the 3-year baseline period used in combination with the baseline period to calculate the prospective trend factor.

* * * * *

■ 23. Section 512.508 is added, under undesignated center heading ''TEAM Participation,'' to read as follows:

§ 512.508 Mandatory participation.

(a) *General.* TEAM participants, as defined in § 512.505, must participate in TEAM for the full duration of the model performance period, unless CMS terminates TEAM or the TEAM participant receives notice of termination from TEAM in accordance with § 512.596.

(b) *New hospital exception.* New hospitals with a Medicare ID with an initial effective date after December 31, 2024, within the PECOS that initiate episodes and are paid under the IPPS with a CCN primary address located in one of the mandatory CBSAs selected for participation in TEAM in accordance with § 512.515, must participate in TEAM at the beginning of the performance year that follows one full performance year since their Medicare ID initial effective date.

(1) As described in § 512.550(b)(2)(ii), CMS performs reconciliation calculations for any new or surviving TEAM participant that results from a TEAM participant's reorganization event, as defined in § 512.505, for episodes where the anchor hospitalization admission or anchor procedure occurred on or after the effective date of the reorganization event. Therefore, new hospitals that result from a TEAM participant's reorganization event begin participation in TEAM on the effective date of the reorganization event.

(2) [Reserved]

(c) *Newly qualifying hospital exception.* (1) Hospitals that begin to satisfy the definition of TEAM participant, as described in § 512.505, must participate in TEAM at the beginning of the performance year that follows one full performance year since the date on which they began to satisfy the definition of TEAM participant.

(2) Hospitals that no longer satisfy the definition of TEAM participant, as described in § 512.505, end TEAM participation on the date they no longer satisfy the definition.

(i) CMS notifies hospitals identified in this paragraph (c)(2) within 30 days of the hospital no longer satisfying the TEAM participant definition or as soon as is reasonably practicable.

(ii) [Reserved]

(d) *Monitoring.* CMS may monitor specifically for the potential shifting of patients with high anticipated treatment costs from TEAM participants to new non-participant hospitals, including hospitals in the participation deferment period in accordance with § 512.505(b) and (c).

■ 24. Section 512.520 is amended by revising paragraph (b)(4)(i) to read as follows:

§ 512.520 Participation tracks.

* * * * *

(b) * * *

(4) * * *

(i) Medicare-dependent hospital (as defined in § 512.505) and the Medicare Dependent Hospital program, as authorized by statute, is not expired at the time Track 2 selections are due, as described in paragraph (b)(2) of this section.

* * * * *

■ 25. Section 512.540 is amended by—

■ a. Revising paragraphs (a)(2) and (3) and (b)(2)(i) through (v);

■ b. In paragraph (b)(4), removing the phrase ''specified in § 512.540(a)(1)(ii)'' and adding in its place the phrase ''specified in paragraph (a)(1)(ii) of this section for each baseline year individually'';

■ c. In paragraph (b)(6) introductory text, removing the phrase ''factor, which is a multiplier'' and adding in its place the phrase ''factor at the MS–DRG/HCPCS region level, which is a multiplier''; and

■ d. Revising paragraphs (b)(7) and (8).

The revisions read as follows:

§ 512.540 Determination of preliminary target prices.

(a) * * *

(2) *Applicable time period for preliminary target prices.* CMS calculates preliminary target prices for each MS–DRG/HCPCS episode type and region for each performance year and applies the preliminary target price to each episode based on the episode's date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable. CMS also does all of the following:

(i) Accounts for MS–DRG and HCPCS/APC code changes between the baseline period and performance year by identifying diagnosis or procedure codes that are being moved from one MS–DRG or HCPCS/APC to another for the relevant performance year and mapping the new or revised MS–DRG or HCPCS/APC codes to the original codes that were used in the baseline period.

(ii) Constructs preliminary target prices using the remapped MS–DRG or HCPCS/APC codes in the same manner described in paragraph (b) of this section, with target prices for each MS–DRG/HCPCS episode type, inclusive of episodes initiated by anchor hospitalizations and anchor procedures that would be related to the remapped MS–DRG or HCPCS/APC codes.

(iii) Adjusts the preliminary target price by calculating and applying the scaling factor to the standardized episode spending of the MS–DRG portion for the anchor hospitalization or standardized episode spending of the HCPCS/APC portion of the anchor procedure.

(3) *Episodes that begin in one performance year and end in the subsequent performance year.* CMS applies the preliminary target price to the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure, as applicable, and reconciles the episode based on the date of discharge from the anchor hospitalization or the date of the anchor procedure.

(b) * * *

(2) * * *

(i) Performance Year 1: Episodes with anchor hospitalization start dates or anchor procedure dates beginning on or after January 1, 2022, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2022, and December 31, 2024.

(ii) Performance Year 2: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 202,3 and anchor hospitalization discharge dates or

anchor procedure dates between January 1, 2023, and December 31, 2025.

(iii) Performance Year 3: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2024, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2024, and December 31, 2026.

(iv) Performance Year 4: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2025, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2025, and December 31, 2027.

(v) Performance Year 5: Episodes with anchor hospitalization or anchor procedure start dates beginning on or after January 1, 2026, and anchor hospitalization discharge dates or anchor procedure dates between January 1, 2026, and December 31, 2028.

* * * * *

(7) *Prospective trend factor.* CMS calculates a multiplier for each MS–DRG/HCPCS episode type and region which is applied to the most recent calendar year of the applicable baseline period. The multiplier is calculated using linear regression on the logarithmically transformed average regional spending for each MS–DRG/HCPCS episode type in the baseline years and trend years at both the regional and national level. CMS exponentiates the coefficient from this regression to calculate the estimated annual change (where an exponentiated coefficient of 1 signifies no change) in average regional spending for each MS–DRG/HCPCS episode type from year to year. CMS then squares this value to calculate the 2-year prospective trend factor. The prospective trend factor for each MS–DRG/HCPCS episode type and region is the average (arithmetic mean) of the multiplier for that MS–DRG/HCPCS episode type and region and the national average for that MS–DRG/HCPCS episode type.

(8) *Communication of preliminary target prices.* CMS communicates the preliminary target prices for each MS–DRG/HCPCS episode type for each region, and the preliminary target prices for each MS–DRG/HCPCS episode type specific to the TEAM participant before the performance year in which they apply.

* * * * *

■ 26. Section 512.545 is amended by—

■ a. In paragraph (a) introductory text—

■ i. Removing the phrase ''social need'' and adding in its place the phrase ''beneficiary economic''; and

■ ii. Removing the text ''paragraph (a)(6)(i) through (v)'' and adding in its place the text ''paragraphs (a)(6)(i) through (v)'';

■ b. In paragraph (a)(1), removing the phrase ''CMS–HCC conditions based on a lookback period'' and adding in its place ''CMS–HCC conditions based on a 180-day lookback period'';

■ c. Revising paragraphs (a)(3) and (6), (e)(1)(i), and (f) introductory text.

The revisions read as follows:

§ 512.545 Determination of reconciliation target prices.

(a) * * *

(3) The beneficiary economic risk adjustment factor uses two variables, representing beneficiaries that, as of the first day of the episode—

(i) Meet one or more of the following economic measures:

(A) [Reserved]

(B) National CDI above the 80th percentile.

(C) Eligibility for the low-income subsidy.

(D) Eligibility for full Medicaid benefits.

(ii) Do not meet any of the three economic measures in paragraph (a)(3)(i) of this section.

* * * * *

(6) Episode category-specific beneficiary level risk adjustment factors represent the presence or absence in beneficiaries, based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure, of each of the following conditions:

(i) CABG episode category.

(A) Prior post-acute care use.

(B) HCC 37: Diabetes with Chronic Complications.

(C) HCC 48: Morbid Obesity.

(D) HCC 125: Dementia, Severe.

(E) HCC 126: Dementia, Moderate.

(F) HCC 127: Dementia, Mild or Unspecified.

(G) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(H) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(I) HCC 213: Cardio-Respiratory Failure and Shock.

(J) HCC 224: Acute on Chronic Heart Failure.

(K) HCC 226: Heart Failure, Except End-Stage and Acute.

(L) HCC 228: Acute Myocardial Infarction.

(M) HCC 229: Unstable Angina and Other Acute Ischemic Heart Disease.

(N) HCC 238: Specified Heart Arrhythmias.

(O) HCC 249: Ischemic or Unspecified Stroke.

(P) HCC 253: Hemiplegia/Hemiparesis.

(Q) HCC 263: Atherosclerosis of Arteries of the Extremities with Ulceration or Gangrene.

(R) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(S) HCC 298: Severe Diabetic Eye Disease, Retinal Vein Occlusion, and Vitreous Hemorrhage.

(T) HCC 326: Chronic Kidney Disease, Stage 5.

(U) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(V) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(W) HCC 409: Amputation Status, Lower Limb/Amputation Complications.

(ii) LEJR episode category.

(A) Ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty.

(B) Disability as the original reason for Medicare enrollment.

(C) Dementia without complications.

(D) Prior post-acute care use.

(E) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.

(F) HCC 36: Diabetes with Severe Acute Complications.

(G) HCC 37: Diabetes with Chronic Complications.

(H) HCC 48: Morbid Obesity.

(I) HCC 125: Dementia, Severe.

(J) HCC 126: Dementia, Moderate.

(K) HCC 127: Dementia, Mild or Unspecified.

(L) HCC 151: Schizophrenia.

(M) HCC 155: Major Depression, Moderate or Severe, without Psychosis.

(N) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.

(O) HCC 224: Acute on Chronic Heart Failure.

(P) HCC 225: Acute Heart Failure (Excludes Acute on Chronic).

(Q) HCC 226: Heart Failure, Except End-Stage and Acute.

(R) HCC 238: Specified Heart Arrhythmias.

(S) HCC 253: Hemiplegia/Hemiparesis.

(T) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.

(U) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.

(V) HCC 326: Chronic Kidney Disease, Stage 5.

(W) HCC 327: Chronic Kidney Disease, Severe (Stage 4).

(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.

(Y) HCC402: Hip Fracture/Dislocation.

(iii) Major Bowel Procedure episode category.
(A) Long-term institutional care use.
(B) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.
(C) HCC 22: Bladder, Colorectal, and Other Cancers.
(D) HCC 37: Diabetes with Chronic Complications.
(E) HCC 48: Morbid Obesity.
(F) HCC 78: Intestinal Obstruction/Perforation.
(G) HCC 125: Dementia, Severe.
(H) HCC 126: Dementia, Moderate.
(I) HCC 127: Dementia, Mild or Unspecified.
(J) HCC 151: Schizophrenia.
(K) HCC 155: Major Depression, Moderate or Severe, without Psychosis.
(L) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.
(M) HCC 201: Seizure Disorders and Convulsions.
(N) HCC 211: Respirator Dependence/Tracheostomy Status/Complications.
(O) HCC 213: Cardio-Respiratory Failure and Shock.
(P) HCC 224: Acute on Chronic Heart Failure.
(Q) HCC 226: Heart Failure, Except End-Stage and Acute.
(R) HCC 238: Specified Heart Arrhythmias.
(S) HCC 253: Hemiplegia/Hemiparesis.
(T) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.
(U) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.
(V) HCC 326: Chronic Kidney Disease, Stage 5.
(W) HCC 327: Chronic Kidney Disease, Severe (Stage 4).
(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.
(Y) HCC 463: Artificial Openings for Feeding or Elimination.
(iv) SHFFT episode category.
(A) HCC 36: Diabetes with Severe Acute Complications.
(B) HCC 37: Diabetes with Chronic Complications.
(C) HCC 38: Diabetes with Glycemic, Unspecified, or No Complications.
(D) HCC 48: Morbid Obesity.
(E) HCC 63: Chronic Liver Failure/End-Stage Liver Disorders.
(F) HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders.
(G) HCC 109: Acquired Hemolytic, Aplastic, and Sideroblastic Anemias.
(H) HCC 125: Dementia, Severe.
(I) HCC 126: Dementia, Moderate.
(J) HCC 127: Dementia, Mild or Unspecified.
(K) HCC 180: Quadriplegia.
(L) HCC 181: Paraplegia.
(M) HCC 191: Quadriplegic Cerebral Palsy.
(N) HCC 198: Multiple Sclerosis.
(O) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.
(P) HCC 211: Respirator Dependence/Tracheostomy Status/Complications.
(Q) HCC 213: Cardio-Respiratory Failure and Shock.
(R) HCC 226: Heart Failure, Except End-Stage and Acute.
(S) HCC 238: Specified Heart Arrhythmias.
(T) HCC 249: Ischemic or Unspecified Stroke.
(U) HCC 253: Hemiplegia/Hemiparesis.
(V) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.
(W) HCC 326: Chronic Kidney Disease, Stage 5.
(X) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.
(Y) HCC 402: Hip Fracture/Dislocation.
(v) Spinal Fusion episode category.
(A) Prior post-acute care use.
(B) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.
(C) HCC 18: Cancer Metastatic to Bone, Other and Unspecified Metastatic Cancer; Acute Leukemia Except Myeloid.
(D) HCC 37: Diabetes with Chronic Complications.
(E) HCC 48: Morbid Obesity.
(F) HCC 93: Rheumatoid Arthritis and Other Specified Inflammatory Rheumatic Disorders.
(G) HCC 125: Dementia, Severe.
(H) HCC 126: Dementia, Moderate.
(I) HCC 127: Dementia, Mild or Unspecified.
(J) HCC 155: Major Depression, Moderate or Severe, without Psychosis.
(K) HCC 180: Quadriplegia.
(L) HCC 181: Paraplegia.
(M) HCC 182: Spinal Cord Disorders/Injuries.
(N) HCC 192: Cerebral Palsy, Except Quadriplegic.
(O) HCC 193: Chronic Inflammatory Demyelinating Polyneuritis and Multifocal Motor Neuropathy.
(P) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.
(Q) HCC 224: Acute on Chronic Heart Failure.
(R) HCC 226: Heart Failure, Except End-Stage and Acute.
(S) HCC 238: Specified Heart Arrhythmias.
(T) HCC 249: Ischemic or Unspecified Stroke.
(U) HCC 253: Hemiplegia/Hemiparesis.
(V) HCC 254: Monoplegia, Other Paralytic Syndromes.
(W) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.
(X) HCC 326: Chronic Kidney Disease, Stage 5.
(Y) HCC 383: Chronic Ulcer of Skin, Except Pressure, Not Specified as Through to Bone or Muscle.
(Z) HCC 401: Vertebral Fractures without Spinal Cord Injury.

* * * * *

(e) * * *
(1) * * *
(i) Is the mean benchmark price for each MS–DRG/HCPCS episode type and region divided by the mean risk-adjusted benchmark price for the same MS DRG/HCPCS episode type and region.

* * * * *

(f) CMS calculates a multiplier for each MS–DRG/HCPCS episode type and region which is applied during reconciliation to the most recent calendar year of the applicable baseline period. The multiplier is calculated as the average regional capped performance year episode spending for each MS–DRG/HCPCS episode type divided by the average regional capped baseline period episode spending for each MS–DRG/HCPCS episode type.

* * * * *

■ 27. Section 512.547 is amended by—
■ a. In paragraph (a)(2) introductory text, removing the phrase ''years 2 through 5'' and adding in its place ''year 2'';
■ b. Adding paragraph (a)(3); and
■ d. Revising paragraph (b)(1)(i)(D).

The addition and revision read as follows:

§ 512.547 Quality measures, composite quality score, and display of quality measures.

(a) * * *
(3) For performance years 3 through 5:
(i) For all episode categories: Hybrid Hospital-Wide All-Cause Readmission Measure with Claims and Electronic Health Record Data (CMIT ID #356) with a CY 2025 CQS baseline period.
(ii) For all episode categories: Hospital Harm—Falls with Injury (CMIT ID #1518) with a CY 2026 CQS baseline period.
(iii) For all episode categories: Hospital Harm—Postoperative Respiratory Failure (CMIT ID #1788) with a CY 2026 CQS baseline period.

(iv) For all episode categories: Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications (Failure-to-Rescue) (CMIT ID #134) with a CY 2026 CQS baseline period.

(v) For LEJR episodes: Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618) with a CY 2025 CQS baseline period.

(vi) For LEJR and Spinal Fusion episodes: Information Transfer PRO–PM (CMIT ID #1797) with a CY 2027 CQS baseline period.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(D) CMS assigns a scaled quality measure of 50 if the TEAM participant has no or an incomplete raw quality measure score for a given quality measure.

* * * * *

■ 28. Section 512.562 is amended by revising paragraph (c)(3) to read as follows:

§ 512.562 Data sharing with TEAM participants.

* * * * *

(c) * * *

(3) Sex.

* * * * *

■ 29. Section 512.563 is amended by:

■ a. Revising the section heading; and

■ b. Removing and reserving paragraphs (a) and (b).

The revision read as follows:

§ 512.563 Health data reporting.

* * * * *

■ 30. Section 512.580 is amended by revising the section heading and paragraph (b)(3) to read as follows:

§ 512.580 TEAM Medicare Program Waivers.

* * * * *

(b) * * *

(3) *Determination of qualified SNFs.* CMS determines the qualified SNFs for each calendar quarter based on a review of the most recent rolling 12 months of overall star ratings on the Five-Star Quality Rating System for SNFs on the Nursing Home Compare website.

(i) Qualified SNFs are rated an overall of 3 stars or better for at least 7 of the 12 months. (ii) Qualified SNFs include providers furnishing SNF services under swing bed agreements, which will not be subject to the star ratings requirement.

* * * * *

§ 512.598 [Removed]

■ 31. Section 512.598 is removed.

Robert F. Kennedy, Jr.,

Secretary, Department of Health and Human Services.

Note: The following addendum and appendices will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2025, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2025

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the proposed prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2026 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2026. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would be effective for cost reporting periods beginning on or after October 1, 2025. In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2026.

In general, except for SCHs and MDHs, for FY 2026, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (including, as discussed in section IV.E. of the preamble of this proposed rule, uncompensated care payments under section 1886(r)(2) of the Act).
- The updated hospital-specific rate based on FY 1982 costs per discharge.
- The updated hospital-specific rate based on FY 1987 costs per discharge.
- The updated hospital-specific rate based on FY 1996 costs per discharge.
- The updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report. Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. We note that if the MDH program were to be extended by law beyond September 30, 2025, into FY 2026, the proposed updates to the hospital-specific rates for SCHs as described in this section would also apply to the hospital-specific rates for MDHs for FY 2026. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program.

As discussed in section V.B.2. of the preamble of this proposed rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are proposing to make changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2026. In section III. of this Addendum, we discuss our proposed policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2026. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2026. In section V. of this Addendum, we discuss proposed policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2026. The tables to which we refer in the preamble of this proposed rule are listed in section VI. of

this Addendum and are available via the internet on the CMS website.

II. Proposed Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2026

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are proposing to use for determining the proposed prospective payment rates for FY 2026.

In summary, the proposed standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2026, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount.

We refer readers to section VI.B. of the preamble of this proposed rule for a complete discussion on the FY 2026 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED FY 2026 APPLICABLE PERCENTAGE INCREASE FOR THE IPPS

FY 2026	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	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.4	0	−2.4
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.4	0.0	1.6	−0.8

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico. In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for FY 2026 and subsequent fiscal years is adjusted by the proposed adjustment for failure to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act. The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as discussed in section II.D.2.c. of the preamble of this proposed rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2025 budget neutrality factor and applying a revised factor.
- An adjustment to the standardized amount to implement in a budget neutral manner the wage index cap policy (as described in section III.G.6. of the preamble of this proposed rule).
- Using our authority under section 1886(d)(5)(I)(i) of the Act, an adjustment to the standardized amount to implement in a budget neutral manner the proposed transition for the discontinuation of the low wage index hospital policy (as described in section III.F.7. of the preamble of this proposed rule).
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Pub. L. 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Pub. L. 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2025 outlier offset and apply an offset for FY 2026, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2026, consistent with current law, we are proposing to apply the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are proposing to apply a uniform, national budget neutrality adjustment to the FY 2026 wage index for the rural floor.

For FY 2026, we are proposing to continue to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell

Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033).

We finally note, as discussed in section III.G.5. of the preamble to this proposed rule, in the FY 2025 IFC we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy. Because we are proposing to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years we are no longer applying the low wage index budget neutrality factor to the standardized amounts.

A. Calculation of the Proposed Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983, interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data in order to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2026, we are proposing to rebase and revise the national labor-related and nonlabor-related shares (based on the proposed 2023-based hospital IPPS market basket discussed in section IV.B.3. of the preamble of this proposed rule). Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2026, as discussed in section III.H. of the preamble of this proposed rule, we are proposing to use a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The proposed standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this proposed rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage increase. Accordingly, we are proposing to calculate the FY 2026 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are proposing to use the proposed 2023-based IPPS operating and capital market baskets for FY 2026. As discussed in section VI.B. of the preamble of this proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are proposing to reduce the FY 2026 applicable percentage increase (which for this proposed rule is based on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2024 forecast of the IPPS hospital market basket percentage increase (as discussed in appendix B of this proposed rule), the forecast of the hospital market basket percentage increase for FY 2026 for this proposed rule is 3.2 percent and the forecast of the productivity adjustment for FY 2026 for this proposed rule is 0.8 percentage point. As discussed earlier, for FY 2026, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section VI.B. of the preamble of this proposed rule for a complete discussion on the proposed FY 2026 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amounts. The proposed standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2026 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2026 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the proposed FY 2026 update factors is set forth in appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed FY 2026 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs and Rural Emergency Hospitals (REHs) at the time of this proposed rule (we finalized to remove REHs in the calculation of the standardized amount in the FY 2025 IPPS/LTCH final rule (89 FR 69941–69942); exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded-cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we are proposing to adjust the FY 2026 standardized amount to remove the effects of the FY 2026 geographic reclassifications and outlier payments before applying the FY 2026 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on proposed FY 2026 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these

payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.

• Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, in order to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).

• Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), in order to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).

• Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are proposing to remove organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are proposing to not remove revenue center 891 charges from MS–DRG 018 claims during ratesetting because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in the FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.

• For FY 2026, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).

• The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2026, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029 and 59030), we are proposing to include all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, we are proposing to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

• Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2026, we are proposing to continue to apply a proxy based on the prior fiscal year hospital readmissions payment adjustment and a proxy based on the prior fiscal year hospital VBP payment adjustment on each side of the comparison, consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). Under this proposed policy for FY 2026, we used the final FY 2025 readmissions adjustment factors from Table 15 of the FY 2025 IPPS/LTCH PPS final rule and the final FY 2025 hospital VBP adjustment factors from Table 16B of the FY 2025 IPPS/LTCH PPS final rule. These proxy factors are applied on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum. We refer the reader to section V.K. of the preamble of this proposed rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.L. of the preamble of this proposed rule for a complete discussion on the Hospital VBP Program.

• The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. In order to properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

Consistent with prior fiscal years, we are proposing to include estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we are proposing to consider estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We also are proposing to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

• When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of

the total payments is greater. As discussed in section IV.G. of the preamble to this proposed rule and later in this section, we are proposing to continue to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are proposing to include estimated uncompensated care payments in this comparison.

As discussed elsewhere in this proposed rule, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. If the MDH program were to be extended by law into FY 2026, we would, depending on the timing of such legislation in relation to the final rule, include the total payments for MDHs in the budget neutrality discussed in this section. We note, for the final rule, if the MDH program were extended by law into FY 2026, consistent with historical practice for MDHs, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we would continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs under any such extension.

- We are proposing to include an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2026. Similar to FY 2025, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the proposed applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2026.
- In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges.

We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49414 through 49415), we finalized a change to the ordering of the budget neutrality factors in the calculation so that the RCH Demonstration budget neutrality factor is applied after all wage index and other budget neutrality factors. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

a. Proposed Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.D. of the preamble of this proposed rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are proposing to make a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2026 proposed rule, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2025 labor-related share percentages, the FY 2025 relative weights, and the FY 2025 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments (as described previously); and
- Aggregate payments using the FY 2025 labor-related share percentages, the proposed FY 2026 relative weights before applying the 10-percent cap, and the FY 2025 pre-reclassified wage data, and applied the same proxy hospital readmissions payment adjustments and proxy hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2026 relative weights (before applying the 10-percent cap), consistent with our proposal in section V.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2026 relative weights, we are proposing to apply the adjustor for certain MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and other immunotherapies) cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section V.I. of the preamble of this proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed adjustment to the FY 2026 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2025. Please see the table later in this section setting forth each of the proposed FY 2026 budget neutrality factors.

b. Proposed Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.D.2.c. of the preamble of this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900), we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As also discussed in section II.D.2.c. of the preamble of this proposed rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we apply a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

To calculate this proposed budget neutrality adjustment factor for FY 2026, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2025 labor-related share percentages, the proposed FY 2026 relative weights before applying the 10-percent cap, and the FY 2025 pre-reclassified wage data, and applied the proposed proxy FY 2026 hospital readmissions payment adjustments and the proposed proxy FY 2026 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2025 labor-related share percentages, the proposed FY 2026 relative weights after applying the 10-percent cap, and the FY 2025 pre-reclassified wage data, and applied the same proposed proxy FY 2026 hospital readmissions payment adjustments and proposed proxy FY 2026 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2026 relative weights, consistent with our proposal in section V.I. of the preamble to this proposed rule and our historical policy, and as discussed in the preceding section, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2025 to FY 2026. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we are proposing to apply this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2024. Please see the table later in this section setting forth each of the proposed FY 2026 budget neutrality factors.

c. Updated Wage Index—Proposed Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2026, we are proposing to adjust 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.D. of the preamble of this proposed rule.

To compute a proposed budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2026 relative weights and the FY 2025 pre-reclassified wage indexes, applied the FY 2025 labor-related share of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proxy FY 2026 hospital readmissions payment adjustment and the proxy FY 2026 hospital VBP payment adjustment.
- Aggregate payments using the proposed FY 2026 relative weights and the proposed FY 2026 pre-reclassified wage indexes, applied the proposed labor-related share for FY 2026 of 66.0 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proxy FY 2026 hospital readmissions payment adjustments and proxy FY 2026 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the proposed cap (derived in the first step) and the 10-percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2025 to FY 2026. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the proposed FY 2026 budget neutrality factors.

d. Reclassified Hospitals—Proposed Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971 through 58977), we finalized a policy beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the proposed budget neutrality adjustment factor for FY 2026, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2026 labor-related share percentage, the proposed FY 2026 relative weights, and the proposed FY 2026 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proxy FY 2026 hospital readmissions payment adjustments and the proxy FY 2026 hospital VBP payment adjustments.
- Aggregate payments using the proposed FY 2026 labor-related share percentage, the proposed FY 2026 relative weights, and the proposed FY 2026 wage data after such reclassifications, and applied the same proxy FY 2026 hospital readmissions payment adjustments and the proxy FY 2026 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2026 and applies the policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed budget neutrality adjustment factor and applied this proposed factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the proposed FY 2026 budget neutrality factors.

The proposed FY 2026 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2025 budget neutrality adjustment factor. We note that the proposed FY 2026 budget neutrality adjustment reflects FY 2026 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this proposed rule.

e. Proposed Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this proposed rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2026, we are proposing to calculate a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2026 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous to (share a border with) the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, all urban Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the proposed FY 2026 rural Puerto Rico wage index is calculated based on the average of the proposed FY 2026 wage indexes for the following urban areas: Aguadilla, PR (CBSA 10380); Arecibo, PR (CBSA 11640), Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); and San Juan-Bayamon-Caguas, PR (CBSA 41980).

We note, in the FY 2024 IPPS/LTCH final rule (88 FR 58971–77), we finalized a policy

beginning with FY 2025 to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and are only excluding ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor.

To calculate the proposed national rural floor budget neutrality adjustment factor, we used FY 2024 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a proposed national rural floor budget neutrality adjustment factor. The proposed national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2026 budget neutrality factors.

As further discussed in section III.G.2. of this proposed rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2022. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2. of the preamble of this proposed rule for a complete discussion regarding the imputed floor.

f. Permanent Cap Policy for Wage Index—Proposed Budget Neutrality Adjustment

As noted previously, in section III.G.6. of the preamble to this proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) we finalized a policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also finalized the application of this permanent cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the permanent cap policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2026, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the proposed FY 2026 labor-related share percentages, the proposed FY 2026 relative weights, and applied the proposed proxy FY 2026 hospital readmissions payment adjustments and the proposed proxy FY 2026 hospital VBP payment adjustments.
- Aggregate payments with the 5-percent cap using the proposed FY 2026 labor-related share percentages, the proposed FY 2026 relative weights, and applied the same proxy FY 2026 hospital readmissions payment adjustments and the proposed proxy FY 2026 hospital VBP payment adjustments applied previously.

g. Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor

As discussed in section III.G.5. of the preamble to this proposed rule, in the FY 2025 IFC we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy. Because we are proposing to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years we would no longer apply the low wage index budget neutrality factor to the standardized amounts.

As noted previously, in section III.G.7. of the preamble to this proposed rule, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, to adopt a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy, and then again to do so in a budget neutral manner. To calculate the proposed transition wage index budget neutrality adjustment factor for FY 2026, we used FY 2024 discharge data to simulate payments and compared the following:

- Aggregate payments without the proposed transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the proposed FY 2026 labor-related share percentages, the proposed FY 2026 relative weights, and applied the proposed proxy FY 2026 hospital readmissions payment adjustments and the proposed proxy FY 2026 hospital VBP payment adjustments.
- Aggregate payments with the proposed transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the proposed FY 2026 labor-related share percentages, the proposed FY 2026 relative weights, and applied the same proxy FY 2026 hospital readmissions payment adjustments and the proposed proxy FY 2026 hospital VBP payment adjustments applied previously. This proposed FY 2026 budget neutrality adjustment factor was applied to the standardized amount.

We note, Table 2 associated with this proposed rule contains the wage index by provider before and after applying 5 percent cap and the proposed transition for the discontinuation of the low wage index hospital policy.

h. Proposed Rural Community Hospital Demonstration Program Adjustment

In section VI.N. of the preamble of this proposed rule, we discuss the Rural Community Hospital (RCH) Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We make an adjustment to the standardized amount to ensure the effects of the RCH Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section VI.N. of the preamble of this proposed rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2026, based on the latest data for this proposed rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $ 47,527,557. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2026, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the Proposed FY 2026 budget neutrality factors. We refer readers to section VI.N. of the preamble of

this proposed rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

The following table is a summary of the proposed FY 2026 budget neutrality factors, as discussed in the previous sections.

SUMMARY OF PROPOSED FY 2026 BUDGET NEUTRALITY FACTORS

MS-DRG Reclassification and Recalibration Budget Neutrality Factor	0.998422
Cap Policy MS–DRG Weights Budget Neutrality Factor	0.999938
Wage Index Budget Neutrality Factor	1.001273
Reclassification Budget Neutrality Factor	0.976960
*Rural Floor Budget Neutrality Factor	0.985942
Cap Policy Wage Index Budget Neutrality Factor	0.993116
Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor	0.999741
Rural Demonstration Budget Neutrality Factor	0.999548

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

i. Proposed Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the ''outlier threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2026 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total projected operating outlier payments by the total projected operating DRG payments plus projected operating outlier payments. As discussed in the next section, for FY 2026, we are incorporating an estimate of the impact of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated total of outlier payments as a proportion of total DRG payments. More information on outlier payments may be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.html*.

(1) Methodology To Incorporate a Proposed Estimate of the Impact of Outlier Reconciliation in the FY 2026 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. Instructions for outlier reconciliation are in section 20.1.2.5 of chapter 3 of the Claims Processing Manual (available at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*). The original instructions issued in July 2003 [1] instruct MACs to identify for CMS any instances where: (1) a hospital's actual operating CCR for the cost reporting period fluctuates plus or minus 10 percentage points or more compared to the interim operating CCR used to calculate outlier payments when a bill is processed; and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. Cost reports that meet these criteria will have the hospital's outlier payments reconciled at the time of cost report final settlement if approved by the CMS Central Office. For the remainder of this discussion, we refer to these criteria as the original criteria for outlier reconciliation (or the original criteria).

On March 28, 2024, we issued Change Request (CR) 13566, which is available at *https://www.cms.gov/medicare/regulations-guidance/transmittals/2024-transmittals/r12558cp*. CR 13566 provides additional instructions to MACs that expand the criteria for identifying cost reports MACs are to refer to CMS for approval of outlier reconciliation. As discussed in the FY 2025 IPPS/LTCH final rule, we anticipate that MACs will identify more cost reports to refer to CMS for outlier reconciliation approval. Specifically, CR 13566 states that for cost reports beginning on or after October 1, 2024, MACs shall identify for CMS any instances where: (1) the actual operating CCR is found to be plus or minus 20 percent or more from the operating CCR used during that time period to make outlier payments, and (2) the total operating and capital outlier payments for the hospital exceeded $500,000 for that cost reporting period. For the remainder of this discussion, we refer to these criteria as the new criteria for outlier reconciliation (or the new criteria). These new criteria for identifying hospital cost reports that MACs identify for outlier reconciliation approval are in addition to the original criteria for reconciliation described previously. That is, under the new criteria, MACs identify hospitals for outlier reconciliation approval that would not have met the original criteria. In addition, CR 13566 instructs that for cost reporting periods that begin on or after October 1, 2024, a hospital in its first cost reporting period will be referred for approval of reconciliation of outlier payments at the time of cost report final settlement. As such, new hospitals will be referred for outlier reconciliation approval regardless of the change to the operating CCR and no matter the amount of outlier payments during the cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual for complete instructions regarding outlier reconciliation, including the update to the outlier reconciliation criteria provided in CR 13566. (Refer to the FY 2025 IPPS/LTCH PS final rule for additional information (89 FR 69950).)

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we

[1] Change Request 2785 (Transmittal A–03–058; July 3, 2003) found at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/a03058.pdf*.

believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. (For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.)

As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69949 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria in CR 13566 (described previously). In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. We refer the reader to the FY 2025 IPPS/LTCH final rule for complete details (89 FR 69950 through 69955).

(a) Incorporating a Proposed Projection of Outlier Reconciliations for the FY 2026 Outlier Threshold Calculation

Under our methodology for incorporating a projection of outlier reconciliation for the outlier threshold calculation, for each year, we typically advance the historical data used by 1 year, using cost report data that is on a 6-year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement.

For FY 2026, we evaluated the use of the FY 2020 cost report data under our methodology as established in FY 2020 and modified in the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of operating outlier reconciliations for the FY 2026 outlier threshold calculation (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for outlier reconciliation approval under the new criteria in CR 13566). Specifically, for FY 2026 we evaluated using the same steps finalized in the FY 2025 IPPS/LTCH PPS final rule.

Specifically, we calculated a projection of outlier reconciliation using cost report data from FY 2020 hospital cost reports in the December 2024 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation approval. In addition, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2020 cost reports that would have met the new criteria if those criteria had been in effect. This allows us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of this estimate, we used the latest quarterly PSF update (December 2024 for the proposed rule).

As explained above, our 5-step methodology to incorporate a projection of outlier payment reconciliations for the outlier threshold calculation is described in detail in the FY 2025 IPPS/LTCH final rule (see 89 FR 69950 through 69952). The 5 steps can be summarized as follows:

Step 1: Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).

Step 2: Determine the aggregate amount of operating outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

Step 3: Calculate the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data.

Step 4: Determine the percentage of total operating outlier reconciliation dollars to total Federal operating payments for the cost report data year.

Step 5: Adjust the outlier target using the percentage from Step 4.

With regard to incorporating outlier reconciliation in the FY 2026 outlier fixed-loss cost threshold, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. As we explain in greater detail in the discussion that follows, we found that using the most recent available data under our 5-step methodology appears to produce anomalous results that may not provide an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation under the new criteria), for this proposed rule we posted a public use file that includes the operating CCR calculated from the FY 2020 cost report in the most recent publicly available quarterly HCRIS extract (the December 2024 HCRIS for the proposed rule), the weighted operating CCR used for claim payment during the FY 2020 cost reporting period from the latest quarterly PSF update (December 2024 for the proposed rule), and the supplemental data from the MACs and operating outlier payment reported on the FY 2020 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2 [2] (operating outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3 [3] (total Federal operating payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments (89 FR 69952). As discussed in previous proposed and final rules, when the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a negative value, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. When the percentage of total operating outlier reconciliation dollars to total Federal operating payments in Step 4 rounds to a positive value, the effect is an increase to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars.

Using the most recent available data for this proposed rule (as described previously), the ratio calculated under Step 4 of the methodology would be 0.095654 percent (($79,574,408/$83,189,787,222) × 100), which, when rounded to the second digit, is +0.1 percent. Under Step 5 of the methodology, this percentage amount would be used to adjust the outlier target for FY 2026. This would mean that for FY 2026, we would incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.0 percent [5.1 percent − (0.1 percent)]. This positive 0.1 percentage point is being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate operating outlier reconciliation dollars under both the original criteria and the new criteria).

Typically, the total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of operating outlier reconciliation dollars to total Federal operating payments in Step 4. Using the most recent available data (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) is a positive amount reflecting that overall, the Medicare program would owe hospitals money at the time of outlier reconciliation, which then produces a positive percentage of operating outlier reconciliation dollars to total Federal operating payments.

As mentioned above, since FY 2020 we have incorporated outlier reconciliation into the outlier fixed loss cost threshold calculation. For the outlier fixed loss cost threshold calculation for FYs 2020 through 2025, the percentage of operating outlier reconciliation dollars to total Federal operating payments from Step 4 has resulted in a negative value (having the effect of a decrease to the outlier threshold). Using the FY 2020 cost report data and PSF values described previously under our methodology would be the first time that the percentage of

[2] Step 2, the numerator of step 4, is the aggregate amount of operating outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69951 through 69952).

[3] Step 3, the denominator of step 4, is the aggregate amount of total Federal operating payments across all applicable hospitals using the cost report data. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Lines 2.02, 2.03, and 2.04), and the outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69952).

operating outlier reconciliation dollars to total Federal operating payments from Step 4 is a positive value (and would have the effect of an increase to the outlier threshold). We believe this positive value may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2026 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation in the FY 2026 outlier fixed-loss cost threshold. Therefore, rather than use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 based on the latest available data (as described previously), for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2026, we are proposing to hold the data constant and to use the percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in that final rule (89 FR 69952), the ratio was a negative 0.041994 percent ((−$36,439,127/$86,772,005,692) × 100), which, when rounded to the second digit, is −0.04 percent. Given the anomaly in the most recent available data described earlier, we believe that this is the best available data to estimate and predict outlier reconciliations for FY 2026 to use to incorporate the effect of outlier reconciliation in the FY 2026 outlier fixed-loss cost threshold. This percentage amount would then be used to adjust the proposed outlier target for FY 2026 as determined in Step 5. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69950 through 69952).)

Under Step 5 of our methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined under Step 4 in determining the outlier threshold. Consistent with the FY 2025 IPPS/LTCH PPS final rule, to incorporate a projection of outlier reconciliation dollars, we are proposing to target an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2026. Therefore, for FY 2026, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (−0.04 percent)]. As explained earlier, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent, the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2026 proposed outlier threshold as calculated for this proposed rule both with and without including this percentage estimate of operating outlier reconciliation.

Consistent with the approach taken in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the proposed operating outlier offset to the standardized amount is 0.949 (1 − 0.051).

We note, for the FY 2026 final rule, consistent with our historical practice, we plan to evaluate the updated data available at the time of the development of that final rule (such as the March 2025 HCRIS extract of the FY 2020 cost report). We would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2026 and, depending on the results of this evaluation, may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2026. We are inviting public comment on our proposed methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed loss cost outlier threshold for FY 2026.

(b) Proposed Adjustment To Account for Capital Outlier Reconciliation Payments in the Projected Proportion of Capital IPPS Payments Paid as Outliers in Determining the FY 2026 Capital Federal Rate

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we are proposing to reduce the FY 2026 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

Under our methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2026 capital Federal rate, each year, we typically advance the historical data used by 1 year and use cost report data that is on a six year lag, which is typically the most recent and complete available data to project the estimate of outlier reconciliation. Accordingly, for FY 2025 we used FY 2019 cost report data. Because the new criteria were not effective until FY 2025 cost reports, to estimate outlier reconciliation dollars under the new criteria, we applied the new criteria to FY 2019 cost reports as if they had been in place at the time of final cost report settlement.

For FY 2026, we evaluated the use of the FY 2020 cost report data under the methodology we used for FY 2025 to incorporate an adjustment to the FY 2026 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the FY 2020 methodology as modified in FY 2025 to reflect additional cost reports that would be identified for reconciliation under the new criteria in CR 13566). Specifically, we calculated an estimate of outlier reconciliation using cost report data from FY 2020 hospital cost reports in the December 2024 HCRIS extract that were reconciled using the original criteria for referral for outlier reconciliation. Similarly, in calculating this estimate, we used data from the Provider Specific File (PSF) and the cost report data to identify the FY 2020 cost reports that would have met the new criteria if those criteria had been in effect. This allows us to account for the additional hospital cost reports that would be referred for outlier reconciliation approval as a result of the new criteria under our methodology. For purposes of this estimate, we used the latest quarterly PSF update (December 2024) for the proposed rule.

As explained above, in the FY 2025 IPPS/LTCH PPS final rule (89 FR 699540 through 69955), we finalized changes to our methodology to incorporate an estimate of outlier reconciliation in the FY 2025 outlier fixed loss cost threshold to reflect the estimated reconciled outlier payments under the new criteria in CR 13566 (described previously). In that final rule, we provided step by step details under our methodology to incorporate a projection of outlier payment reconciliations for the FY 2025 outlier threshold calculation. (For complete details on our 5-step methodology to incorporate an adjustment to the capital outlier adjustment factor, we refer readers to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).) The 5 steps can be summarized as follows:

Step 1: Identify hospital cost reports that meet the original criteria (Step 1a) or the new criteria (Step 1b).

Step 2: Determine the aggregate amount of capital outlier reconciliation dollars (under both the original criteria (Step 2a) and the new criteria (Steps 2b)).

Step 3: Calculate the aggregate amount of total Federal capital Federal payments across all applicable hospitals using the cost report data.

Step 4: Determine the percentage of total capital outlier reconciliation dollars to total capital Federal payments for the cost report data year.

Step 5: Adjust the capital outlier adjustment factor using the percentage from Step 4.

Under this methodology, because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, in Step 5 the estimate of capital outlier payments are determined by adding the percentage determined in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and

hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.)

As discussed in previous proposed and final rules, when the aggregate capital outlier reconciliation dollars in Step 2 is negative, the estimate of capital outlier payments under our methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold. Under Step 5 this would be a relatively smaller outlier budget neutrality adjustment factor which would have the effect of an increase to the capital Federal rate. When the aggregate capital outlier reconciliation dollars from Step 2 are positive, the estimate of capital outlier payments under our methodology would be higher than the percentage of capital outlier payments otherwise determined using the shared outlier threshold. Under Step 5 this would be a relatively larger outlier budget neutrality adjustment factor which would have the effect of a decrease to the capital Federal rate.

With regard to incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers, we evaluated the use of the most recent available data (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. As we explain in greater detail in the discussion that follows, we found that using the most recent available data under our 5-step methodology appears to produce anomalous results that may not provide an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year. (We note, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation approval under the new criteria), for this proposed rule we posted a public use file that includes the capital CCR calculated from the FY 2020 cost report in the most recent publicly available quarterly HCRIS extract (the December 2024 HCRIS for the proposed rule), the weighted capital CCR used for claim payment during the FY 2020 cost reporting period from the latest quarterly PSF update (December 2024 for the proposed rule), and the supplemental data from the MACs and capital outlier payment reported on the FY 2020 cost report.)

Step 4 of the methodology divides the aggregate amount from Step 2 [4] (capital outlier reconciliation dollars under both the original criteria and the new criteria or total reconciled dollars) by the amount from Step 3 [5] (total Federal capital payments across all applicable hospitals using the cost report data) and multiplies the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments (89 FR 69955). Under the methodology, in Step 5 this amount is added to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold (as explained above).

For this proposed rule, the estimated percentage of FY 2026 capital outlier payments otherwise determined using the shared outlier threshold is 4.16 percent (estimated capital outlier payments of $289,418,426 divided by (estimated capital outlier payments of $289,418,426 plus the estimated total capital Federal payment of $6,670,448,919)). Using the most recent available data (described previously), the total in Step 2 is $1,529,376, which is a positive amount. The percentage calculated in Step 4 is a positive 0.021188 percent (($1,529,376/$7,218,168,555) × 100), which, when rounded to the second digit, is +0.02 percent. Under Step 5 of the methodology, this percentage amount would be used to adjust the estimate of capital outlier payments for FY 2026. This would mean that for FY 2026 we would increase the estimated percentage of FY 2026 aggregate capital outlier payments by 0.02 percent. This positive 0.02 percentage point is being driven by the numerator in Step 4 (that is, the total reconciled dollars or the aggregate capital outlier reconciliation dollars under both the original criteria and the new criteria).

Typically, the total reconciled dollars in Step 2 (the numerator of Step 4) is a negative amount reflecting that overall, providers would owe the Medicare program money at the time of outlier reconciliation, which then produces a negative percentage of capital outlier reconciliation dollars to total Federal capital payments in Step 4. Using the most recent available data (described previously), the total reconciled dollars in Step 2 (the numerator of Step 4) is a positive amount reflecting that overall, the Medicare program would owe hospitals money at the time of outlier reconciliation, which then produces a positive percentage of capital outlier reconciliation dollars to total Federal capital payments.

As mentioned above, since FY 2020 we have incorporated an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2026 capital Federal rate. This adjustment (the percentage of capital outlier reconciliation dollars to total capital Federal payments from Step 4) has resulted in a negative value for FYs 2020 through 2025 (having the effect of an increase to the capital Federal amount, as described previously). Using the FY 2020 cost report data and PSF values described previously under our methodology would be the first time that the adjustment under Step 4 (the percentage of capital outlier reconciliation dollars to total capital Federal payments) is a positive value (and would have the effect of a decrease to the capital Federal amount). We believe this positive value may be an anomaly and may not be an accurate predictor of outlier reconciliations for FY 2026 to use as an estimate of outlier reconciliation dollars for incorporating the effect of outlier reconciliation to adjust the capital standard Federal rate. Therefore, rather than use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 based on the latest available data (as described previously), for purposes of incorporating an adjustment to the capital standard Federal rate for FY 2026, we are proposing to hold the data constant and to use the percentage of total capital outlier reconciliation dollars to total capital Federal payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in that final rule (89 FR 69955), the ratio was a negative 0.028042 percent ((−$2,181,440/$7,779,306,800) × 100), which, when rounded to the second digit, is −0.03 percent. Accordingly, for this proposed rule, taking into account projected capital outlier reconciliation under our methodology would decrease the estimated percentage of FY 2026 aggregate capital outlier payments by 0.03 percent. This percentage amount would be used to adjust the proposed estimated percentage of FY 2026 aggregate capital outlier payments under Step 5 of the methodology. (For complete details on the calculation, refer to the FY 2025 IPPS/LTCH final rule (89 FR 69953 through 69955).) Given the anomaly in the most recent available data described earlier, we believe that this is the best available data to estimate and predict outlier reconciliations for FY 2026 to use to incorporate an adjustment to the FY 2026 capital standard Federal rate.

As discussed in section III.A.2. of this Addendum, we are incorporating the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2026.

We note, for the FY 2026 final rule, consistent with our historical practice, we plan to evaluate the updated data available at the time of the development of that final

[4] Step 2, the numerator of step 4, is the aggregate amount of capital outlier reconciliation dollars under both the original criteria and the new criteria which is the sum of the amounts from Steps 2a and 2b. (89 FR 69954 through 69955).

[5] Step 3, the denominator of step 4, is the aggregate amount of total capital Federal payments across all applicable hospitals using the cost report data. The total capital Federal payments consist of the capital DRG payments, capital outlier payments, capital indirect medical education (IME) Payments, capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69955).

rule (such as the March 2025 HCRIS extract of the FY 2020 cost report). We would evaluate the use of that updated data in the methodology to assess whether that data still shows an anomaly such that it would not be appropriate to use in calculating the projection of outlier reconciliation dollars for FY 2026 and, depending on the results of this evaluation, may consider use of that data for purposes of projecting an estimate of outlier reconciliation dollars and incorporating an adjustment to the FY 2026 capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers. We are inviting public comment on our proposed methodology for incorporating an adjustment to account for capital outlier reconciliation payments in the projected proportion of capital IPPS payments paid as outliers in determining the FY 2026 capital Federal rate.

(2) Proposed FY 2026 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the proposed FY 2026 outlier threshold, we simulated payments by applying proposed FY 2026 payment rates and policies using cases from the FY 2024 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the Provider-Specific File (PSF) while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

In order to determine the proposed FY 2026 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2024 to FY 2026. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we are proposing to use the following methodology to calculate the charge inflation factor for FY 2026:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs and REHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we proposing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).
- Because this payment simulation uses the proposed FY 2026 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this proposed rule, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For the same reasons discussed in that rulemaking, for FY 2026, we are proposing to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2026, we are proposing to use the MedPAR files for the two most recent available Federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for this proposed rule we used the December 2023 MedPAR file of FY 2023 (October 1, 2023, to September 30, 2023) charge data (released for the FY 2025 IPPS/LTCH PPS proposed rule) and the December 2024 MedPAR file of FY 2024 (October 1, 2023, to September 30, 2024) charge data (released for this FY 2026 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We are proposing that for the FY 2026 final rule, we would use more recently updated data, that is the MedPAR files from March 2024 for the FY 2023 time period and March 2025 for the FY 2024 time period.

For FY 2026, under this proposed methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $86,031.03 ($592,911,386,867/6,891,832) from October 1, 2022, through September 30, 2023, to the average covered charge per case of $90,711.54 ($624,034,862,796/6,879,333) from October 1, 2023, through September 30, 2024. This rate-of-change was 5.440 percent (1.05440) or 11.18 percent (1.1118) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in this FY 2026 IPPS/LTCH PPS proposed rule, we are proposing to establish the FY 2026 outlier threshold using hospital CCRs from the December 2024 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2026, we are proposing to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also are proposing that, if more recent data become available, we would use that data to calculate the final FY 2026 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital

CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done in the past, we are proposing to adjust the CCRs from the December 2024 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2023 update of the PSF to the national average case weighted operating CCR and capital CCR from the December 2024 update of the PSF. We note that we used total transfer-adjusted cases from FY 2024 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for this proposed rule, we calculated a December 2023 operating national average case-weighted CCR of 0.252119 and a December 2024 operating national average case-weighted CCR of 0.244584.We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2023 operating national average case-weighted CCR from the December 2024 operating national average case-weighted CCR and then dividing the result by the December 2023 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 0.970113.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2023 capital national average case-weighted CCR of 0.017659 and a December 2024 capital national average case-weighted CCR of 0.016912. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2023 capital national average case-weighted CCR from the December 2024 capital national average case-weighted CCR and then dividing the result by the December 2023 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.957699.

For purposes of estimating the proposed outlier threshold for FY 2026, we used a wage index that reflects the policies discussed in this proposed rule. This includes the following:

- Application of the proposed rural and imputed floor adjustment.
- The proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The proposed out-migration adjustment as added by section 505 of Public Law 108–173.
- Incorporating our policy (described in section III.6. of the preamble of this proposed rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.
- The proposed transition for the discontinuation of the low wage index hospital policy (as described in section III.F.7. of the preamble of this proposed rule).

If we did not take the aforementioned into account, our estimate of total FY 2026 payments would be too low, and, as a result, our proposed outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this proposed rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the proposed outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we are proposing to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2026, we are proposing to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally.

Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2026, we are proposing to include estimated FY 2026 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, consistent with the methodology finalized in the FY 2023 final rule, we are proposing to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the FY 2026 proposed outlier fixed-loss cost threshold. Specifically, we are proposing to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are proposing to incorporate an estimate of FY 2026 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2026 proposed rule, we are proposing to hold the data constant and to use the FY 2025 final rule percentage of total operating outlier reconciliation dollars to total Federal operating payments from Step 4 from the FY 2025 IPPS/LTCH PPS final rule which is based on FY 2019 cost reports and PSF data. As discussed in the FY 2025 IPPS/LTCH PPS final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) was a negative 0.041994 percent, which, when rounded to the second digit, is −0.04 percent. Therefore, for FY 2026, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (− .04 percent)]. Under this proposed approach, we determined a proposed threshold of $44,305 and calculated total outlier payments of $4,420,494,091and total operating Federal payments of $81,579,487,131. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.14 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $44,644. We

are proposing an outlier fixed-loss cost threshold for FY 2026 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 $44,305.

(3) Other Proposed Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2026 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 4.12 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we are proposing to reduce the FY 2026 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2026 outlier threshold are as follows:

	Operating standardized amounts	Capital federal rate *
National	0.949	0.958716

* The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2026 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III.A.2 in this Addendum.

We are proposing to apply the outlier adjustment factors to the FY 2026 payment rates after removing the effects of the FY 2025 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.273 or capital CCRs greater than 0.133 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2025, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable proposed statewide average capital CCRs. As previously stated, the proposed CCRs in Tables 8A and 8B would be used during FY 2026 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the proposed statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2024 Outlier Payments

Our current estimate, using available FY 2024 claims data, is that actual outlier payments for FY 2024 were approximately 5.13 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2024, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2024. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2024 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an across-the-board 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. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2025 period would not be available until after September 30, 2025, we are unable to provide an estimate of actual outlier payments for FY 2025 based on FY 2025 claims data in this proposed rule. We will provide an estimate of actual FY 2025 outlier payments in the FY 2027 IPPS/LTCH PPS proposed rule.

5. Proposed FY 2026 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2026. The proposed standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The proposed amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 66.0 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are proposing to apply a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000. In addition, Tables 1A and 1B include the proposed standardized amounts reflecting the

proposed applicable percentage increases for FY 2026.

The proposed labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2026 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2025 national standardized amounts to the proposed FY 2026 national standardized amounts. The second through fifth columns display the changes from the FY 2025 standardized amounts for each proposed applicable FY 2026 standardized amount. The first row of the table shows the updated (through FY 2025) average standardized amount after restoring the FY 2025 offsets for outlier payments, geographic reclassification, rural demonstration, and wage index cap policy budget neutrality. The MS–DRG reclassification and recalibration wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2025 adjustment factors have not been removed from the base rate in the following table.

CHANGES FROM FY 2025 STANDARDIZED AMOUNTS TO THE PROPOSED FY 2026 STANDARDIZED AMOUNTS

	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
FY 2026 Base Rate after removing: ..... 1. FY 2025 Geographic Reclassification Budget Neutrality (0.962786). 2. FY 2025 Operating Outlier Offset (0.949) ..... 3. FY 2025 Rural Demonstration Budget Neutrality Factor (0.999811). 4. FY 2025 Cap Policy Wage Index Budget Neutrality Factor (0.999166).	If Wage Index is Greater Than 1.0000: Labor (66.0%): ..... $4,790.03 ..... Nonlabor (34.0%): ..... $2,467.59 ..... If Wage Index is less Than or Equal to 1.0000: Labor (62%): ..... $4,499.73 ..... Nonlabor (38%): $2,757.90.	If Wage Index is Greater Than 1.0000: Labor (66.0%): ..... $4,790.034 ..... Nonlabor (34.0%): ..... $2,467.59 ..... If Wage Index is less Than or Equal to 1.0000: Labor (62%): ..... $4,499.73 ..... Nonlabor (38%): $2,757.90.	If Wage Index is Greater Than 1.0000: Labor (66.0%): ..... $4,790.034 ..... Nonlabor (34.0%): ..... $2,467.59 ..... If Wage Index is less Than or Equal to 1.0000: Labor (62%): ..... $4,499.73 ..... Nonlabor (38%): $2,757.90.	If Wage Index is Greater Than 1.0000: Labor (66.0%): $4,790.034. Nonlabor (34.0%): $2,467.59. If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,499.73. Nonlabor (38%): $2,757.90.
Proposed FY 2026 Update Factor	1.024	1.0	1.016	0.992.
Proposed FY 2026 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap.	0.998422	0.998422	0.998422	0.998422.
Proposed FY 2026 Cap Policy MS–DRG Weight Budget Neutrality Factor.	0.999938	0.999938	0.999938	0.999938.
Proposed FY 2026 Wage Index Budget Neutrality Factor.	1.001273	1.001273	1.001273	1.001273.
Proposed FY 2026 Reclassification Budget Neutrality Factor.	0.976960	0.976960	0.976960	0.976960.
Proposed FY 2026 Cap Policy Wage Index Budget Neutrality Factor.	0.993116	0.993116	0.993116	0.993116.
Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor.	0.999741	0.999741	0.999741	0.999741.
Proposed FY 2026 RCH Demonstration Budget Neutrality Factor.	0.999548	0.999548	0.999548	0.999548.
Proposed FY 2026 Operating Outlier Factor	0.949	0.949	0.949	0.949.
Proposed National Standardized Amount for FY 2026 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (66.0/34.0).	Labor: $4,511.41 ..... Nonlabor: $2,324.06	Labor: $4,405.67 ..... Nonlabor: $2,269.59	Labor: $4,476.16 ..... Nonlabor: $2,305.90	Labor: $4,370.43. Nonlabor: $2,251.43.
Proposed National Standardized Amount for FY 2026 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38).	Labor: $4,237.99 ..... Nonlabor: $2,597.48	Labor: $4,138.66 ..... Nonlabor: $2,536.60	Labor: $4,204.88 ..... Nonlabor: $2,577.18	Labor: $4,105.55. Nonlabor: $2,516.31.

B. Proposed Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the proposed labor-related and nonlabor-related shares that we are proposing to use to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2026. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Proposed Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2026, as discussed in section IV.B.3. of the preamble of this proposed rule, we are proposing to apply a labor-related share of 66.0 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are proposing to apply the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this proposed rule, we discuss the data and methodology for the FY 2026 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher non-labor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the COLA factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years

(coinciding with the update to the labor-related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule and Consumer Price Indices (CPIs) data through 2020. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii.

In general, under our existing methodology, we update the 2009 OPM COLA factors by a comparison of the growth in the CPIs for the areas of Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. Lastly, we exercised our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors. (For additional information, refer to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547).)

We previously stated our intention to update the COLA factors at the same time as the update to the labor-related share of the IPPS market basket. In section III.H. of the preamble of this proposed rule, we are proposing to update the labor-related share of the IPPS market basket. The following table lists the COLA factors for Alaska and Hawaii hospitals as calculated under our current methodology, using updated CPI data through 2024 and the approximate 60 percent commodities/40 percent services shares obtained from the proposed 2023-based IPPS market basket.

Area	FY 2022 through FY 2025 COLA factors	Updated COLA factors under current methodology	Difference
Alaska:			
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
City of Juneau and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
Rest of Alaska	1.24	1.20	−0.04
Hawaii:			
City and County of Honolulu	1.25	1.25	0
County of Hawaii	1.22	1.21	−0.01
County of Kauai	1.25	1.25	0
County of Maui and County of Kalawao	1.25	1.25	0

At this time, we believe it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the adjustment we make to IPPS payments to account for the unique circumstances of hospitals located in Alaska and Hawaii. Therefore, we are proposing to continue to use the FY 2025 COLA factors to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii for FY 2026. The following table lists the proposed FY 2026 COLA factors.

PROPOSED FY 2026 COST-OF-LIVING ADJUSTMENT (COLA) FACTORS: ALASKA AND HAWAII HOSPITALS

Area	Proposed COLA
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

We are interested in and soliciting comments on any possible data sources that could be considered in the development of the COLA factors beyond the methodology (as summarized previously and described in more detail in the FY 2022 IPPS/LTCH PPS final rule, 86 FR 45546) that relies on service and commodity prices as measured by the CPI for the average U.S. city and for the areas of Urban Hawaii and Urban Alaska.

C. Calculation of the Proposed Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2026

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2026 equals the Federal rate (which includes uncompensated care payments). As previously discussed, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 further extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment:

- The Federal national rate (which, as discussed in section V.E. of the preamble of this proposed rule, includes uncompensated care payments).

• The updated hospital-specific rate based on FY 1982 costs per discharge.
• The updated hospital-specific rate based on FY 1987 costs per discharge.
• The updated hospital-specific rate based on FY 1996 costs per discharge.
• The updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2026 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for discharges occurring before September 30, 2025, equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim primarily based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))
—Federal Payment for Capital Costs = MS–DRG Relative Weight x Federal Capital Rate × Geographic Adjustment Fact × (l + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)
—Capital Costs = (Billed Charges × Capital CCR)

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)
—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount
—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)
—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)
—Operating Outlier Payment = (Operating Costs—Operating Outlier Threshold) × Marginal Cost Factor
—Capital Outlier Payment = (Capital Costs—Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment and supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments, supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. As discussed previously, currently MDHs are paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the greater of the updated hospital-specific rates based on either FY 1982, FY 1987, or FY 2002 costs per discharge. As noted, under current law, the MDH program is effective for FY 2025 discharges on or before September 30, 2025.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990, final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2026

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. As discussed in section V.F. of the preamble of this proposed rule, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 further extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. We refer readers to section V.F. of the preamble of this proposed rule for further discussion of the MDH program. We note that if the MDH program were to be extended by law beyond September 30, 2025, into FY 2026, the proposed updates to the hospital-specific rates for SCHs as described in this section would also apply to the hospital-specific rates for MDHs for FY 2026.

Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs are the following:

FY 2026	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	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.4	0	−2.4
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.4	0.0	1.6	−0.8

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.F. of the preamble of this proposed rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or MDH is adjusted by the proposed MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.E.2.d. of the preamble this proposed rule and previously, we are applying a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as finalized in the FY 2023 IPPS/LTCH PPS final rule. Because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900 and 49432 through 49433), the hospital specific-rate for an SCH would be adjusted by the proposed MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH would receive for its discharges beginning on or after October 1, 2025.

III. Proposed Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2026

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we are proposing to use to determine the capital Federal rate for FY 2026, which would be effective for discharges occurring on or after October 1, 2025.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2026

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2026. In particular, we explain why the proposed FY 2026 capital Federal rate would increase approximately 3.28 percent, compared to the FY 2025 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 2.7 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The proposed update factor for FY 2026 under that framework is 2.6 percent based on a projected 2.6 percent increase in the proposed 2023-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed forecast error correction of 0.0 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2026 CIPI projection in that same section of this Addendum. In this proposed rule, we describe the policy adjustments that we are proposing to apply in the update framework for FY 2026.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of

cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004, IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2026, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2026. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, the proposed net adjustment for case-mix change in FY 2026 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this proposed rule, we have the FY 2024 MedPAR claims data available to evaluate the effects of the FY 2024 DRG reclassification and recalibration as part of our update for FY 2026. We assume for purposes of this adjustment, that the estimate of FY 2024 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, we are proposing to make a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2026.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if the difference in the actual increase and projected increase of the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. The forecast error in any given year can be derived as the actual CIPI increase less the forecasted CIPI increase. A forecast error of −0.1 percentage point was calculated for the FY 2024 update, for which there are historical data. That is, current historical data indicate that actual realized price increases (2.8 percent) were 0.1 percentage point lower than the forecasted FY 2024 CIPI increase (2.9 percent) used in calculating the FY 2024 update factor. As this does not exceed the 0.25 percentage point threshold, we are not proposing an adjustment for forecast error in the update for FY 2026.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the Consumer Price Index for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this proposed rule, we are proposing to continue to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2026 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2026, we are proposing to use an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2019 and extending through FY 2023. Based on these data, we estimated that case-mix constant intensity declined during FYs 2019 through 2023. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity declined during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2026. Therefore, we are proposing to make a 0.0 percentage point adjustment for intensity in the update for FY 2026.

Earlier, we described the basis of the components we used to develop the proposed 2.6 percent capital update factor under the capital update framework for FY 2026, as shown in the following table.

PROPOSED FY 2026 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.6
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	−0.5
Real Across DRG Change	0.5
Subtotal	0.0
Effect of FY 2024 Reclassification and Recalibration	0.0
Forecast Error Correction	0.0
Total Update	2.6

*The capital input price index represents the proposed 2023-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2026, we are proposing to continue to incorporate the impact of estimated operating outlier reconciliation payment amounts into the outlier threshold model. (For more details on our proposal to incorporate an estimate of the impact of operating outlier reconciliation payment amounts into the outlier threshold model, see section II.A.4.i. of this Addendum to this proposed rule.)

For FY 2025, we estimated that outlier payments for capital-related PPS payments would equal 4.23 percent of inpatient capital-related payments based on the capital Federal rate. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs would equal 4.16 percent of inpatient capital-related payments based on the proposed capital Federal rate in FY 2026. Using the proposal outlined in section II.A.4.i. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments would decrease the estimated percentage of FY 2026 capital outlier payments by 0.03 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 4.13 percent (4.16 percent − 0.03 percent) of inpatient capital-related payments based on the proposed capital Federal rate in FY 2026. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9587 in determining the capital Federal rate for FY 2026. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2026 would be lower than the percentage we estimated for FY 2025.

The outlier reduction factors are not built permanently into the capital rates; that is,

they are not applied cumulatively in determining the capital Federal rate. The proposed FY 2026 outlier adjustment of 0.9587 is a 0.11 percent change from the FY 2025 outlier adjustment of 0.9577. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2026 is 1.0011 (0.9587/0.9577) so that the proposed outlier adjustment would increase the FY 2026 capital Federal rate by approximately 0.11 percent compared to the FY 2025 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.5. of the preamble of this proposed rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to address wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy would be effective for at least 4 years, beginning in FY 2020. This policy was applied in FYs 2020 through 2024. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301 through 69308), we adopted an extension of this policy for at least three more years, beginning in FY 2025. However, in the FY 2025 IPPS/LTCH PPS interim final action with comment period (IFC) titled ''Medicare Program; Changes to the Fiscal Year 2025 Hospital Inpatient Prospective Payment System (IPPS) Rates Due to Court Decision'' (referred to herein as the FY 2025 IFC) (89 FR 80406 through 80408), after consideration of the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we recalculated the FY 2025 hospital wage index to remove the low wage hospital policy for FY 2025. The recalculation of the FY 2025 hospital wage index impacted the FY 2025 GAFs. In- the FY 2025 IFC (89 FR 80412), we also modified the calculation of the GAF budget neutrality adjustment factor that ensured budget neutrality for changes to the GAFs due to the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy (our policy to place a 5 percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year). Specifically, we modified this calculation to ensure budget neutrality for changes to the GAFs due only to the 5-percent cap on wage index decreases policy.

As discussed in section III.G.5. of the preamble of this proposed rule, for FY 2026 and subsequent fiscal years, we are proposing to discontinue the low wage index hospital policy and associated budget neutrality adjustment. In addition, as discussed in section IIII.G.7. of the preamble of this proposed rule, we recognize that some hospitals that previously benefitted from the low wage index hospital policy would experience decreases of 10 percent or more over the two years from their FY 2024 wage index (with the low wage index hospital policy applied) to their proposed FY 2026 wage index. Therefore, in addition to our permanent 5-percent wage index cap policy at 42 CFR 412.64(h)(7), we are proposing to establish a narrow transitional exception to the calculation of FY 2026 payments for hospitals significantly impacted by the discontinuation of the low wage index hospital policy, that would be implemented in a budget neutral manner. Specifically, we are proposing that for hospitals that benefitted from the low wage index hospital policy in FY 2024 and whose FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index, we would establish a transitional payment exception for FY 2026 for that hospital that would be equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index. Under that proposal, we indicated we are proposing to make a budget neutral equivalent exception under the capital IPPS. In this section, we refer to this proposed policy as the transition for the discontinuation of the low wage index hospital policy.

As referenced previously, beginning in FY 2023, we finalized at 42 CFR 412.64(h)(7) a permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY regardless of the circumstances causing the decline. That is, under this policy, a hospital's wage index value would not be less than 95 percent of its prior year value (87 FR 49018 through 49021). In this section, we refer to our permanent policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year as the 5-percent cap on wage index decreases policy. We note that the proposed transitional payment exception for FY 2026 discussed previously would be applied after the application of the 5-percent cap on wage index decreases policy. Given these proposed changes, we are proposing to augment our historical methodology for computing the budget neutrality factor for proposed changes in the GAFs.

Specifically, we are proposing to use a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those proposed wage index changes on the GAFs. In the first step, we propose to calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we propose to calculate a factor to ensure budget neutrality for changes to the GAFs due to the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. However, the budget neutrality factor for the 5-percent cap on wage index decreases policy is not permanently built into the capital Federal rate. This is because the GAFs with 5-percent cap on wage index decreases policy applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the proposed GAF budget neutrality factors for FY 2026, we removed from the capital Federal rate the budget neutrality factor applied in FY 2025 for the 5-percent cap on wage index decreases policy. Specifically, we divided the capital Federal rate by the FY 2025 budget neutrality factor of 0.9992 (89 FR 80412). (We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing from the capital Federal rate the prior year budget neutrality factor(s) that are not used in the budget neutrality factor calculations for the current year.)

We discuss our proposed 2-step calculation of the proposed GAF budget neutrality factors for FY 2026 as follows. To determine the GAF budget neutrality factors for FY 2026, we first compared estimated aggregate capital Federal rate payments based on the FY 2025 MS–DRG classifications and relative weights and the FY 2025 GAFs to estimated aggregate capital Federal rate payments based on the FY 2025 MS–DRG classifications and relative weights and the proposed FY 2026 GAFs without incorporating the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 1.0140 for FY 2026.

Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2026 GAFs with and without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2026 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the proposed FY 2026 GAFs (both with and without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy). (We note, for this calculation the proposed GAFs included the imputed floor, out-migration, and Frontier State adjustments.) To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy on the proposed FY 2026 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9927.

The budget neutrality factor for the 5-percent cap on wage index decreases policy

and the proposed transition for the discontinuation of the low wage index hospital policy is not permanently built into the capital Federal rate. Consistent with this, we present the proposed budget neutrality factor for the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy calculated under the second step of this 2-step methodology separately from the other proposed budget neutrality factors in the discussion that follows, and this proposed factor is not included in the calculation of the proposed combined GAF/DRG adjustment factor described later in this section.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. Consistent with our historical methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we finalized to apply an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner (87 FR 49436). Specifically, we augmented our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS–DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS–DRG relative weight decreases.

To determine the proposed DRG budget neutrality factors for FY 2026, we first compared estimated aggregate capital Federal rate payments based on the FY 2025 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the proposed FY 2026 MS–DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the proposed FY 2026 GAFs without the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. The proposed incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 0.9982. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2026 MS–DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the proposed FY 2026 MS–DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the proposed FY 2026 GAFs without the 5 percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. The proposed incremental adjustment factor for the application of the 10-percent cap on relative weight decreases is 0.9999. Therefore, to achieve budget neutrality for the proposed FY 2026 MS–DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we are proposing to apply an incremental budget neutrality adjustment factor of 0.9982 (0.9982×0.9999) for FY 2026 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The proposed incremental adjustment factor for the proposed FY 2026 MS–DRG reclassification and recalibration (0.9982) and for proposed changes in the FY 2026 GAFs due to the proposed update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (1.0140) is 1.0121 (0.9982×1.0140). This incremental adjustment factor is built permanently into the capital Federal rates.

To achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy on the FY 2026 GAFs, as described previously, we calculated a proposed budget neutrality adjustment factor of 0.9927 for FY 2026. We refer to this proposed budget neutrality factor for the remainder of this section as the cap/transition adjustment factor.

We applied the proposed budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the 5-percent cap on wage index decreases policy, or the proposed transition for the discontinuation of the low wage index hospital policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The proposed incremental GAF/DRG adjustment factor of 1.0121 accounts for the proposed MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for proposed changes in the GAFs that result from proposed updates to the wage data, the effects on the GAFs of FY 2026 geographic reclassification decisions made by the MGCRB compared to FY 2025 decisions, and the application of the rural floor policy. The proposed cap/transition adjustment factor of 0.9927 accounts for changes that result from the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2026

For FY 2025, we established a capital Federal rate of $512.14 (89 FR 80412). We are proposing to establish an update of 2.6 percent in determining the FY 2026 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $528.95 for FY 2026. The proposed national capital Federal rate for FY 2026 was calculated as follows:

- The proposed FY 2026 update factor is 1.026; that is, the proposed update is 2.6 percent.
- The proposed FY 2026 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and proposed changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 1.0121.
- The proposed FY 2026 cap/transition budget neutrality adjustment factor that is applied to the capital Federal rate for changes due to the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy is 0.9927.
- The proposed FY 2026 outlier adjustment factor is 0.9587.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2026 affects the computation of the proposed FY 2026 national capital Federal rate in comparison to the FY 2025 national capital Federal rate. The proposed FY 2026 update factor has the effect of increasing the capital Federal rate by 2.6 percent compared to the FY 2025 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of increasing the capital Federal rate by 1.21 percent. The proposed FY 2026 cap/transition budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.65 percent compared to the FY 2025 capital Federal rate. The proposed FY 2026 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.11 percent compared to the FY 2025 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by

approximately 3.28 percent, compared to the FY 2025 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS—FY 2025 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2026 CAPITAL FEDERAL RATE

	FY 2025	Proposed FY 2026	Change	Percent change
Update Factor [1]	1.0310	1.0260	1.0260	2.60
GAF/DRG Adjustment Factor [1]	0.9854	1.0121	1.0121	1.21
GAF Cap/Transition Adjustment Factor [2]	0.9992	0.9927	0.9935	−0.65
Outlier Adjustment Factor [3]	0.9577	0.9587	1.0011	0.11
Capital Federal Rate	$512.14	$528.95	1.0328	[4] 3.28

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2025 to FY 2026 resulting from the application of the proposed 1.0121 GAF/DRG budget neutrality adjustment factor for FY 2025 is a net change of 1.0121 (or 1.21 percent).

[2] For FY 2025 the GAF Cap/Transition budget neutrality adjustment factor reflects only the FY 2025 budget neutrality factor for the 5-percent cap on wage index decreases policy. The GAF Cap/Transition budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2026 GAF Cap/Transition budget neutrality adjustment factor is 0.9927/0.9992 or 0.9935 (or −0.65 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the proposed FY 2026 outlier adjustment factor is 0.9587/0.9577 or 1.0011 (or 0.11 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Proposed Inpatient Capital-Related Prospective Payments for FY 2026

For purposes of calculating payments for each discharge during FY 2026, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The proposed outlier threshold for FY 2026 is in section II.A. of this Addendum. For FY 2026, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the 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 the proposed fixed-loss amount of $44,305.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted average of past capital purchase prices up to and including the current year.

For this proposed rule, we are proposing to use the IPPS operating and capital market baskets that reflect a 2023 base year. For a complete discussion of the proposal to rebase the IPPS operating and capital market baskets, we refer readers to section IV. of the preamble of this proposed rule.

2. Forecast of the CIPI for FY 2026

Based on IHS Global Inc.'s (IGI) fourth quarter 2024 forecast, for this proposed rule, we are forecasting the proposed 2023-based CIPI to increase 2.6 percent in FY 2026. This reflects a projected 3.2 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.4 percent increase in other capital expense prices in FY 2026, partially offset by a projected 0.8 percent decline in vintage-weighted interest expense prices in FY 2026. The weighted average of these three factors produces the forecasted 2.6 percent increase for the proposed 2023-based CIPI in FY 2026.

We are also proposing that if more recent data become available (for example, a more recent estimate of the percentage increase in the proposed 2023-based CIPI), we would use such data, if appropriate, to determine the FY 2026 capital update factor for the final rule.

IV. Proposed Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2026

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are paid on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For this FY 2026 IPPS/LTCH PPS proposed rule, based on IGI's 2024 fourth quarter forecast, we estimate that the proposed 2023-based IPPS operating market basket percentage increase for FY 2026 is 3.2 percent (that is, the estimate of the market basket rate-of-increase). Based on this estimate, the proposed FY 2026 rate-of-increase percentage that will be applied to the FY 2025 target amounts in order to calculate the proposed FY 2026 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals will be 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are also proposing that if more recent data become available (for example a more recent estimate of the market basket rate-of-increase), we would use such data, if appropriate, to

calculate the final IPPS operating market basket update for FY 2026.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble and section V. of the Addendum of this proposed rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2026. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2026

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2026

1. Overview

In section IX. of the preamble of this proposed rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2026.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section IX.C.2. of the preamble of this proposed rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section IX.C.2. of the preamble of this proposed rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the Proposed FY 2026 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2026, we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2026, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2026 LTCH PPS standard Federal payment rate, we are proposing to apply a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.6. of this Addendum.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.6 percent (that is, the most recent estimate of the 2022-based LTCH market basket increase of 3.4 percent less the proposed productivity adjustment of 0.8 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply an update factor of 1.026 to the FY 2025 LTCH PPS standard Federal payment rate of $49,383.26 to determine the proposed FY 2026 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2026 as required under the LTCH QRP. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 0.6 percent (or an update factor of 1.006). This proposed update reflects the proposed annual market basket update of 3.4 percent reduced by the proposed 0.8 percentage point productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act, minus 2.0 percentage points for LTCHs failing to submit quality data under the LTCH QRP, as required by section 1886(m)(5) of the Act. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2026 LTCH PPS standard Federal payment rate of 1.0012146, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section), and proposed labor-related share) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $50,728.77 (calculated as $49,383.26 × 1.026 × 1.0012146) for FY 2026. For LTCHs that fail to submit quality reporting data for FY 2026, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $49,739.90 (calculated as $49,383.26 × 1.006 × 1.0012146) for FY 2026.

B. Proposed Adjustment for Area Wage Levels Under the LTCH PPS for FY 2026

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The proposed FY 2026 LTCH PPS standard Federal payment rate wage index values that would be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2025, through September 30, 2026, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of this Addendum and available via the internet on the CMS website.

2. Proposed Geographic Classifications (Labor Market Areas) Under the LTCH PPS

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS are based on the Core Based Statistical Areas (CBSAs) established by OMB. In the July 16, 2021, **Federal Register** (86 FR 37777), OMB finalized a schedule for future updates based on results of the decennial Census updates to commuting patterns from the American Community Survey. In accordance with that schedule, on July 21, 2023, OMB released Bulletin No. 23–01. According to OMB, the delineations reflect the 2020 Standards for Delineating Core Based Statistical Areas (''the 2020 Standards''), which appeared in the **Federal Register** on July 16, 2021 (86 FR 37770 through 37778), and the application of those standards to Census Bureau population and journey-to-work data (that is, 2020 Decennial Census, American Community Survey, and Census Population Estimates Program data). A copy of OMB Bulletin No. 23–01 may be obtained at *https://bidenwhitehouse.archives.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf.*

In the FY 2025 IPPS/LTCH PPS final rule, we stated that we believe that adopting the

CBSA-based labor market area delineations established in OMB Bulletin 23–01 will ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). We also noted that our adoption of the revised delineations announced in OMB Bulletin No. 23–01 is consistent with the changes under the IPPS for FY 2025. Therefore, in that same final rule, we adopted the updates set forth in OMB Bulletin No. 23–01, under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, for the LTCH PPS effective for FY 2025. We refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through 69975), for a full discussion of our implementation of the OMB delineations based on OMB Bulletin No. 23–01 for the LTCH PPS. For additional information on the CBSA-based labor market area (geographic classification) delineations used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).

We continue to believe that the CBSA-based labor market area delineations, as established in OMB Bulletin 23–01, would ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (89 FR 69974). Therefore, for FY 2026, we are proposing to continue to use the CBSA-based labor market area delineations as established in OMB Bulletin 23–01 and adopted in the FY 2025 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. For FY 2026, we are continuing to use the Federal Information Processing Standard (FIPS) county codes, maintained by the U.S. Census Bureau, for purposes of crosswalking counties to CBSAs. The current county-to-CBSA crosswalk was adopted under the LTCH PPS in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69973 through 69975) and is located on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/long-term-care-hospital/other-files-download*.

3. Proposed Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

Effective FY 2025, we rebased and revised the 2017-based LTCH market basket to reflect a 2022 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2022-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2025 IPPS/LTCH PPS final rule (89 FR 69435 through 69455).)

In this proposed rule, consistent with our historical practice, we are proposing that the LTCH PPS labor-related share for FY 2026 would be the sum of the FY 2026 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specially, we are proposing that the labor-related share for FY 2026 is the sum of the labor-related portion of operating costs from the 2022-based LTCH market basket (that is, the sum of the FY 2026 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) and a portion of the relative importance of Capital-Related cost weight from the 2022-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2022) and FY 2026. Based on IHS Global Inc.'s fourth quarter 2024 forecast of the 2022-based LTCH market basket, the sum of the FY 2026 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services is 69.2 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based, 2013-based, and 2017-based LTCH market basket capital-related costs relative importance). Since the FY 2026 relative importance for capital-related costs is 8.4 percent based on IHS Global Inc.'s fourth quarter 2024 forecast of the 2022-based LTCH market basket, we took 46 percent of 8.4 percent to determine the labor-related share of capital-related costs for FY 2026 of 3.9 percent. Therefore, we are proposing a total labor-related share for FY 2026 of 73.1 percent (the sum of 69.2 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of capital-related costs). Consistent with our historical practice, we are proposing that if more recent data become available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2022-based LTCH market basket), we will use such data, if appropriate, to determine the FY 2026 LTCH PPS labor-related share.

4. Proposed Wage Index for FY 2026 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2026 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we are proposing to continue to employ our historical practice of using the same data we used to compute the proposed FY 2026 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2022) because these data are the most recent complete data available.

In addition, we are proposing to compute the FY 2026 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. We are also proposing to continue to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2026, we are proposing to continue to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2022 IPPS wage data that we are proposing to use to determine the proposed FY 2026 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent

with our existing methodology, we calculated the proposed FY 2026 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, proposed CBSAs 10500, 12020, 12054, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 31924, 40660, 42340, 46660, and 47580), as shown in Table 12A, which is listed in section VI. of this Addendum.

Based on the FY 2022 IPPS wage data that we are proposing to use to determine the proposed FY 2026 LTCH PPS area wage index values in this proposed rule, there are no IPPS wage data for rural North Dakota (CBSA 35). Consistent with our existing methodology, we calculated the proposed FY 2026 wage index value for CBSA 35 as the average of the wage index values for all proposed CBSAs that are contiguous to the rural counties of the State (that is, proposed CBSAs 13900, 22020, 24220, and 33500), as shown in Table 12B, which is listed in section VI. of this Addendum. We note that, as IPPS wage data are dynamic, it is possible that the number of urban and rural areas without IPPS wage data will vary in the future.

5. Cap on Wage Index Decreases

a. Cap on LTCH PPS Wage Index Decreases

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49440 through 49442), we finalized a policy that applies a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. Consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we include the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of this Addendum.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. An LTCH's wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2026 would not be eligible for the LTCH PPS wage index cap in FY 2026. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage index cap. The cap on wage index decreases policy is reflected at § 412.525(c)(1).

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

b. Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information on this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49442 through 49443), we finalized a policy that applies a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

Under this policy, an LTCH's applicable IPPS comparable wage index will not be less than 95 percent of its applicable IPPS comparable wage index for the prior fiscal year. An LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year, these LTCHs will not be subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. For example, newly opened LTCHs that become operational during FY 2026 would not be eligible for the applicable IPPS comparable wage index cap in FY 2026. This means that these LTCHs would receive the calculated applicable IPPS comparable wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. The cap on IPPS comparable wage index decreases policy is reflected at § 412.529(d)(4)(ii)(B) and (d)(4)(iii)(B).

Similar to the information we are making available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this proposed rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

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

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2026, in accordance with § 412.523(d)(4), we are applying a proposed area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.5. of this Addendum, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the proposed area wage

level budget neutrality factor. Specifically, we are proposing to determine an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2026 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2025 wage index values and the FY 2025 labor-related share of 72.8 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the proposed FY 2026 wage index values (including the application of the 5-percent cap on wage index decreases) and the proposed FY 2026 labor-related share of 73.1 percent. (As noted previously, the proposed changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the proposed labor-related share is discussed in section V.B.3. of this Addendum.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2025 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the proposed FY 2026 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed budget neutrality factor for updates to the area wage level adjustment for FY 2026 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the proposed FY 2026 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2026 LTCH PPS standard Federal payment rate after the application of the proposed FY 2026 annual update.

We are proposing to use the most recent data available, including claims from the FY 2024 MedPAR file, in calculating the FY 2026 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2026 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2026 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0012146. Accordingly, in section V.A. of this Addendum, we applied the proposed area wage level adjustment budget neutrality factor of 1.0012146 to determine the proposed FY 2026 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Proposed Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels.

The current methodology used to determine the COLA factors for Alaska and Hawaii is based on the 2009 OPM COLAs (which are the last COLA factors OPM published prior to transitioning from COLA to locality pay) by a comparison of the growth in the Consumer Price Indexes (CPIs) for Urban Alaska and Urban Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). We use the comparison of the growth in the overall CPI relative to the growth in the CPI for those areas to update the COLA factors for all areas in Alaska and Hawaii, respectively, because BLS publishes CPI data for only Urban Alaska and Urban Hawaii. Using the respective CPI commodities index and CPI services index and using the approximate commodities/services shares obtained from the IPPS market basket, we create reweighted CPIs for each of the respective areas to reflect the underlying composition of the IPPS market basket nonlabor-related share. The methodology also includes our discretionary authority to adjust payments to hospitals in Alaska and Hawaii by incorporating the statutorily mandated cap of 25 percent that was applied when determining OPM's COLA factors (77 FR 53482). Under this policy, we have updated the COLA factors using this methodology every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482) for a detailed description of this methodology.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560), we last updated the COLA factors for LTCHs using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482) and CPI data through 2020. We utilized these COLA factors for FYs 2022 through 2025 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. (We note the same COLA methodology and factors were used under the IPPS and LTCH PPS for FYs 2022 through 2025.)

As stated previously, we have historically updated the COLA factors at the same time as the update to the labor-related share of the IPPS market basket (77 FR 53482). In section III.H. the preamble of this proposed rule, we are proposing to update the labor-related share of the IPPS market basket. The table below lists the COLA factors for Alaska and Hawaii hospitals as calculated under the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53481 through 53482), using updated CPI data through 2024 and the approximate 60 percent commodities/40 percent services shares obtained from the proposed 2023-based IPPS market basket. For comparison purposes, we also are presenting the COLA factors for FYs 2022 through 2025.

COMPARISON OF COST-OF-LIVING ADJUSTMENT (COLA) FACTORS—ALASKA AND HAWAII UNDER THE LTCH PPS

Area	FY 2022 through FY 2025	Updated COLA factors under current methodology	Difference
Alaska:			
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
City of Juneau and 80-kilometer (50-mile) radius by road	1.22	1.18	−0.04
Rest of Alaska	1.24	1.20	−0.04
Hawaii:			
City and County of Honolulu	1.25	1.25	.....
County of Hawaii	1.22	1.21	−0.01
County of Kauai	1.25	1.25	.....
County of Maui and County of Kalawao	1.25	1.25	.....

At this time, consistent with the approach proposed under the IPPS as discussed in section II.B.2. of this Addendum, we believe it would be appropriate to maintain the current COLA factors for FY 2026 to allow us to consider whether it would be appropriate to incorporate additional data sources or other methodology changes in determining the adjustment we make to LTCH PPS payments to account for the unique circumstances of LTCHs located in Alaska and Hawaii. Therefore, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, for FY 2026 we are proposing to continue to use the FY 2025 COLA factors (which were originally established in the FY 2022 IPPS/LTCH PPS final rule, as described previously). The following table lists the proposed FY 2026 COLA factors.

PROPOSED FY 2026 COLA FACTORS—ALASKA AND HAWAII UNDER THE LTCH PPS

Area	Proposed COLA
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

We are interested in and soliciting comments on any possible data sources that could be considered in the development of the COLA factors beyond the methodology (as summarized previously and described in more detail in the FY 2022 IPPS/LTCH PPS final rule, 86 FR 45559) that relies on service and commodity prices as measured by the CPI for the average U.S. city and for the areas of Urban Hawaii and Urban Alaska.

D. Proposed Adjustment for LTCH PPS High-Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and are also used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. Proposed LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the best available data to determine the LTCH total CCR ceiling for

FY 2026 in this proposed rule. Specifically, in this proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2024 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are proposing an LTCH total CCR ceiling of 1.359 under the LTCH PPS for FY 2026 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to determine the LTCH total CCR ceiling for FY 2026 in the final rule. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this proposed rule, we are proposing to use our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2024 update of the PSF. We are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2025, through September 30, 2026, in Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2026 in the final rule.

Under the current LTCH PPS labor market areas, all areas in the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, we are proposing to continue to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are proposing to use this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

Furthermore, although Connecticut, Massachusetts, Nevada, and North Dakota have areas that are designated as rural under the current LTCH PPS labor market areas, in our calculation of the LTCH statewide average CCRs, there were no trimmed CCR data available from IPPS hospitals located in these rural areas as of December 2024. We refer the reader to section II.A.4.i.(2). of this Addendum for details on the trims applied to the IPPS CCR data from the December 2024 update of the PSF, which are the same data used to calculate the LTCH statewide average total CCRs. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut, Massachusetts, Nevada, and North Dakota in Table 8C. We note that there were no LTCHs located in these rural areas as of December 2024.

d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010) and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821), and most recently modified by Change Request 13566 (Transmittal 12558; March 28, 2024) with an update to the outlier reconciliation criteria.

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

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

Under the regulations at § 412.525(a)(2)(ii) and 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 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

In this section of this Addendum, we discuss our proposed methodology for determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026. When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

(1) Proposed Charge Inflation Factor for Use in Determining the Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges

on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor.

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.i.(2). of this Addendum), our methodology determines the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data. In this section of this Addendum, we describe our charge inflation factor methodology.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases.

The first step in our methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers.

The next step in our methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. We remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. Then we remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor.

The final step in our methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. Then we calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

Following the methodology described previously, we computed a proposed charge inflation factor based on the most recently available data. Specifically, we used the December 2024 update of the FY 2024 MedPAR file and the December 2023 update of the FY 2023 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. Therefore, we trimmed the December 2024 update of the FY 2024 MedPAR file and the December 2023 update of the FY 2023 MedPAR file as described in steps 1 and 2 of our methodology. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $302,638 ($12,632,704,879/41,742 cases) from FY 2023 to the average covered charge per case of $340,622 ($14,523,112,734/42,637 cases) from FY 2024. This rate-of-change was 12.5512 percent, which results in a 1-year charge inflation factor of 1.125512, and a 2-year charge inflation factor of 1.266777 (calculated by squaring the 1-year factor). We propose to inflate the billed charges obtained from the FY 2024 MedPAR file by this 2-year charge inflation factor of 1.266777 when determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026.

(2) CCRs for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.i.(2). of this Addendum), our methodology adjusts CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case-weighted CCR for LTCHs. We believe these adjusted CCRs more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs. In this section of this Addendum, we describe our CCR adjustment factor methodology.

Step 1—Assign Providers Their Historical CCRs.

The first step in our methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available one year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data.

The next step in our methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers.

The next step in our methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate a CCR Adjustment Factor.

The final step in our methodology is to calculate, across all remaining providers after application of Step 3, an average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short stay outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Following the methodology described previously, we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the December 2024 PSF as the most recently available PSF and the December 2023 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our methodology. In addition, we used claims from the December 2024 update of the FY 2024 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. Specifically, following the methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the December 2024 update of the FY 2024 MedPAR file, we identified their CCRs from both the December 2023 PSF and December 2024 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2024 MedPAR file (classified using proposed Version 43 of the GROUPER) to calculate case-weighted average CCRs. Based on this data, we calculated a December 2023 national average case-weighted CCR of 0.238634 and a December 2024 national average case-weighted CCR of 0.226588. We then calculated the proposed national CCR adjustment factor by dividing the December 2024 national average case-weighted CCR by the December 2023 national average case-weighted CCR. This results in a proposed 1-year national CCR adjustment factor of

0.949522. When calculating the proposed fixed-loss amount for FY 2026, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the December 2024 PSF or whose CCR was missing in the December 2024 PSF. For all other providers, we multiplied their CCR from the December 2024 PSF by the proposed 1-year national CCR adjustment factor of 0.949522.

(3) Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

In this proposed rule, for FY 2026, using the best available data and the steps described previously, we calculated a proposed fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases as required by section 1886(m)(7) of the Act and in accordance with § 412.525(a)(2)(ii) (based on the proposed payment rates and policies for these cases presented in this proposed rule). Consistent with our historical practice, we are proposing to use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 in the final rule. Therefore, based on LTCH claims data from the December 2024 update of the FY 2024 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2024 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 of $91,247 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2026 payments for such cases. As such, we would make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $91,247).

The proposed fixed-loss amount for FY 2026 ($91,247) is approximately $14,000 higher than the fixed-loss amount for FY 2025 ($77,048). We seek comment on the proposed fixed-loss amount and will consider these comments when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 in the final rule.

4. Proposed High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2025, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases and the provisions of section 3711(b)(2) of the CARES Act, the historical claims data available in each of these years were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2025, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2025 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2025. In particular, in FY 2025, we established the fixed-loss amount for site neutral payment rate cases as the FY 2025 IPPS fixed-loss amount of $46,217 (89 FR 80412). For this proposed rule, we used FY 2024 data in the FY 2026 LTCH PPS proposed ratesetting. We note that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases. This waiver applied to patients admitted during the COVID–19 PHE period and expired on May 11, 2023. Although the vast majority of LTCH discharges in FY 2024 were not subject to the waiver of the application of the site neutral payment rate, we believe LTCHs' admission patterns may still have been adapting to the expiration of the waiver of the application of the site neutral payment rate. Therefore, at this time, we do not believe it would be appropriate to use FY 2024 data to develop a fixed-loss amount for site neutral payment rate cases for FY 2026. As discussed earlier in this section, we also continue to believe LTCH PPS site neutral payment rate cases should not receive dramatically different HCO payments from those cases that would be paid under the IPPS while we continue to evaluate the actuarial assumptions discussed previously and the use of LTCH PPS site neutral payment rate data to determine an appropriate outlier threshold for such cases.

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2026 is the IPPS fixed-loss amount for FY 2026. Accordingly, for FY 2026, we are 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, we are proposing a fixed-loss amount for site neutral payment rate cases of $44,305, which is the same proposed FY 2026 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of this Addendum. Accordingly, under this policy, for FY 2026, we would calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the proposed fixed-loss amount for site neutral payment rate cases of $44,305).

In establishing an HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2026 would not result in any increase in estimated aggregate FY 2026 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2026. Consistent with our historical practice, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed fixed-loss threshold would result in FY 2026 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2026 would not result in any increase in estimated aggregate FY 2026 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2026. To achieve this, for FY 2026, we are proposing to apply a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as $1.0 - 5.1/100 = 0.949$) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed Update to the IPPS Comparable Amount To Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals under the age of 65 who are uninsured, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments.

To reflect the Medicare DSH payment adjustment methodology statutory changes in section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766) that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

For FY 2026, as discussed in greater detail in section IV.E.2.b. of the preamble of this proposed rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 60.71 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2026. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 45.53 percent (the product of 75 percent and 60.71 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2026, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 70.53 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 45.53 percent = 70.53 percent).

Therefore, for FY 2026, we are proposing to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 70.53 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we are proposing that, if more recent data became available, we would use that data to determine the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in the final rule.

F. Computing the Proposed Adjusted LTCH PPS Federal Prospective Payments for FY 2026

Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages; we make this adjustment by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the proposed FY 2026 values are shown in Tables 12A through 12B listed in section VI. of this Addendum and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the proposed FY 2026 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2026 of $50,728.77, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2026, applying our proposed LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

Example:

During FY 2026, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a proposed FY 2026 LTCH PPS wage index value of 1.0267 (as shown in Table 12A listed in section VI. of this Addendum). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative weight for FY 2026 of 0.9485 (as shown in Table 11 listed in section VI. of this Addendum). The LTCH submitted quality reporting data for FY 2026 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted proposed Federal prospective payment for this Medicare patient case in FY 2026, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2026 LTCH PPS standard Federal payment rate ($50,728.77) by the proposed labor-related share (73.1 percent) and the proposed wage index value (1.0267). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (26.9 percent; adjusted for cost of living, if

applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9485) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2026 ($49,055.36). The table illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$50,728.77
Proposed Labor-Related Share	× 0.731
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $37,082.73
Proposed Wage Index (CBSA 16984)	× 1.0267
Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $38,072.84
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($50,728.77 × 0.269)	+ $13,646.04
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $51,718.88
Proposed MS–LTC–DRG 189 Relative Weight	× 0.9485
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $49,055.36

VI. Tables Referenced in This Proposed Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2025, for the FY 2026 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be on the CMS website. Specifically, all IPPS tables listed in the proposed rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available on the CMS website. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules.

Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49452), we finalized beginning with FY 2023, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file. The AOR/BOR files can be found on the FY 2026 IPPS proposed rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

As discussed in section II.E.6. of the preamble to this proposed rule, for certain FY 2026 new technology add-on payment applications, we are making available separate tables listing the ICD–10–CM codes and/or ICD–10–PCS codes that we believe would be used to identify cases relevant to the Breakthrough Device-designated indications, or would be appropriate to exclude for cases related to FDA market authorized indications that are not covered by the Breakthrough Device designation indications, for purposes of the new technology add-on payment, if approved, in Table 10 associated with this proposed rule.

After hospitals have been given an opportunity to review and correct their calculations for FY 2026, we will post Table 15 (which will be available via the CMS website) to display the final FY 2026 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2025. We expect Table 15 will be posted on the CMS website in the Fall 2025.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified in this proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed rule are generally available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed Rule Home Page'' or ''Acute Inpatient-Files-for Download.''

Table 2.—Proposed Case-Mix Index and Wage Index Table by CCN—FY 2026 Proposed Rule
Table 3.—Proposed Wage Index Table by CBSA—FY 2026 Proposed Rule
Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2026 Proposed Rule
Table 4B.—Proposed Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2026 Proposed Rule
Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2026 Proposed Rule
Table 6A.—New Diagnosis Codes—FY 2026
Table 6B.—New Procedure Codes—FY 2026
Table 6C.—Invalid Diagnosis Codes—FY 2026
Table 6D.—Invalid Procedure Codes—FY 2026
Table 6E.—Revised Diagnosis Code Titles—FY 2026
Table 6F.—Revised Procedure Code Titles—FY 2026
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026
Table 6I.1.—Proposed Additions to the MCC List—FY 2026
Table 6J.1.—Proposed Additions to the CC List—FY 2026
Table 6J.2.—Proposed Deletions to the CC List—FY 2026
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG Changes—FY 2026 (Table 6P contains multiple tables, 6P.1a. through 6P.8a that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG changes or other analyses). These tables are referred to throughout section II.C. of the preamble of this proposed rule.
Table 8A.—Proposed FY 2026 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)
Table 8B.—Proposed FY 2026 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals
Table 10.—Relevant ICD–10 Codes for Certain FY 2026 New Technology Add-On Payment Applications
Table 16.—Proposed Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2026
Table 18.—Proposed FY 2026 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2026 proposed rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1833–P:

Table 8C.—Proposed FY 2026 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)
Table 11.—Proposed MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2025, through September 30, 2026
Table 12A.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2025, through September 30, 2026
Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2025, through September 30, 2026

TABLE 1A—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (66.0 PERCENT LABOR SHARE/34.0 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)

[FY 2026]

Hospital submitted quality data and is a meaningful EHR user (update = 2.4 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.0 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.6 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.8 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,511.41	$2,324.06	$4,405.67	$2,269.59	$4,476.16	$2,305.90	$4,370.43	$2,251.43

TABLE 1B—PROPOSED NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)

[FY 2026]

Hospital submitted quality data and is a meaningful EHR user (update = 2.4 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.0 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.6 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.8 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,237.99	$2,597.48	$4,138.66	$2,536.60	$4,204.88	$2,577.18	$4,105.55	$2,516.31

TABLE 1C—PROPOSED ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1)

[FY 2026]

	Rates if wage index greater than 1		Hospital is a meaningful EHR user and wage index less than or equal to 1 (update = 2.4)		Hospital is NOT a meaningful EHR user and wage index l ess than or equal to 1 (update = 0.0)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$4,237.99	$2,597.48	$4,138.66	$2,536.60

[1] For FY 2026, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE

[FY 2026]

	Rate
National	$528.95

TABLE 1E—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE

[FY 2026]

	Full update (2.6 percent)	Reduced update * (0.6 percent)
Standard Federal Rate	$50,728.77	$49,739.90

* For LTCHs that fail to submit quality reporting data for FY 2026 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A: Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This proposed rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this Appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Proposed Update to the IPPS Payment Rates

As discussed in section IV. of the preamble of this proposed rule, we are proposing to rebase and revise the 2018-based IPPS market basket to reflect a 2023 base year. In addition, using the cost category weights from the proposed 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we are proposing to use for discharges occurring on or after October 1, 2025. The proposed labor-related share of 66.0 percent is 1.6 percentage points lower than the current labor-related share of 67.6 percent. As discussed in section IV.B.3. of the preamble of this proposed rule, this downward revision to the labor-related share is primarily the result of incorporating the more recent 2023 Medicare cost report data for Wages and Salaries, Employee Benefits, and Contract Labor costs. This is partially offset by an increase in the Professional Fees: Labor-Related cost weight.

In accordance with section 1886(b)(3)(B) of the Act and as described in section VI.B. of the preamble to this proposed rule, we are proposing to update the national standardized amount for inpatient hospital operating costs by the proposed applicable percentage increase of 2.4 percent (that is, a proposed 3.2 percent market basket update with a proposed reduction of 0.8 percentage point for the productivity adjustment). We are also proposing to apply the proposed applicable percentage increase (including the market basket update and the proposed productivity adjustment) to the hospital-specific rates.

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive a proposed applicable percentage increase of 1.6 percent which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data. Hospitals that are not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of 0.0 percent which reflects a three-quarter percent reduction of the market basket update for not being a meaningful EHR user.

Hospitals that are not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a proposed applicable percentage increase of −0.8 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for not meeting the requirements to be a meaningful EHR user.

b. Proposed Changes for the Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, we review applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(f)(1), we consider whether a technology meets the criteria for the new technology add-on payment and announce the results as part of the annual updates and changes to the IPPS. New technology add-on payments are not budget neutral.

c. Proposed Transition for the Discontinuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. We also stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301 through 69308), we adopted an extension of the low wage index hospital policy and the related budget neutrality adjustment effective for at least three more years, beginning in FY 2025, in order for sufficient wage data from after the end of the COVID–19 Public Health Emergency to become available.

As discussed in section III.F.5. of the preamble of this proposed rule, on July 23, 2024, the Court of Appeals for the D.C. Circuit held that the Secretary lacked authority under section 1886(d)(3)(E) of the Act or under the ''adjustments'' language of section 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020, and that the policy and related budget neutrality adjustment must be vacated. After considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* in the FY 2025 IFC (89 FR 80405 through 80421), we recalculated the FY 2025 IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. We also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. In addition, we established an interim transition policy for hospitals significantly impacted by the removal of the FY 2025 low wage index hospital policy using our authority under section 1886(d)(5)(I) of the Act.

For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are proposing to discontinue the low wage index hospital policy and would no longer apply a low wage index budget neutrality factor to the standardized amounts. As discussed in section III.F.7. of the preamble of this proposed rule, we are proposing to use our authority under section 1886(d)(5)(I)(i) of the Act to adopt a narrow transitional exception to the calculation of FY 2026 IPPS payments for low wage index hospitals significantly impacted by the discontinuation of the low wage index hospital policy, that would be implemented in a budget neutral manner. This proposed transitional exception policy would apply to hospitals that benefitted from the FY 2024 low wage index hospital policy and would compare the hospital's proposed FY 2026 wage index to the hospital's FY 2024 wage index. If the hospital's proposed FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index, then the proposed transitional payment exception for FY 2026 for that hospital would be equal to the additional FY 2026 amount the hospital would be paid under the IPPS if its FY 2026 wage index were equal to 90.25 percent of its FY 2024 wage index. We proposed to make this policy budget neutral through an adjustment applied to the standardized amounts for all hospitals.

d. Additional Payment for Uncompensated Care to Medicare Disproportionate Share Hospitals (DSHs) and Supplemental Payment

In this proposed rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the 3 factors used to determine uncompensated care payments for FY 2026. Beginning with FY 2023, we adopted a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which would help to mitigate against large fluctuations in uncompensated care payments from year to year. Under this methodology, for FY 2025 and subsequent fiscal years, we would determine Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. We propose to use a 3-year average of audited data on uncompensated care costs from Worksheet S–10 from the FY 2020, FY 2021, and FY 2022 cost reports to calculate Factor 3 for FY 2026 for all eligible hospitals.

Beginning with FY 2023 (87 FR 49047 through 49051), we also established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico. In section V.D. of the preamble of this proposed rule, we summarize the ongoing methodology for supplemental payments.

e. Rural Community Hospital Demonstration Program

The Rural Community Hospital Demonstration (RCHD) was authorized originally for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and it was extended for another 5-year period by section 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Section 15003 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) extended the demonstration for an additional 5-year period, and section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–159) included an additional 5-year re-authorization. CMS has conducted the demonstration since 2004, which allows enhanced, cost-based payment for Medicare inpatient services for up to 30 small rural hospitals.

The authorizing legislation imposes a strict budget neutrality requirement. In this proposed rule, we summarize the status of the demonstration program, and the ongoing

methodologies for implementation and budget neutrality.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this proposed rule, we propose to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

3. Proposed Update to the LTCH PPS Payment Rates

The proposed update to the LTCH PPS standard Federal payment rate for FY 2026 is discussed in section IX.C. of the preamble of this proposed rule. For FY 2026, we are proposing to establish an annual market basket update to the LTCH PPS standard Federal payment rate to 2.6 percent (that is, the 3.4 percent proposed market basket increase with a proposed reduction of 0.8 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act would receive a proposed update of 0.6 percent for FY 2025, which reflects a 2.0 percentage point reduction for failure to submit quality data.

4. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality and links the quality data submission to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health care and link the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and in order to avoid a 2-percentage point reduction. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital VBP Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring HACs, linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring readmissions, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-exempt cancer hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs. However, there is no reduction in payment to a PCH that does not report data.

5. Other Proposed Provisions—Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this proposed rule, we discuss the alternative payment model called the Transforming Episode Accountability Model (TEAM), which will be tested under the authority at section 1115A of the Act. Section 1115A of the Act authorizes the testing of innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and CHIP beneficiaries while reducing program expenditures. The underlying issue addressed by TEAM is that under the traditional fee-for-service (FFS) payment system, Medicare makes separate payments to providers and suppliers for items and services furnished to a beneficiary over the course of an episode of care. Because providers and suppliers are paid for each individual item or service delivered, this may lead to care that is fragmented, unnecessary or duplicative, while making it challenging to invest in quality improvement or care coordination that would maximize patient benefit. We anticipate TEAM may reduce costs while maintaining or improving quality of care by bundling payment for items and services for a given episode and holding TEAM participants accountable for spending and quality performance, as well as by providing incentives to promote high quality and efficient care. Further, testing TEAM would allow us to learn more about the patterns of potentially inefficient utilization of health care services, as well as how to improve the beneficiary care experience during care transitions and incentivize quality improvements for common surgical episodes. This information could inform future Medicare payment policy and potentially establish the framework for managing clinical episodes as a standard practice in Traditional Medicare.

TEAM was finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986) and we indicated that we intended to go through future rulemaking to promulgate new policies before the model start date. The proposals contained within this proposed rule would address policy gaps, make technical or conforming updates, and establish new policies to ensure TEAM has sound and well developed technical, administrative, and operational policies before the model starts.

B. Overall Impact

We have examined the impacts of this proposed rule as required by Executive Order 12866, ''Regulatory Planning and Review''; Executive Order 13132, ''Federalism''; Executive Order 13563, ''Improving Regulation and Regulatory Review''; Executive Order 14192, '' Unleashing Prosperity Through Deregulation''; the Regulatory Flexibility Act (RFA) (Pub. L. 96–354); section 1102(b) of the Social Security Act; section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select those regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may: (1) have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise novel legal or policy issues arising out of legal mandates, or the President's priorities.

A regulatory impact analysis (RIA) must be prepared for a regulatory action that is significant under section 3(f)(1) of E.O. 12866. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1). We have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the

rulemaking. OMB has reviewed these regulations, and the Departments have provided the following assessment of their impact.

We estimate that the proposed changes for FY 2026 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $4.0 billion increase in FY 2026 payments, primarily driven by the changes in FY 2026 operating payments, including uncompensated care payments, FY 2026 capital payments, the expiration of the temporary changes in the low-volume hospital program and the expiration of the MDH program. These changes are relative to payments made in FY 2025. The impact analysis of the capital payments can be found in section I.I. of this Appendix. In addition, as described in section I.J. of this Appendix, LTCHs are expected to experience an increase in payments of approximately $61 million in FY 2026 relative to FY 2025.

Our operating payment impact estimate includes the proposed 2.4 percent applicable percentage increase to the standardized amount (reflecting the proposed 3.2 percent market basket increase reduced by the proposed 0.8 percentage point productivity adjustment). The estimates of IPPS operating payments to acute care hospitals generally do not reflect any changes in hospital admissions or real case-mix intensity, which would also affect overall payment changes.

The analysis in this Appendix, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This proposed rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this proposed rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this proposed rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2026, on various hospital groups. We estimate the effects of individual proposed policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally, unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific proposed policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related-costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 26 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2025, there were 3,038 IPPS acute care hospitals included in our analysis. This represents approximately 52 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,375 CAHs. These small, limited-service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed update and policy changes to the LTCH PPS for FY 2026 is discussed in section I.J. of this Appendix.

F. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs and Medicare Uncompensated Care Payments

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2026 for operating costs of acute care hospitals and for uncompensated care payments. The proposed FY 2026 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix. A more detailed analysis of the proposed updated to uncompensated care payments is discussed in section I.G.2 of this Appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2026 operating payments and uncompensated care payments, would increase by 3.4 percent, compared to FY 2025. The operating payment impacts generally do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the proposed changes on the operating and capital prospective payment systems. This section primarily deals with the proposed changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain proposed changes in this proposed rule. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of proposed changes in operating payments per case presented in this section are taken from the FY 2024 MedPAR file and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals. Our analysis has several qualifications. First, in this analysis, we do not generally adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2024 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals

and hospitals in Maryland were excluded from the simulations. The impact of proposed payments under the capital IPPS, and the impact of proposed payments other than inpatient operating payments and uncompensated care payments are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2026 are discussed in section I.I. of this Appendix.

We discuss the following proposed changes:

- The estimated effects of proposed outlier payments returning to their targeted levels in FY 2026 as compared to the estimated outlier payments for FY 2025 produced from our payment simulation model.
- The effects of the application of the proposed applicable percentage increase of 2.4 percent (that is, a proposed 3.2 percent market basket update with a reduction of 0.8 percentage point for the proposed productivity adjustment), and the proposed applicable percentage increase (including the proposed market basket update and the proposed productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to estimated uncompensated care payments in FY 2026 as compared to FY 2025.
- The effects of the expiration of the special payment status for MDHs beginning October 1, 2025 under current law.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed changes in hospitals' wage index values due to the effects of the proposed incorporation of updated wage data from hospitals' cost reporting periods, the proposed update to the labor and non-labor share percentages, and the proposed changes in wage index reclassifications.
- The total estimated change in payments based on the proposed FY 2026 policies relative to payments based on FY 2025 policies.

To illustrate the impact of the proposed FY 2026 changes, our analysis begins with a FY 2025 baseline simulation model using: the FY 2025 national adjusted operating standardized amount; the FY 2025 MS–DRG GROUPER (Version 42); the FY 2025 CBSA designations for hospitals based on the OMB definitions from the 2020 Census; the FY 2025 wage index, including the FY 2025 labor and nonlabor share percentages; FY 2025 uncompensated care payments; and FY 2025 outlier payments which reflects our estimate of 4.8 percent of total operating MS–DRG and outlier payments as produced by our payment simulation model based on FY 2024 MedPAR data.

Our comparison illustrates the proposed percent change in payments per case from FY 2025 to FY 2026. The update to the standardized amount is a significant factor in the percent change in payments per case. In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2026, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four proposed possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section VI.B. of the preamble of this proposed rule for a complete discussion of the FY 2026 inpatient hospital update, including the four proposed possible applicable percentage increases. For purposes of the simulations shown later in this section, we modeled the proposed payment changes for FY 2026 using a reduced update for hospitals that (1) failed to submit quality data but are meaningful EHR users; (2) are identified as not meaningful EHR users that do submit quality data; and (3) are identified as not meaningful EHR users that do not submit quality data. The reduced updates used for these hospitals are discussed in section VI.B. of the preamble of this proposed rule and these hospitals are identified in the impact file posted in conjunction with this proposed rule.

We note, section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act for hospitals that fail to submit quality data or are not a meaningful EHR users. Accordingly, the proposed applicable percentage increases to the hospital-specific rates applicable to SCHs (and MDHs, if the program is extended by subsequent legislation) for FY 2026 are the same as the four proposed applicable percentage increases discussed in section VI.B. of the preamble of this proposed rule.

2. Impact Analysis of Proposed Changes on Payments for IPPS Operating Costs and Uncompensated Care Payments

Table I displays the results of our analysis of the proposed changes for FY 2026 on payments for IPPS operating costs and uncompensated care payments. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2026 payment classifications, including any reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under section 1886(d)(8)(B) of the Act, also known as Lugar hospitals, and section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103).

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH payment purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs and RRCs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These data were taken from the most recent available Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2026 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act as implemented at 42 CFR 412.103. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act, also known as Lugar hospitals.

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES ON PAYMENTS FOR IPPS OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2026

	Number of hospitals [1]	Proposed FY 2026 outlier payments (1) [2]	Proposed FY 2026 hospital rate update (2) [3]	MDH expiration (3) [4]	Proposed FY 2026 uncompensated care payments (4) [5]	Proposed FY 2026 weights and DRG changes with application of recalibration budget neutrality (5) [6]	Proposed FY 2026 wage index (6) [7 8 9]	All proposed FY 2026 changes (7) [10]
All Hospitals	3,038	0.2	2.3	−0.1	1.3	0.0	−0.2	3.4
By Geographic Location:								
Urban hospitals	2,369	0.2	2.3	−0.1	1.3	0.0	−0.2	3.5
Rural hospitals	669	0.1	2.3	−0.6	1.0	−0.5	0.3	2.5
Bed Size (Urban):								
0–99 beds	643	0.1	2.3	−1.5	1.3	0.2	0.1	2.6
100–199 beds	675	0.1	2.3	−0.3	1.1	−0.3	−0.2	2.8
200–299 beds	405	0.2	2.3	0.0	1.3	−0.1	−0.3	3.3
300–499 beds	393	0.2	2.3	0.0	1.2	0.0	−0.3	3.4
500 or more beds	251	0.3	2.2	0.0	1.4	0.2	−0.2	4.0
Bed Size (Rural):								
0–49 beds	320	0.0	2.3	−1.3	1.6	−0.6	0.5	2.3
50–99 beds	182	0.0	2.3	−1.6	1.0	−0.7	−0.2	0.9
100–149 beds	94	0.0	2.3	−0.1	1.0	−0.7	0.3	2.9
150–199 beds	42	0.1	2.3	0.0	0.8	−0.4	0.5	3.3
200 or more beds	31	0.1	2.3	0.0	0.6	−0.1	0.7	3.7
Urban by Region:								
New England	104	0.2	2.3	−0.2	0.6	−0.1	−2.0	0.8
Middle Atlantic	274	0.3	2.3	−0.1	1.0	−0.1	−0.5	2.8
East North Central	366	0.2	2.3	−0.3	0.7	0.0	−0.5	2.4
West North Central	156	0.2	2.3	0.0	0.7	0.2	1.7	5.1
South Atlantic	393	0.2	2.2	−0.1	1.7	0.0	−0.5	3.7
East South Central	142	0.2	2.3	0.0	1.8	0.1	1.0	5.3
West South Central	352	0.2	2.1	−0.1	3.4	0.1	0.5	6.3
Mountain	180	0.2	2.3	0.0	1.1	0.2	0.0	3.8
Pacific	351	0.3	2.3	0.0	0.6	0.1	−0.4	2.9
Rural by Region:								
New England	19	0.2	2.4	−1.5	0.3	−0.2	0.7	1.8
Middle Atlantic	50	0.1	2.4	−0.2	0.5	−0.5	0.0	2.2
East North Central	107	0.0	2.3	−1.5	0.7	−0.5	−0.4	0.6
West North Central	74	0.1	2.4	−0.4	0.3	−0.5	0.9	2.8
South Atlantic	108	0.0	2.2	−0.8	1.8	−0.6	0.3	3.0
East South Central	128	0.0	2.3	−0.4	1.5	−0.6	0.9	3.7
West South Central	118	0.1	2.2	−0.2	2.0	−0.5	0.4	4.0
Mountain	41	0.0	2.4	0.0	0.4	−0.2	0.5	3.1
Pacific	24	0.0	2.4	0.0	0.2	−0.8	−0.3	1.6
Puerto Rico:								
Puerto Rico Hospitals	51	0.1	1.6	0.0	8.5	0.0	−0.9	9.4
By Payment Classification:								
Urban hospitals	1,609	0.2	2.3	0.0	1.5	−0.1	−0.1	3.8
Rural areas	1,429	0.2	2.3	−0.2	1.1	0.0	−0.3	3.2
Teaching Status:								
Nonteaching	1,765	0.1	2.3	−0.4	1.2	−0.2	−0.1	3.0
Fewer than 100 residents	980	0.2	2.3	−0.1	1.1	0.0	−0.1	3.3
100 or more residents	293	0.4	2.2	0.0	1.5	0.1	−0.4	3.8
Urban DSH:								
Non-DSH	334	0.1	2.4	−0.1	0.0	0.3	−0.2	2.6
100 or more beds	916	0.2	2.3	0.0	1.6	−0.1	−0.1	3.9
Less than 100 beds	359	0.1	2.2	−0.3	2.2	−0.5	0.2	3.9
Rural DSH:								
Non-DSH	91	0.2	2.4	−1.7	0.0	0.2	−1.2	−0.3
SCH	231	0.0	2.3	0.0	0.6	−0.6	0.0	2.4
RRC	858	0.3	2.3	−0.1	1.1	0.1	−0.3	3.4
100 or more beds	45	0.2	2.2	−0.5	3.2	0.0	0.2	5.2
Less than 100 beds	204	0.1	2.2	−4.3	2.2	−0.6	0.7	−0.1
Urban teaching and DSH:								
Both teaching and DSH	531	0.2	2.3	0.0	1.7	−0.1	0.0	4.1
Teaching and no DSH	54	0.1	2.4	−0.3	0.0	0.0	−0.3	1.9
No teaching and DSH	744	0.2	2.3	0.0	1.5	−0.2	−0.2	3.5
No teaching and no DSH	280	0.1	2.4	0.0	0.0	0.6	−0.1	3.1
Special Hospital Types:								
RRC	132	0.1	2.3	−0.5	1.3	−0.3	0.2	3.1
RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	649	0.3	2.3	−0.1	1.2	0.1	−0.4	3.3
SCH	225	0.0	2.3	0.0	0.8	−0.6	0.0	2.5
SCH that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	38	0.0	2.4	0.0	0.1	−0.4	0.0	2.1
SCH and RRC	116	0.1	2.4	0.0	0.4	−0.4	0.3	2.7

TABLE I—IMPACT ANALYSIS OF PROPOSED CHANGES ON PAYMENTS FOR IPPS OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2026—Continued

	Number of hospitals [1]	Proposed FY 2026 outlier payments (1) [2]	Proposed FY 2026 hospital rate update (2) [3]	MDH expiration (3) [4]	Proposed FY 2026 uncompensated care payments (4) [5]	Proposed FY 2026 weights and DRG changes with application of recalibration budget neutrality (5) [6]	Proposed FY 2026 wage index (6) [7 8 9]	All proposed FY 2026 changes (7) [10]
SCH and RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	50	0.0	2.4	0.0	0.2	0.0	0.4	3.0
Type of Ownership:								
Voluntary	1,903	0.2	2.3	−0.2	0.9	0.0	−0.2	3.1
Proprietary	723	0.1	2.3	−0.1	1.4	0.0	−0.4	3.4
Government	412	0.3	2.1	−0.1	3.0	0.0	0.0	5.5
Medicare Utilization as a Percent of Inpatient Days:								
0–25	1,543	0.3	2.2	0.0	1.8	0.0	0.0	4.4
25–50	1,400	0.2	2.4	−0.3	0.6	−0.1	−0.5	2.3
50–65	65	0.1	2.4	−0.4	0.2	0.3	−0.8	1.9
Over 65	14	0.3	2.5	−0.6	0.0	3.1	0.7	6.0
Medicaid Utilization as a Percent of Inpatient Days:								
0–25	1,861	0.2	2.3	−0.2	0.9	0.0	−0.2	3.0
25–50	1,052	0.3	2.3	0.0	1.4	0.0	−0.2	3.7
50–65	93	0.3	2.0	0.0	5.6	−0.4	−0.5	6.9
Over 65	31	0.1	1.6	0.0	14.3	−0.4	−0.2	15.5
FY 2026 Reclassifications:								
All Reclassified Hospitals	1,172	0.2	2.3	−0.2	1.1	0.0	−0.3	3.3
Non-Reclassified Hospitals	1,866	0.2	2.3	−0.1	1.5	−0.1	−0.1	3.7
Urban Hospitals Reclassified	1,011	0.3	2.3	−0.1	1.2	0.1	−0.3	3.4
Urban Non-reclassified Hospitals	1,371	0.2	2.3	0.0	1.5	−0.1	−0.1	3.7
Rural Hospitals Reclassified Full Year	280	0.0	2.3	−0.4	0.9	−0.5	0.4	2.8
Rural Non-reclassified Hospitals Full Year	376	0.1	2.3	−0.8	1.1	−0.5	0.3	2.4
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	812	0.3	2.3	−0.2	1.2	0.1	−0.3	3.3
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	52	0.1	2.3	−2.3	1.1	−0.6	0.3	0.7

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2024, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the effects of estimated outlier payments returning to their targeted levels in FY 2026 as compared to the estimated outlier payments for FY 2025.

[3] This column displays the payment impact of the hospital rate update, including the proposed 2.4 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.2 percent IPPS market basket rate-of-increase reduced by the proposed 0.8 percentage point for the productivity adjustment).

[4] This column displays the impact of the expiration of the MDH status on October 1, 2025, a non-budget neutral payment provision.

[5] This column displays the effects of the proposed changes to estimated uncompensated care payments in FY 2026 as compared to FY 2025. See also the table in section I.G.2 of this Appendix.

[6] This column displays the payment impact of proposed Version 43 GROUPER, the proposed changes to the relative weights and the proposed recalibration of the MS–DRG weights based on FY 2024 MedPAR data, and the 10-percent cap where the relative weight for a MS–DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the proposed recalibration budget neutrality factor and the proposed 10-percent cap budget neutrality factor (which can be found in section II.A.4 of the Addendum of this proposed rule).

[7] This column displays the effects of the changes to the proposed FY 2026 wage index. This includes (1) the proposed update to wage index data using FY 2022 cost report data, the application of the proposed wage budget neutrality factor and the proposed update to the labor and nonlabor shares. (2) The effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB), showing the payment impact of going from FY 2025 reclassifications to the reclassifications scheduled to be in effect for FY 2026. (3) The effects of the application of the proposed rural floor. (4) The effects of urban to rural reclassifications under section 1886(d)(8) of the Act on the proposed wage index. (5) The effects of the application of ''LUGAR'' status under section 1886(d)(10) of the Act on the proposed wage index. (6) The proposed adjustments to the wage index driven by non-budget neutral policies. These include (a) the imputed floor for all-urban states; (b) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (c) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. The budget neutrality factors for the effects that are budget neutral can be found in section II.A.4 of the Addendum of this proposed rule.

[8] For the traditional wage index information showing the effect of including or excluding particular wage index polices from the computation of the FY 2026 wage index instead of the impact of the wage index changes from FY 2025 to FY 2026 shown in Table I, we refer readers to the data file available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed Rule Home Page''.)

[9] We note that because the low wage index hospital policy was removed for FY 2025, the proposed discontinuation of the policy effective FY 2026 has no impact on the estimated change in proposed payments from FY 2025 to FY 2026. However, the proposed budget neutral transition for the discontinuation of the low wage index hospital policy will redistribute payments from hospitals that do not benefit from the proposed transition to hospitals that do benefit (primarily all the hospitals located in Puerto Rico) due to the associated budget neutrality factor. The budget neutrality factor for the proposed transition can be found in section II.A.4 of the Addendum of this proposed rule.

[10] This column shows the estimated change in proposed payments from FY 2025 to FY 2026.

a. Effects of the Outlier Adjustment (Column 1)

This column reflects the effect of estimated outlier payments returning to their targeted levels in FY 2026 as compared to the estimated outlier payments for FY 2025 produced from our payment simulation model. As discussed in section II.A.4.i. of the Addendum to this proposed rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2025. Therefore, our proposed estimate of payments per discharge for FY 2026 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2025 were less than that target by approximately 0.3 percentage point.

Overall, hospitals would experience a 0.2 percent increase in payments primarily due to the estimated 0.3 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2026 in combination with interactive effects among the various add-on payment factors.

b. Effects of the Proposed Hospital Update (Column 2)

As discussed in section VI.B. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.2 percent IPPS market basket rate-of-increase reduced by 0.8 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.4 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.2 percent market basket rate-of-increase reduced by 0.8 percentage point for the proposed productivity adjustment. As a result, we are proposing to make a 2.4 percent update to the hospital-specific rates. This column also includes any applicable adjustments for hospitals that fail to comply with the quality data submission requirements and/or are not meaningful EHR users.

Overall, hospitals would experience a 2.3 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rates.

c. Effects of the Expiration of MDH Special Payment Status (Column 3)

Column 3 shows our estimate of the changes in payments due to the expiration of MDH status, a nonbudget neutral payment provision. Section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 further extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. Hospitals that qualify to be MDHs receive the higher of payments made based on the Federal rate or the payments made based on the Federal rate amount plus 75 percent of the difference between payments based on the Federal rate and payments based on the hospital-specific rate (a hospital-specific cost-based rate). Because this provision is not budget neutral, the expiration of this payment provision is estimated to result in a 0.1 percent decrease in IPPS payments overall. There are currently 164 MDHs, of which we estimate 84 would be paid under the blended payment of the Federal rate and hospital-specific rate if the MDH program were not set to expire. Because those 84 MDHs will no longer receive the blended payment and will be paid only under the Federal rate for FY 2026, it is estimated that those hospitals would experience an overall decrease in payments of approximately $154 million (relative to the MDH program payments they received for FY 2025 discharges).

d. Effects of the Proposed Changes in Uncompensated Care Payments (UCP) (Column 4)

Column 4 shows the effects of the proposed changes in uncompensated care payments made to hospitals in FY 2026. As discussed in section IV.E. of the preamble of this proposed rule, the total proposed UCP and proposed supplemental payments equal approximately $7.3 billion. Overall, hospitals would experience a 2.9 percent increase in total operating IPPS payments due to the proposed change in uncompensated care payments. For a more detailed impact analysis of the proposed changes to uncompensated care payment, we refer readers to section I.G.2 of appendix A to this proposed rule.

e. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights with Recalibration Budget Neutrality (Column 5)

Column 5 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a proposed recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.D. of the preamble of this proposed rule, for FY 2026, we calculated the proposed MS–DRG relative weights using the FY 2024 MedPAR data grouped to the proposed Version 43 (FY 2026) MS–DRGs. The proposed reclassification changes to the GROUPER are described in more detail in section II.C. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 5 indicates that changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor (discussed in section II.A.4.a. of the Addendum to this proposed rule) and the recalibration cap budget neutrality factor to the standardized amount (discussed in section II.A.4.b. of the Addendum to this proposed rule).

f. Effects of the Proposed Wage Index Changes (Column 6)

Column 6 shows the impact of the proposed changes to hospitals' FY 2026 wage index as compared to hospitals' FY 2025 wage index. Overall, the FY 2026 wage index changes would lead to a 0.2 percent decrease for all hospitals, as shown in Column 6. This change is a result of the proposed updates to the wage data reported by hospitals, the proposed change to the labor and nonlabor shares, changes in the geographic reclassifications of hospitals, and the interactions of those changes with statutory wage index floors and exceptions. We combine these changes because the complex and interactive ways in which hospitals increasingly seek to maximize their wage index values in a given year render isolation of these effects in a year-over-year context less informative. For example, the impact of the proposed updates to the wage data reported by hospitals in the absence of the changes in geographic reclassification and especially the interaction of both of those with statutory wage index floors and exceptions is less meaningful than showing the combined effect of those factors. For the traditional wage index information showing the effect of including or excluding particular wage index polices from the computation of the FY 2026 wage index instead of the impact of the wage index changes from FY 2025 to FY 2026 shown in Table I, we refer readers to the data file available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* (click on the link on the left side of the screen titled ''FY 2026 IPPS Proposed Rule Home Page'').

Specifically, this column in Table I shows the combined effects of the application of the following proposed FY 2026 wage index changes relative to FY 2025:

(1) Effects of the Proposed Changes to the Wage Data

Column 6 reflects the effects of the proposed updated wage data and the proposed labor and non-labor shares, with the application of the proposed wage index budget neutrality factor for FY 2026 relative to FY 2025.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the proposed wage index for acute care hospitals for FY 2026 is based on data submitted for hospital cost reporting periods, beginning on or after October 1,

2021, and before October 1, 2022. Column 6 reflects the proposed percentage change in payments when going from a model using the FY 2025 wage index based on FY 2025 reclassifications and the FY 2025 labor-related share of 67.6 percent, to a model using the proposed FY 2026 wage index based on FY 2026 reclassifications (as described in further detail in the next section) and the proposed labor-related share of 66.0 percent, while holding other payment parameters, such as use of the proposed Version 43 MS–DRG GROUPER, constant.

In addition, the column incorporates the application of the proposed wage budget neutrality to the national standardized amount. As discussed in section II.A.4.c. of the Addendum to this proposed rule, for FY 2026 we calculated the proposed wage budget neutrality factor to ensure that payments under the proposed updated wage data and the proposed labor-related share of 66.0 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. This proposed budget neutrality factor can be found in the summary table of the proposed FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

(2) Effects of MGCRB, Urban to Rural and ''Lugar'' Reclassifications

Column 6 reflects the impact of MGCRB reclassification decisions under section 1886(d)(10) of the Act, urban to rural reclassifications under section 1886(d)(8)(E) of the Act, and Lugar status redesignations under section 1886(d)(8)(B) of the Act on the proposed wage index for FY 2026 relative to FY 2025. The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, as discussed in section II.A.4.d. of the Addendum to this proposed rule, we apply a proposed reclassification budget neutrality adjustment to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral. This proposed budget neutrality factor can be found in the summary table of the proposed FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

Table 2 listed in section VI. of the Addendum to this proposed rule and available on the CMS website reflects the reclassifications for FY 2026 at the time of development of this proposed rule. For further information on MGCRB reclassifications, urban to rural reclassifications and Lugar status redesignations, we refer readers to section III. of the preamble of this proposed rule.

(3) The Effects of the Proposed Rural Floor, Including Proposed Budget Neutrality Adjustment

Column 6 reflects the effects of the application of the proposed rural floor and the application of the proposed rural floor budget neutrality on the proposed wage index for FY 2026 relative to FY 2025. As discussed in section III.F.1. of the preamble of this proposed rule, section 4410 of Public Law 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index as discussed in section II.A.4.e. of the Addendum to this proposed rule. All IPPS hospitals in our model have their wage indexes reduced by the proposed rural floor budget neutrality adjustment. This proposed budget neutrality factor can be found in the summary table of the proposed FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this proposed rule.

(4) Effects of the Application of the Proposed Imputed Floor, Proposed Frontier State Wage Index and Proposed Out-Migration Adjustment

Lastly, this column also reflects the combined effects of the application of the following non-budget neutral provisions for FY 2026 relative to FY 2025: (a) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act for certain all-urban States (as discussed in section III.F.2. of the preamble of this proposed rule); (b) the minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States'' as required by section 1886(d)(3)(E)(iii) Act (as discussed in section III.F.3. of the preamble of this proposed rule); and (c) the effects of the proposed out- migration adjustment under section 1886(d)(13) of the Act (as discussed in section III.F.4. of the preamble of this proposed rule).

g. Effects of All Proposed FY 2026 Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2025 and FY 2026, resulting from all proposed changes for FY 2026 included in Table I. It includes the combined effects of the year-over-year change of the factors described in the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 3.4 percent for FY 2026 relative to FY 2025, which is primarily driven by the proposed changes reflected in Column 2 (proposed hospital update) and Column 4 (proposed uncompensated care payments). As described in Column 2, the proposed annual hospital update for hospitals paid under the national standardized amount, combined with the proposed annual hospital update for hospitals paid under the hospital-specific rates would result in a 2.3 percent increase in payments in FY 2026 relative to FY 2025 for all hospitals. As described in Column 4, proposed uncompensated care payments would result in a 1.3 percent increase in payments in FY 2026 relative to FY 2025 for all hospitals.

Overall payments to hospitals paid under the IPPS are estimated to increase by 3.4 percent for FY 2026 (as compared to FY 2025) due to the proposed outlier adjustment, the proposed applicable percentage increase, the MDH program expiration, proposed uncompensated care payments, and proposed changes to the wage index and labor and nonlabor shares. Hospitals in urban areas would experience a 3.5 percent increase in payments per discharge in FY 2026 compared to FY 2025. Hospital payments per discharge in rural areas are estimated to increase by 2.5 percent in FY 2026. The relatively lower projected increase for rural hospitals is due in part to the MDH program expiration (Column 3) and the proposed MS–DRG and relative weight changes with application budget neutrality (Column 5). Hospital categories that generally treat relatively less complex cases, such as rural hospitals and smaller urban hospitals, would experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, would experience an increase in their payments as a result of the proposed changes to the relative weights.

3. Estimated Average Payments per Discharge

Table II displays the results of our analysis of the proposed changes for FY 2026 on estimated average payments per discharge for IPPS operating costs and uncompensated care payments. It presents the impact for the categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2025 with the estimated average payments per discharge for FY 2026, as calculated under our models. It reflects the combined effects of the proposed changes presented in Table I, and therefore the estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES ON AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND UNCOMPENSATED CARE

	Number of hospitals	Estimated average FY 2025 payment per discharge	Estimated proposed average FY 2026 payment per discharge	Proposed FY 2026 changes
	(1)	(2)	(3)	(4)
All Hospitals	3,038	17,753	18,363	3.4
By Geographic Location:				
Urban hospitals	2,369	18,187	18,823	3.5

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES ON AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND UNCOMPENSATED CARE—Continued

	Number of hospitals	Estimated average FY 2025 payment per discharge	Estimated proposed average FY 2026 payment per discharge	Proposed FY 2026 changes
	(1)	(2)	(3)	(4)
Rural hospitals	669	12,917	13,242	2.5
Bed Size (Urban):				
0–99 beds	643	12,977	13,308	2.6
100–199 beds	675	14,306	14,705	2.8
200–299 beds	405	16,072	16,600	3.3
300–499 beds	393	17,879	18,487	3.4
500 or more beds	251	22,854	23,773	4.0
Bed Size (Rural):				
0–49 beds	320	11,003	11,261	2.3
50–99 beds	182	12,337	12,445	0.9
100–149 beds	94	12,224	12,576	2.9
150–199 beds	42	14,051	14,516	3.3
200 or more beds	31	15,704	16,286	3.7
Urban by Region:				
New England	104	19,636	19,789	0.8
Middle Atlantic	274	21,085	21,675	2.8
East North Central	366	17,224	17,635	2.4
West North Central	156	16,872	17,739	5.1
South Atlantic	393	16,123	16,717	3.7
East South Central	142	14,930	15,720	5.3
West South Central	352	16,821	17,885	6.3
Mountain	180	17,653	18,323	3.8
Pacific	351	22,173	22,825	2.9
Rural by Region:				
New England	19	17,831	18,143	1.8
Middle Atlantic	50	14,462	14,779	2.2
East North Central	107	12,596	12,677	0.6
West North Central	74	12,852	13,217	2.8
South Atlantic	108	12,206	12,569	3.0
East South Central	128	11,257	11,677	3.7
West South Central	118	10,991	11,429	4.0
Mountain	41	14,755	15,218	3.1
Pacific	24	17,321	17,590	1.6
Puerto Rico:				
Puerto Rico Hospitals	51	13,794	15,090	9.4
By Payment Classification:				
Urban hospitals	1,609	15,986	16,586	3.8
Rural areas	1,429	19,124	19,741	3.2
Teaching Status:				
Nonteaching	1,765	13,346	13,743	3.0
Fewer than 100 residents	980	15,884	16,414	3.3
100 or more residents	293	26,583	27,602	3.8
Urban DSH:				
Non-DSH	334	13,068	13,414	2.6
100 or more beds	916	16,797	17,451	3.9
Less than 100 beds	359	12,320	12,807	3.9
Rural DSH:				
Non-DSH	91	16,332	16,290	−0.3
SCH	231	13,850	14,184	2.4
RRC	858	19,834	20,500	3.4
100 or more beds	45	17,594	18,516	5.2
Less than 100 beds	204	10,660	10,651	−0.1
Urban teaching and DSH:				
Both teaching and DSH	531	18,345	19,097	4.1
Teaching and no DSH	54	14,438	14,715	1.9
No teaching and DSH	744	13,810	14,296	3.5
No teaching and no DSH	280	12,293	12,678	3.1
Special Hospital Types:				
RRC	132	13,389	13,798	3.1
RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	649	20,533	21,220	3.3
SCH	225	13,180	13,515	2.5
SCH that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	38	15,661	15,992	2.1
SCH and RRC	116	14,381	14,774	2.7
SCH and RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	50	17,935	18,465	3.0
Type of Ownership:				
Voluntary	1,903	17,558	18,095	3.1
Proprietary	723	15,747	16,281	3.4
Government	412	21,557	22,738	5.5
Medicare Utilization as a Percent of Inpatient Days:				
0–25	1,543	19,747	20,613	4.4
25–50	1,400	15,837	16,200	2.3

TABLE II—IMPACT ANALYSIS OF PROPOSED CHANGES ON AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND UNCOMPENSATED CARE—Continued

	Number of hospitals (1)	Estimated average FY 2025 payment per discharge (2)	Estimated proposed average FY 2026 payment per discharge (3)	Proposed FY 2026 changes (4)
50–65	65	15,213	15,495	1.9
Over 65	14	12,428	13,179	6.0
Medicaid Utilization as a Percent of Inpatient Days:				
0–25	1,861	15,631	16,098	3.0
25–50	1,052	20,518	21,274	3.7
50–65	93	28,086	30,036	6.9
Over 65	31	29,824	34,440	15.5
FY 2026 Reclassifications:				
All Reclassified Hospitals	1,172	19,236	19,865	3.3
Non-Reclassified Hospitals	1,866	15,782	16,366	3.7
Urban Hospitals Reclassified	1,011	19,610	20,268	3.4
Urban Non-reclassified Hospitals	1,371	15,977	16,572	3.7
Rural Hospitals Reclassified Full Year	280	13,084	13,450	2.8
Rural Non-reclassified Hospitals Full Year	376	12,666	12,969	2.4
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	812	20,082	20,741	3.3
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	52	12,131	12,221	0.7

G. Effects of Other Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.D. of this Appendix, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other proposed changes are discussed in this section.

1. Effects of the Proposed Changes Relating to New Medical Service and Technology Add-On Payments

a. Proposed FY 2026 Status of Technologies Approved for FY 2025 New Technology Add-On Payments

In section II.E.4. of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for the technologies listed in the following table in FY 2026 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway, or for the gene therapies, Casgevy™ (exagamglogene autotemcel) and Lyfgenia™ (lovotibeglogene autotemcel), when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs; for technologies approved under the LPAD pathway; or for the gene therapies, Casgevy™ and Lyfgenia™, when indicated and used specifically for the treatment of SCD, which were approved for new technology add-on payments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69128 through 69135, and 89 FR 69188 through 69196)). Because it is difficult to predict the actual new technology add-on payment for each case, our estimates in this proposed rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2026 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table are estimates for the 26 new technology add-on payments which we are proposing to continue in FY 2026:

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS PROPOSED TO CONTINUE FOR FY 2026

Technology name	Estimated cases	Proposed FY 2026 NTAP amount (65% or 75%)	Estimated total FY 2026 impact
1. CYTALUX® (pafolacianine) (lung indication)	300	$2,762.50	$828,750.00
2. EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm) *	157	6,504.07	1,021,138.99
3. Aveir™ AR Leadless Pacemaker	245	10,725.00	2,627,625.00
4. Aveir™ Dual-Chamber Leadless Pacemaker	2,250	15,600.00	35,100,000.00
5. Ceribell Status Epilepticus Monitor	2,477	913.90	2,263,730.30
6. DETOUR System	600	16,250.00	9,750,000.00
7. DefenCath™ (taurolidine/heparin)	12,000	3,656.10	43,873,200.00
8. Phagenyx® System	294	3,250.00	955,500.00
9. REZZAYO™ (rezafungin for injection)	795	4,387.50	3,488,062.50
10. TOPS™ System	1,200	11,375.00	13,650,000.00
11. XACDURO® (sulbactam/durlobactam)	654	13,680.00	8,946,720.00
12. Annalise Enterprise CTB Triage—OH	271,200	241.39	65,464,968.00

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS PROPOSED TO CONTINUE FOR FY 2026—Continued

Technology name	Estimated cases	Proposed FY 2026 NTAP amount (65% or 75%)	Estimated total FY 2026 impact
13. ASTar® System	69,000	97.50	6,727,500.00
14. Edwards EVOQUE™ Tricuspid Valve Replacement System	800	31,850.00	25,480,000.00
15. GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)	518	47,238.75	24,469,672.50
16. LimFlow™ System	561	16,250.00	9,116,250.00
17. Paradise™ Ultrasound Renal Denervation System	200	14,950.00	2,990,000.00
18. PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter	3,402	6,337.50	21,560,175.00
19. Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter	55	10,400.00	572,000.00
20. TriClip™ G4	150	26,000.00	3,900,000.00
21. VADER® Pedicle System	200	28,242.50	5,648,500.00
22. ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications	245	2,812.50	689,062.50
23. ZEVTERA™ (ceftobiprole medocaril); SAB indication	571	8,625.00	4,924,875.00
24. CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication	117	1,650,000.00	193,050,000.00
25. HEPZATO™ KIT (melphalan for injection/hepatic delivery system)	149	118,625.00	17,675,125.00
26. LYFGENIA™ (lovotibeglogene autotemcel))	40	2,325,000.00	93,000,000.00
Aggregate Estimated Total FY 2026 Impact	.....	.....	597,772,854.79

*These two technologies were determined to be substantially similar to each other and were therefore evaluated as one application for new technology add-on payments under the IPPS.

b. Proposed FY 2026 Applications for New Technology Add-On Payments

In sections II.E.5. and 6. of the preamble to this proposed rule are 43 discussions of technologies with respect to add-on payments for new medical services and technologies for FY 2026. We note that of the 53 applications (34 alternative and 19 traditional) we received, 3 applications were not eligible for consideration for new technology add-on payment (1 alternative and 2 traditional), and 7 applicants withdrew their application (4 alternative and 3 traditional) prior to the issuance of this proposed rule. As explained in the preamble to this proposed rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral. As discussed in section II.E.6. of the preamble of this proposed rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are designated under the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2- to 3-year newness period, as discussed in section II.E.1.a.(1). of the preamble this proposed rule, and must also still meet the cost criterion.

As also discussed in section II.E.6. of the preamble of this proposed rule, we are proposing to approve 28 new technology add-on payments for the alternative pathway applications submitted for FY 2026 new technology add-on payments.

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the 28 technologies that applied under the alternative pathway, if approved, would be approximately $405.5 million for FY 2026. Total estimated FY 2026 payments for new technologies that are designated as a QIDP are approximately $5.0 million, and the total estimated FY 2026 payments for new technologies that are part of the Breakthrough Device program are approximately $400.5 million. Because cost or volume information has not yet been provided for 5 of the 28 technologies under the alternative pathway, we have not included those technologies in the estimate. We did not receive any LPAD applications for add-on payments for new technologies for FY 2026. We note that the estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the technologies discussed in section II.E.5. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2026 under the traditional pathway. Consequently, it is challenging to estimate the potential payment impact of these technologies for any potential new technology add-on payments for FY 2026. We note that, as in past years, if any of the technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2026, we would discuss the estimated payment impact for FY 2026 in the FY 2026 IPPS/LTCH PPS final rule.

2. Medicare DSH Uncompensated Care Payments and Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section V.E. of the preamble of this proposed rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has reported uncompensated care. Each hospital that is eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments (UCP) to DSH-eligible hospitals for FY 2026, which is $7,190,037,075.00. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 60.71 percent. For FY 2025, the amount available to be distributed for uncompensated care was $5,705,743,275.00 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 54.29 percent. In addition, eligible IHS/Tribal hospitals and hospitals located in Puerto Rico are estimated to receive approximately $100,623,613.55 million in supplemental payments in FY 2026, as determined based on the difference between each hospital's FY 2022 UCP (increased by 26.01 percent, which is the projected change between the FY 2026 total uncompensated care payment amount and the total uncompensated care payment amount for FY 2025) and its FY 2026 UCP as calculated using the methodology for FY

2026. If this difference is less than or equal to zero, the hospital will not receive a supplemental payment. For this proposed rule, the total proposed UCP and proposed supplemental payments equal approximately $7.291 billion. For FY 2026, we are proposing to use 3 years of data on uncompensated care costs from Worksheet S–10 of the FYs 2020, 2021, and 2022 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the methodology for calculating Factor 3 for FY 2026, we refer readers to section V.E. of the preamble of this proposed rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section V.D. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare UCP along with changes to supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico, we compared total UCP and supplemental payments estimated in the FY 2025 IPPS/LTCH PPS final rule correction notice (89 FR 68986) to the combined total of the proposed UCP and the proposed supplemental payments estimated in this FY 2026 IPPS/LTCH PPS proposed rule. For FY 2025, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 54.29 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2025 IPPS/LTCH PPS final rule. For FY 2026, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2025 absent section 3133 of the Affordable Care Act, adjusted by a proposed Factor 2 of 60.71 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this proposed rule, the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals are calculated as the difference between the hospital's adjusted base year amount (as determined based on the hospital's FY 2022 uncompensated care payment) and the hospital's FY 2026 uncompensated care payment.

Our analysis included 2,385 hospitals that are projected to be DSH-eligible in FY 2026. Our analysis did not include hospitals that had terminated their participation in the Medicare program as of January 22, 2025, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 16 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the proposed changes in Factors 1, 2, and 3 on UCP and supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be DSH-eligible in FY 2026, by hospital characteristic, is presented in the following table:

MODELED UNCOMPENSATED CARE PAYMENTS * AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2026 DSHS BY HOSPITAL TYPE

	Number of estimated DSHs	FY 2025 final rule estimated uncompensated care payments and supplemental payments ($ in millions)	FY 2026 proposed uncompensated care payments and supplemental payments ** ($ in millions)	Dollar difference: FY 2025–FY 2026 ($ in millions)	Percent change ***
	(1)	(2)	(3)	(4)	(5)
Total	2,385	$5,786	$7,291	$1,505	26.0%
By Geographic Location:					
Urban Hospitals	1,911	5,456	6,882	1,426	26.1
Other Urban Areas	993	2,433	3,042	609	25.0
Large Urban Areas	918	3,023	3,840	817	27.0
Rural Hospitals	474	328	409	81	24.7
Bed Size (Urban):					
0 to 99 Beds	373	242	292	50	20.6
100 to 249 Beds	778	1,200	1,494	294	24.5
250+ Beds	760	4,014	5,096	1,082	26.9
Bed Size (Rural):					
0 to 99 Beds	360	177	223	46	26.0
100 to 249 Beds	105	120	151	31	25.5
250+ Beds	9	30	35	4	14.1
Urban by Region:					
New England	85	145	189	43	29.9
Middle Atlantic	220	618	804	187	30.2
South Atlantic	304	576	685	109	18.9
East North Central	106	289	340	52	17.9
East South Central	320	1,406	1,772	366	26.1
West North Central	129	348	438	90	25.8
West South Central	248	1,248	1,616	368	29.5
Mountain	147	245	323	78	31.8
Pacific	308	508	622	114	22.4
Puerto Rico	44	72	91	19	26.0
Rural by Region:					
New England	9	9	11	2	19.8
Middle Atlantic	36	17	23	6	34.1
South Atlantic	70	42	50	8	18.2
East North Central	32	18	24	6	29.8
East South Central	83	95	115	21	22.0
West North Central	108	61	79	18	29.3
West South Central	105	70	86	16	23.4
Mountain	23	10	14	4	38.3

MODELED UNCOMPENSATED CARE PAYMENTS * AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2026 DSHS BY HOSPITAL TYPE—Continued

	Number of estimated DSHs	FY 2025 final rule estimated uncompensated care payments and supplemental payments ($ in millions)	FY 2026 proposed uncompensated care payments and supplemental payments ** ($ in millions)	Dollar difference: FY 2025–FY 2026 ($ in millions)	Percent change ***
	(1)	(2)	(3)	(4)	(5)
Pacific	8	6	7	1	25.8
By Payment Classification:					
Urban Hospitals	1,248	2,625	3,294	668	25.5
Large Urban Areas	661	1,577	1,981	404	25.6
Other Urban Areas	587	1,048	1,313	265	25.3
Rural Hospitals	1,137	3,158	3,997	838	26.5
Teaching Status:					
Nonteaching	1,266	1,420	1,757	337	23.7
Fewer than 100 residents	829	2,070	2,569	499	24.0
100 or more residents	290	2,293	2,965	671	29.3
Type of Ownership:					
Voluntary	1,524	3,345	4,154	809	24.2
Proprietary	497	811	1,015	203	25.0
Government	364	1,628	2,122	495	30.5
Medicare Utilization Percent ****:					
0 to 25	1,384	4,456	5,640	1,184	26.6
25 to 50	975	1,319	1,640	321	24.3
50 to 65	24	9	11	2	23.7
Greater than 65	2	0	0	0	-100.0
Medicaid Utilization Percent ****:					
0 to 25	1,282	2,237	2,783	546	24.4
25 to 50	978	2,861	3,596	735	25.7
50 to 65	95	553	723	170	30.8
Greater than 65	30	134	189	55	41.2

Source: Dobson | DaVanzo analysis of 2020, 2021 and 2022 Hospital Cost Reports.

* Dollar UCP calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, UCP and supplemental payments are estimated to be $5.786 million in FY 2025, and UCP and supplemental payments are estimated to be $ 7,291 million in FY 2026.

** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.

*** Percentage change is determined as the difference between Medicare UCP and supplemental payments modeled for this FY 2026 IPPS/LTCH PPS proposed rule (column 3) and Medicare UCP and supplemental payments modeled for the FY 2025 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare UCP and supplemental payments modeled for the FY 2025 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

**** Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

The changes in projected FY 2026 UCP and supplemental payments compared to the total of UCP and supplemental payments in FY 2025 are driven by increases in Factor 1 and Factor 2. The proposed Factor 1 has increased from the FY 2025 final rule's Factor 1 of $10.509 billion to this proposed rule's Factor 1 of $11.843 billion. The proposed Factor 2 has increased from FY 2025 final rule's Factor 2 of 54.29 percent to this proposed rule's Factor 2 of 60.71 percent. In addition, we note that there is a decrease in the number of projected DSH-eligible hospitals to 2,385 at the time of the development of this proposed rule compared to the 2,398 DSHs in the FY 2025 IPPS/LTCH PPS final rule (88 FR 58640). Based on the changes, the impact analysis found that, across all projected DSH-eligible hospitals, proposed FY 2026 UCP and supplemental payments are estimated at approximately $7.291 billion, or an increase of approximately 26.01 percent from FY 2025 UCP and supplemental payments (approximately $5.786 billion). While the changes would result in a net increase in the total amount available to be distributed in UCP and supplemental payments, the projected payment increases vary by hospital type. This redistribution of proposed payments is caused by changes in proposed Factor 3 and the amount of the proposed supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than 26.01 percent indicates that hospitals within the specified category are projected to experience a smaller increase in proposed payments, on average, compared to the universe of projected FY 2026 DSH-eligible hospitals. Conversely, a percentage change greater than 26.01 percent indicates that a hospital type is projected to have a larger increase compared to the overall average. The variation in the distribution of overall proposed payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the proposed supplemental payment.

Urban hospitals, in general, are projected to experience a slightly larger increase in proposed UCP compared to the increase their rural counterparts are projected to experience. Overall, urban hospitals are projected to receive a 26.1 percent increase in proposed payments, while rural hospitals are projected to receive a 24.73 percent increase in proposed payments, which is slightly less than the overall hospital average.

By bed size, rural hospitals with 0 to 99 beds are projected to receive a larger than average increase of approximately 26.0 percent, while rural hospitals with 100 to 249 beds and rural hospitals with 250+ beds are projected to receive smaller than average increases of 25.5 percent and 14.1 percent, respectively. Among urban hospitals, the largest urban hospitals, those with 250+ beds, are projected to receive an increase in payments (27.0 percent) that is greater than the overall hospital average. In contrast, smaller urban hospitals with 0–99 beds and 100–249 beds are projected to receive smaller than average increases in proposed payments of 20.6 and 24.5 percent, respectively.

By region, rural hospitals are projected to receive a varied range of payment changes. Rural hospitals in the New England, South

Atlantic, East South Central, West South Central, and Pacific regions are projected to receive smaller than average increases in proposed payments. Rural hospitals in all other regions are projected to receive larger than average increases in proposed payments. Urban hospitals in the South Atlantic, East North Central, West North Central, and Pacific regions are projected to receive smaller than average increases in proposed payments, while urban hospitals in all other regions are projected to receive larger than average increases in proposed payments.

By payment classification, hospitals in urban payment areas overall are expected to receive a smaller than average increase in proposed UCP and proposed supplemental payments of 25.5 percent. Hospitals in large urban payment areas and other urban payment areas are projected to receive a smaller than average increase in proposed payments of 25.6 percent and 25.3 percent, respectively. In contrast, hospitals in rural payment areas are projected to receive a larger than average increase in proposed payments of 26.5 percent.

Nonteaching hospitals and teaching hospitals with fewer than 100 residents are projected to receive smaller than average payment increases of 23.7 percent and 24.1 percent, respectively. Teaching hospitals with 100+ residents are projected to receive larger than average proposed payment increases of 29.3 percent. Voluntary hospitals and proprietary hospitals are projected to receive smaller than average increases of 24.1 percent and 25.0 percent, respectively, while government-owned hospitals are expected to receive a larger than average proposed payment increase of 30.4 percent. Hospitals with less than 25 percent Medicare utilization are projected to receive larger than average increases of 26.6 percent, while hospitals with Medicare utilization between 25–50 percent and 50–65 percent are projected to receive smaller than average proposed payment increases of 24.3 percent and 23.7 percent, respectively. There are 2 hospitals with greater than 65 percent Medicare utilization, and the hospitals are projected to have a decrease in payments of 100.0 percent, which reflects the hospitals' projected DSH eligibility. Hospitals with 50–65 percent Medicaid utilization and those with greater than 65 percent Medicaid utilization are projected to receive larger than average increases in proposed payments of 30.8 and 41.2 percent, respectively, while hospitals with less than 25 percent Medicaid utilization and those with Medicaid utilization between 25–50 percent are projected to receive smaller than average increases of 24.4 percent and 25.7 percent, respectively.

The impact table reflects the modeled FY 2026 proposed UCP and supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the proposed supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $100.6 million in FY 2026.

3. Effects of Expiration of the Temporary Changes to the Low-Volume Hospital Payment Policy

In section VI.D. of the preamble of this proposed rule, we discuss the extension of the temporary changes to the low-volume hospital payment policy originally provided for by the Affordable Care Act and extended by subsequent legislation. Specifically, section 2201 of the Full-Year Continuing Appropriations and Extensions, 2025 further extended the modified definition of low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals under section 1886(d)(12) through September 30, 2025. Prior to the enactment of the Full-Year Continuing Appropriations and Extensions, 2025, the temporary changes to the low-volume hospital payment adjustment were set to expire on April 1, 2025. Under the extension provided by section 2201 of the Full-Year Continuing Appropriations and Extensions, 2025, FY 2025 payments to IPPS hospitals are projected to increase by approximately $90 million relative to what the payments would have been in the absence of section 2201.

Beginning October 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. Therefore, absent further Congressional action, effective for FY 2026 and subsequent years, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 25 road miles from another subsection (d) hospital and have less than 200 discharges (that is, less than 200 discharges total, including both Medicare and non-Medicare discharges) during the fiscal year.

Using the same methodology used in developing the quantitative analyses of changes in payments per case discussed previously in section I.G. of this Appendix, based upon the best available data at this time, we estimate the expiration of the temporary changes to the low-volume hospital payment policy effective for discharges occurring on or after October 1, 2025, and subsequent years would decrease aggregate low-volume hospital payments by $375 million in FY 2026 as compared to FY 2025. This payment estimate was determined based on the estimated payments for the approximately 580 providers that are expected to no longer qualify under the criteria that are effective beginning on October 1, 2025.

Of those 580 hospitals, currently approximately 100 hospitals have a low-volume hospital payment adjustment based on 500 or fewer total discharges, while the remaining approximately 480 hospitals have an adjustment based on having between 500 and 3,800 total discharges. Approximately 55 of the 580 hospitals that currently qualify for a low-volume hospital payment adjustment in FY 2025 have 200 or fewer total discharges. However, the distance information needed to project whether those hospitals are more than 25 road miles from another subsection (d) hospital (instead of 15 road miles), and therefore would continue to qualify for a low-volume hospital payment adjustment for FY 2026, is evaluated by each hospitals' MAC. Therefore, we are unable to estimate how many of these 55 hospitals would continue to qualify for the low-volume hospital payment adjustment for FY 2026.

4. Impact for Proposed Revision to Regulation Text Regarding Calculation of Net Cost of NAH Education Programs (42 CFR 413.85(d)(2)(i))

In section V.G.3. of the preamble of this proposed rule, we discuss our proposal to revise our regulations at 42 CFR 413.85(d)(2)(i) to state clearly that when calculating the allowable net cost of approved nursing and allied health (NAH) education programs, the correct order of operations is to determine direct costs, subtract tuition and fees, and then add indirect costs. This is in response to an adverse ruling in the U.S. District Court for the District of Columbia (DC) involving five plaintiff hospitals (Mercy Health—St. Vincent Medical Center LLC d/b/a Mercy St. Vincent Medical Center, et al., v. Xavier Becerra, Case No. 22–cv–3578 (TNM)). The proposed effective date of this proposed regulation change would be cost reporting periods beginning on or after October 1, 2025. Regarding the financial impact of this change to the regulations text, other than the amounts in dispute in the specific court case, the national impact is unknown, as it is unclear how many hospitals will change their reporting practices in the absence of this rulemaking. Therefore, we are unable to estimate the impact.

5. Effects Under the Hospital Readmissions Reduction Program for FY 2026

In section VI.K. of the preamble of this proposed rule, we are proposing to modify the six readmission measures in the program to include Medicare Advantage (MA) beneficiaries into the patient cohorts and modify the applicable performance period from a 3-year period to a 2-year period beginning with the FY 2027 program year; the remaining policies finalized in FY 2025 IPPS/LTCH PPS final rule (89 FR 69400) continue to apply. The Hospital Readmissions Reduction Program requires a reduction to a hospital's base operating diagnosis-related group (DRG) payments to account for excess readmissions of selected applicable conditions and procedures. The table and analysis in this section illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2020, and June 30, 2023 (that is, the FY 2025 Hospital Readmissions Reduction Program's applicable period, which is the most recently available data at the time of publication of this proposed rule). Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain budget neutrality. In the FY 2026 IPPS/LTCH

PPS final rule, we will provide an updated estimate of the financial impact using the proportion of dually eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2026 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2021, through June 30, 2024).

The results in Table I.G.5.–01 include 2,828 non-Maryland hospitals estimated as eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure between July 1, 2021, and June 30, 2024. The second column in Table I.G.5.–01 indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in Table I.G.5.–01 indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 78.34 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.57 percent of eligible hospitals with fewer than 100 residents and 90.14 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in Table I.G.5.–01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.5.–01 also shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2022, through September 30, 2023 (FY 2023). For example, the penalty as a share of payments for non-teaching hospitals is 0.45 percent. This means that total penalties for all non-teaching hospitals are 0.45 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

TABLE I.G.5.–01—ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2026 HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

Hospital characteristic	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized [c] (%)	Penalty as a share of payments [d] (%)
All Hospitals	2,828	2,342	82.81	0.42
By Geographic Location (n=2,828):				
Urban hospitals	2,164	1,836	84.84	0.42
1–99 beds	505	336	66.53	0.39
100–199 beds	624	549	87.98	0.48
200–299 beds	397	368	92.70	0.48
300–399 beds	268	250	93.28	0.43
400–499 beds	123	112	91.06	0.46
500 or more beds	247	221	89.47	0.34
Rural hospitals	664	506	76.20	0.41
1–49 beds	312	203	65.06	0.31
50–99 beds	186	151	81.18	0.46
100–149 beds	92	82	89.13	0.39
150–199 beds	44	41	93.18	0.43
200 or more beds	30	29	96.67	0.40
By Teaching Status [e] (n=2,828):				
Non-teaching	1,634	1,280	78.34	0.45
Fewer than 100 Residents	910	806	88.57	0.44
100 or more Residents	284	256	90.14	0.36
By Ownership Type (n=2,828):				
Government	403	313	77.67	0.29
Proprietary	636	519	81.60	0.55
Voluntary	1,789	1,510	84.40	0.41
By Safety-Net Status [f] (n=2,828):				
Safety-net hospitals	544	453	83.27	0.34
Non-safety-net hospitals	2,284	1,889	82.71	0.44
By Disproportionate Share Hospital (DSH) Patient Percentage [g] (n=2,828):				
0–24	1,058	828	78.26	0.48
25–49	1,469	1,273	86.66	0.39
50–64	177	147	83.05	0.36
65 and over	124	94	75.81	0.43
By Medicare Cost Report (MCR) Percentage [h] (n=2,827):				
0–24	1,183	995	84.11	0.33
25–49	1,572	1,296	82.44	0.48
50–64	62	43	69.35	0.75
65 and over	10	7	70.00	0.29
By Region (n=2,828):				
New England	122	106	86.89	0.64
Middle Atlantic	313	287	91.69	0.46
East North Central	444	379	85.36	0.43
West North Central	228	172	75.44	0.23
South Atlantic	483	421	87.16	0.46
East South Central	253	210	83.00	0.47
West South Central	425	342	80.47	0.39
Mountain	211	151	71.56	0.31

TABLE I.G.5.–01—ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2026 HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC—Continued

Hospital characteristic	Number of eligible hospitals [a]	Number of penalized hospitals [b]	Percentage of hospitals penalized [c] (%)	Penalty as a share of payments [d] (%)
Pacific	349	274	78.51	0.34

Source: The table results are based on the data used to calculate the FY 2025 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2025 payment adjustment factors are based on discharges from July 1, 2020, through June 30, 2023. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2024 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the multi-year performance period. Hospital characteristics are from the FY 2025 IPPS Proposed Rule Impact File.

Note: The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for MCR percentage (n=2,827; missing=1).

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2022, through September 30, 2023 (FY 2023), are used to estimate the total base operating DRG payments.

[e] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[f] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[g] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[h] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

6. Effects of Changes Under the FY 2026 Hospital Value-Based Purchasing (VBP) Program

The Secretary makes value-based incentive payments to hospitals under the Hospital Value-Based Purchasing Program based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2026 through a reduction to the FY 2026 base operating DRG payment amount for hospital discharges for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2026 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary. In section VI.L.1.b. of the preamble of this proposed rule, we estimate the available pool of funds for value-based incentive payments in the FY 2026 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.7 billion. This estimated available pool for FY 2026 is based on the historical pool of hospitals that were eligible to participate in the FY 2025 program year and the payment information from the December 2024 update to the FY 2024 MedPAR file.

The proposed estimated impacts of the FY 2026 program year by hospital characteristic, found in Table I.G.6.–01., are based on historical TPSs, sepsis measure results and the Health Equity Adjustment previously finalized in the FY 2024 IPPS rule (88 FR 59092 through 59106). Table I.G.6.–02 are based on the same data and reflect our proposal to remove the Health Equity Adjustment as discussed in this proposed rule. We used the FY 2025 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the December 2024 update to the FY 2024 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

The proposed estimated impact analysis shows that, for the FY 2026 program year, the number of hospitals with a positive percent change in base operating DRG (51.5 percent) is higher than the number of hospitals with a negative percent change (48.5 percent). Approximately half of all hospitals experience a percent change in base operating DRG between −1.9 percent and 0.0 percent. On average, both urban and rural hospitals in the Pacific region have the highest positive percent change in base operating DRG. Urban hospitals in the Middle Atlantic, East South Central, South Atlantic, and West South Central regions experience an average negative percent change in base operating DRG. All other regions (both urban and rural) experience an average positive percent change in base operating DRG. As the MCR percent increases, the average percent change in base operating DRG generally increases, except for the four hospitals with the highest MCR percentage. As DSH percent increases, the average percent change in base operating DRG decreases except for hospitals with greater than 65 DSH percent. On average, non-teaching hospitals have a higher percent change in base operating DRG compared to teaching hospitals.

TABLE I.G.6.–01—IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2026 HOSPITAL VBP PROGRAM

	Number of hospitals	Average net percentage payment adjustment
BY GEOGRAPHIC LOCATION:		
All Hospitals	2,532	0.170
Urban Area	1,984	0.066
Rural Area	547	0.543
Missing	1	0.786

TABLE I.G.6.–01—IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2026 HOSPITAL VBP PROGRAM—Continued

	Number of hospitals	Average net percentage payment adjustment
Urban Hospitals	1,984	0.066
0–99 beds	364	0.570
100–199 beds	602	0.139
200–299 beds	402	−0.111
300–499 beds	379	−0.202
500 or more beds	237	−0.163
Rural Hospitals	547	0.543
0–49 beds	212	0.810
50–99 beds	178	0.505
100–149 beds	86	0.445
150–199 beds	41	0.043
200 or more beds	30	−0.147
BY REGION:		
Urban By Region	1,984	0.066
New England	96	0.170
Middle Atlantic	244	−0.026
South Atlantic	365	−0.075
East North Central	311	0.171
East South Central	117	−0.274
West North Central	131	0.214
West South Central	246	−0.095
Mountain	154	0.001
Pacific	320	0.383
Rural By Region	547	0.543
New England	19	0.529
Middle Atlantic	41	0.624
South Atlantic	90	0.452
East North Central	100	0.759
East South Central	100	0.210
West North Central	68	0.624
West South Central	73	0.358
Mountain	32	0.979
Pacific	24	1.008
BY MCR PERCENT:		
0–25	1,118	0.115
25–50	1,369	0.201
50–65	38	0.528
Over 65	4	0.449
Missing	3	1.387
BY DSH PERCENT:		
0–25	887	0.239
25–50	1,394	0.127
50–65	146	0.070
Over 65	104	0.275
Missing	1	0.786
BY TEACHING STATUS:		
Non-Teaching	1,370	0.319
Teaching	1,161	−0.007
Missing	1	0.786

The proposed estimated impact analysis shows that, for the FY 2026 program year, with the proposal to remove the Health Equity Adjustment the number of hospitals with a negative percent change in base operating DRG (50.8 percent) is higher than the number of hospitals with a positive percent change (49.2 percent). Approximately half of all hospitals experience a percent change in base operating DRG between −2.1 percent and 0.0 percent. On average, both urban hospitals in the West North Central region and rural hospitals in the Mountain region have the highest positive percent change in base operating DRG. Urban hospitals in the Middle Atlantic, East South Central, and West South Central regions experience an average negative percent change in base operating DRG. All other regions (both urban and rural) experience an average positive percent change in base operating DRG. Hospitals in higher MCR percent categories have higher average net percentage payment increases compared to hospitals with lower MCR percent. Hospitals in higher DSH percent categories (50–65 and greater than 65) have negative average net percentage payment, compared to hospitals in the lower DSH categories. On average, non-teaching hospitals have a higher percent change in base operating DRG compared to teaching hospitals.

TABLE I.G.6.–02—IMPACT ANALYSIS OF BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2026 HOSPITAL VBP PROGRAM—PROPOSAL TO REMOVE THE HEALTH EQUITY ADJUSTMENT

	Number of hospitals	Average net percentage payment adjustment
BY GEOGRAPHIC LOCATION:		
All Hospitals	2,532	0.168
Urban Area	1,984	0.077
Rural Area	547	0.499
Missing	1	0.466
Urban Hospitals	1,984	0.077
0–99 beds	364	0.713
100–199 beds	602	0.137
200–299 beds	402	−0.130
300–499 beds	379	−0.244
500 or more beds	237	−0.186
Rural Hospitals	547	0.499
0–49 beds	212	0.823
50–99 beds	178	0.478
100–149 beds	86	0.288
150–199 beds	41	−0.077
200 or more beds	30	−0.267
BY REGION:		
Urban By Region	1,984	0.077
New England	96	0.103
Middle Atlantic	244	−0.095
South Atlantic	365	0.024
East North Central	311	0.107
East South Central	117	−0.132
West North Central	131	0.302
West South Central	246	−0.003
Mountain	154	0.142
Pacific	320	0.246
Rural By Region	547	0.499
New England	19	0.443
Middle Atlantic	41	0.491
South Atlantic	90	0.375
East North Central	100	0.699
East South Central	100	0.121
West North Central	68	0.688
West South Central	73	0.273
Mountain	32	1.242
Pacific	24	0.936
BY MCR PERCENT:		
0–25	1,118	0.085
25–50	1,369	0.222
50–65	38	0.533
Over 65	4	0.473
Missing	3	1.682
BY DSH PERCENT:		
0–25	887	0.418
25–50	1,394	0.058
50–65	146	−0.178
Over 65	104	−0.001
Missing	1	0.466
BY TEACHING STATUS:		
Non-Teaching	1,370	0.360
Teaching	1,161	−0.058
Missing	1	0.466

The actual FY 2026 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2026 IPPS/LTCH PPS final rule has published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2025 program year would be used for the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2026 are not finalized.

7. Effects of Requirements Under the Hospital-Acquired Condition (HAC) Reduction Program for FY 2026

We present the estimated impact of the FY 2026 HAC Reduction Program on hospitals by hospital characteristic based on previously adopted policies for the program. In this proposed rule, we are not proposing to add or remove any measures from the HAC Reduction Program, nor are we proposing any changes to reporting or submission requirements which would have any significant economic impact for the FY 2026 program year. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2021, through June 30, 2023, and version 14.0 of the CMS PSI software. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream

Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the CDC's National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2022, and December 31, 2023. Hospital characteristics are based on the FY 2025 IPPS proposed rule Impact File.

This table includes 2,933 non-Maryland hospitals with an estimated FY 2026 Total HAC Score based on the most recently available data at the time of publication of this proposed rule. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. Actual results for FY 2026 will be determined in the fall of 2025 after a 30-day review and corrections period for hospitals to review their program results. The first column presents a breakdown of each characteristic, and the second column indicates the number of hospitals for the respective characteristic.

The third column in the table indicates the estimated number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. For example, with regard to teaching status, 426 hospitals out of 1,700 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 196 out of 935 hospitals with fewer than 100 residents and 102 out of 285 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the estimated proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2026 HAC Reduction Program. For example, 25.1 percent of the 1,700 hospitals characterized as non-teaching hospitals, 21.0 percent of the 935 teaching hospitals with fewer than 100 residents, and 35.8 percent of the 285 teaching hospitals with 100 or more residents would be subject to a payment reduction.

TABLE I.G.7.–01—ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2026 HAC REDUCTION PROGRAM (BY HOSPITAL CHARACTERISTIC)

Hospital characteristic	Number of hospitals	Number of hospitals in the worst-performing quartile [a]	Percent of hospitals in the worst-performing quartile [b]
All hospitals [c]	2,933	732	25.0
By Geographic Location (n=2,920): [d]			
Urban hospitals	2,268	530	23.4
1–99 beds	574	147	25.6
100–199 beds	644	149	23.1
200–299 beds	409	86	21.0
300–399 beds	270	49	18.1
400–499 beds	123	31	25.2
500 or more beds	248	68	27.4
Rural hospitals	652	194	29.8
1–49 beds	298	82	27.5
50–99 beds	188	61	32.4
100–149 beds	92	23	25.0
150–199 beds	44	18	40.9
200 or more beds	30	10	33.3
By Teaching Status [d] (n=2,920): [d]			
Non-teaching	1,700	426	25.1
Fewer than 100 residents	935	196	21.0
100 or more residents	285	102	35.8
By Ownership (n=2,920):			
Government	404	138	34.2
Proprietary	684	120	17.5
Voluntary	1,832	466	25.4
By Safety-Net Status [e] (n=2,920): [d]			
Safety-net	580	163	28.1
Non-safety net	2,340	561	24.0
By Disproportionate Share Hospital (DSH) Patient Percentage [f] (n=2,920):			
0–24	1,112	235	21.1
25–49	1,471	385	26.2
50–64	186	55	29.6
65 and over	151	49	32.5
By Medicare Cost Report (MCR) Percentage (n=2,915):			
0–24	1,273	307	24.1
25–49	1,571	395	25.1
50–64	56	14	25.0
65 and over	15	4	26.7
By Region (n=2,933):			
New England	125	36	28.8
Middle Atlantic	322	90	28.0
East North Central	462	131	28.4
West North Central	232	55	23.7
South Atlantic	494	111	22.5
East South Central	255	73	28.6
West South Central	444	93	20.9
Mountain	224	39	17.4

TABLE I.G.7.–01—ESTIMATED PROPORTION OF HOSPITALS IN THE WORST-PERFORMING QUARTILE (>75TH PERCENTILE) OF THE TOTAL HAC SCORES FOR THE FY 2026 HAC REDUCTION PROGRAM (BY HOSPITAL CHARACTERISTIC)—Continued

Hospital characteristic	Number of hospitals	Number of hospitals in the worst-performing quartile [a]	Percent of hospitals in the worst-performing quartile [b]
Pacific	375	104	27.7

Source: FY 2026 HAC Reduction Program estimated proposed rule results are based on CMS PSI 90 data from July 1, 2021, through June 30, 2023, and CDC's NHSN HAI results from January 1, 2022, through December 31, 2023. Hospital Characteristics are based on the FY 2025 IPPS proposed rule Impact File.

Note: The total number of hospitals with hospital characteristic data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership, Safety-net status, and DSH percent (n=2,920; missing=13), and MCR percent (n=2,915; missing=18).

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.

[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.

[c] The number of non-Maryland hospitals with a Total HAC Score (n=2,933).

[d] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.

[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.

[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

8. Effects of the Implementation of the Rural Community Hospital Demonstration (RCHD) Program in FY 2026

In section VI.N.2 of the preamble of this proposed rule for FY 2026, we discussed our budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals. Section 128 of Public Law 116–260 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

While the statute does not call for any new hospitals to join the demonstration, CMMI issued a notice on December 20, 2024, in the **Federal Register** for a solicitation (CMS–5051–N2) (89 FR 105049) for up to 10 additional eligible hospitals to participate in the RCHD. Applications were due March 1, 2025. Hospitals that enter the demonstration under this solicitation will be able to participate from May 1, 2025, through June 30, 2028. Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). To ensure budget neutrality, we propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. This proposed methodology applies budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented but does not identify the range across which aggregate payments must be held equal.

For this proposed rule, the resulting amount applicable to FY 2026 is $47,527,557, which we are proposing as the budget neutrality offset adjustment for FY 2026. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the IPPS/LTCH PPS final rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the IPPS/LTCH PPS final rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2018 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS/LTCH PPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we propose to continue this general procedure. At this time, for the FY 2026 IPPS/LTCH PPS proposed rule, not all of the finalized cost reports are available for the 20 hospitals that completed cost report periods beginning in FY 2020 under the demonstration payment methodology. If all of these cost reports are available, we will include in the budget neutrality offset amount in the FY 2026 IPPS/LTCH PPS final rule the amount by which the actual costs of the demonstration, as determined from these cost reports, differed from the estimated costs identified in the FY 2020 IPPS/LTCH PPS final rule.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VIII.B.2. of the preamble of this proposed rule, we discuss the implementation of the FCHIP Demonstration, which was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L. 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027. Section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do

not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Budget neutrality estimates for the demonstration described in the preamble of this proposed rule are based on the demonstration extension period.

As described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), CMS waived certain Medicare rules for CAHs participating in the demonstration extension period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing the three intervention services.

As explained in the FY 2025 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration extension period of performance in the FY 2025 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2025 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2025 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2025 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2025 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented and does not identify the range across which aggregate payments must be held equal.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2025 IPPS/LTCH PPS final rule, we finalized a policy to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period to be used for the demonstration extension period. As stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69416 through 69419), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we are not proposing to apply a budget neutrality payment offset to payments to CAHs in FY 2026. This policy will have no impact for any national payment system for FY 2026.

10. Effects of the Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this proposed rule, we discuss testing the mandatory episode-based payment model titled the Transforming Episode Accountability Model (TEAM) under the authority of the CMS Center for Medicare and Medicaid Innovation (CMS Innovation Center). Section 1115A of the Act authorizes the CMS Innovation Center to test innovative payment and service delivery models that preserve or enhance the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries while reducing program expenditures. The intent of TEAM is to improve beneficiary care through financial accountability for episode categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM will benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare fee-for-service (FFS) payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

As finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), TEAM will be mandatory for acute care hospitals located within mandatory CBSAs and will also include acute care hospitals that were eligible for voluntary opt-in participation.[6] TEAM will begin on January 1, 2026, and end on December 31, 2030. Payment approaches that hold providers accountable for episode cost and performance can potentially create incentives for the implementation and coordination of care redesign between participants and other providers and suppliers such as physicians and post-acute care providers. We anticipate TEAM will enable hospitals to consider the most appropriate strategies for care redesign, including (1) increasing post-hospitalization follow-up and medical management for patients; (2) coordinating care across the inpatient and post-acute care spectrum; (3) conducting appropriate discharge planning; (4) improving adherence to treatment or drug regimens; (5) reducing readmissions and complications during the post-discharge period; (6) managing chronic diseases and conditions that may be related to the episodes; (7) choosing the most appropriate post-acute care setting; and (8) coordinating between providers and suppliers such as hospitals, physicians, and post-acute care providers.

Under TEAM, TEAM participants will continue to bill Medicare under the traditional FFS system for items and services

[6] Acute care hospitals that participate in the BPCI Advanced or the CJR model, that are not located in a mandatory CBSA selected for TEAM participation, and continue to participate in BPCI Advanced or CJR until the last day of the last performance period or last performance year of the respective model, were eligible to voluntarily opt into TEAM.

furnished to Medicare FFS beneficiaries. The TEAM participant may receive a reconciliation payment from CMS if Medicare FFS expenditures for a performance year are less than the reconciliation target price, subject to a quality adjustment. TEAM will not have downside risk for Track 1, meaning TEAM participants will only be accountable for performance year spending below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount. For Track 2 and Track 3, TEAM will be a two-sided risk model that requires TEAM participants to be accountable for performance year spending above or below their reconciliation target price, subject to a quality adjustment, that would result in a reconciliation payment amount or a repayment amount.

a. Effects on the Medicare Program

TEAM is a mandatory episode-based payment model which will have a direct effect on the Medicare program because TEAM participants will be incentivized to reduce Medicare spending. Additionally, TEAM participants could receive a reconciliation payment amount from CMS or have to pay CMS a repayment amount based on their spending and quality performance. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 70026), we estimated and projected financial impacts of TEAM over the course of the five-year model test. We estimated that on net, TEAM participants would pay CMS $442 million, and that TEAM would save the Medicare program approximately $481 million over the five performance years (2026 through 2030). In this proposed rule, we are proposing several policies and soliciting comment on policy considerations. We believe the policies that are being proposed would not have a material impact on the Medicare savings estimate. For example, we do not anticipate there will be many new hospitals that would be affected by a deferred participation period, nor would capturing an additional quality measure in the model or allowing TEAM participants to use swing-bed arrangements in the 3-Day SNF Rule waiver have a significant effect on Medicare spending or savings. Additionally, the proposals that affect the pricing methodology, such as changes to the construction of the prospective trend factor and normalization factors or using a 180-day lookback period for risk adjustment, aim to improve the accuracy of target prices but should not result in dramatic shifts to the Medicare savings estimate. We note that certain policy considerations that we are seeking comment on and not proposing, such as a low volume hospital policy could impact the Medicare savings estimate in magnitude, but we anticipate the direction of the Medicare savings to remain the same. Generally, Medicare savings estimates are based on the proposed policies to reflect the potential financial implications of the proposals and are not generally updated based on policies that are only soliciting comments. Therefore, TEAM's financial impact to the Medicare program remains unchanged from the FY 2025 IPPS/LTCH PPS final rule. While the Medicare savings estimate remains unchanged for TEAM, we note in section I.O. of this Appendix, that we assessed the potential financial impact of a low volume policy on the model. Further, we anticipate updating the Medicare savings estimate for the final rule to reflect actual TEAM participants participating in the model, inclusive of those hospitals that voluntarily opt into the model, and updated baseline spending assumptions. Additionally, should a policy that we considered become finalized, such as the low volume hospital policy, we anticipate we would update the Medicare savings estimate to reflect that policy as well.

b. Effects on the Medicare Beneficiaries

We believe the refinements to TEAM proposed in this proposed rule would not materially alter the potential effects of the model on beneficiaries that we had initially indicated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 70028). We believe the majority of the changes would not alter the effects of the model on beneficiaries because the changes predominantly alter how hospitals interact with the model, rather than how beneficiaries receive care. However, we believe any changes proposed that may have a direct effect on TEAM beneficiaries are positive. In section XI.A.2.b.(3) of the preamble of this proposed rule that we are proposing to include the Information Transfer PRO–PM, specific to episodes initiated in the hospital outpatient department setting, in the quality measure set that would be tied to payment with the belief that doing so would encourage TEAM participants to focus on and deliver improved quality of care for Medicare beneficiaries. We also note in section XI.A.2.f. of the preamble of this proposed rule that we are proposing to allow TEAM participants to use the SNF 3-day rule waiver for TEAM beneficiaries discharged to hospitals and CAHs providing PAC under swing bed arrangements. This proposal would help improve beneficiary freedom of choice and access to care, such that beneficiaries in rural or underserved areas could receive PAC services closer their home.

We welcome public comments on our impact of TEAM on Medicare beneficiaries.

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of January 2025, there were 91 children's hospitals, 11 cancer hospitals, 6 short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 1 extended neoplastic disease care hospital, and 9 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this proposed rule. The impacts of the changes on LTCHs are discussed in section I.J. of this appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated proposed FY 2026 percentage increase in the proposed 2023-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket increase, we are estimating the FY 2026 update to be 3.2 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this proposed rule. We proposed that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2026. Section 1886(b)(3)(B)(xi)(I) of the Act requires a productivity adjustment (0.8 percentage point reduction proposed for FY 2026), resulting in a proposed 2.4 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.B. of the preamble of this proposed rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under section 1886(b)(3)(B)(xi)(I) of the Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the proposed 2023-based IPPS operating market basket for FY 2026, currently estimated at 3.2 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section of this proposed rule, we used data from the December 2024 update of the FY 2024 MedPAR file and the December 2024 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used the December 2024 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of this proposed rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the December 2024 update of the FY 2024 MedPAR file, we simulated payments under the capital IPPS for FY 2025 and the proposed payments for FY 2026 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2026 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this proposed rule, the proposed update to the capital Federal rate is 2.6 percent for FY 2026.
- In addition to the proposed FY 2026 update factor, the proposed FY 2026 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 1.0121, a proposed budget neutrality factor for the 5-percent cap on wage index decreases policy and the proposed transition for the discontinuation of the low wage index hospital policy of 0.9927, and a proposed outlier adjustment factor of 0.9587.

2. Results

We used the payment simulation model previously described in section I.I. of this Appendix to estimate the potential impact of the proposed changes for FY 2026 on total capital payments per case, using a universe of 3,038 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2024 update of the FY 2024 MedPAR file, the December 2024 update to the PSF, and the most recent available cost report data from the December 2024 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2025 and estimated proposed total payments per case for FY 2026 based on the proposed FY 2026 payment policies. Column 2 shows estimates of payments per case under our model for FY 2025. Column 3 shows estimates of proposed payments per case under our model for FY 2026. Column 4 shows the total proposed percentage change in payments from FY 2025 to FY 2026. The change represented in Column 4 includes the proposed 2.6 percent update to the capital Federal rate and other proposed changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2026 are expected to increase 2.7 percent compared to capital payments per case in FY 2025. This expected increase is primarily due to the proposed 2.6 percent update to the capital Federal rate. In general, regional variations in estimated capital payments per case in FY 2026 as compared to capital payments per case in FY 2025 are primarily due to the proposed changes in GAFs, and are generally consistent with the projected changes in payments due to the proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.F. of this appendix.

The net impact of these proposed changes is an estimated 2.7 percent increase in capital payments per case from FY 2025 to FY 2026 for all hospitals (as shown in Table III). The geographic comparison shows that, on average, hospitals in both urban and rural classifications would experience an increase in capital IPPS payments per case in FY 2026 as compared to FY 2025. Capital IPPS payments per case would increase by an estimated 2.7 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 2.9 percent from FY 2025 to FY 2026. The primary factor contributing to the difference in the projected increase in capital IPPS payments per case for rural hospitals as compared to urban hospitals is the estimated increase in capital payments to rural hospitals due to the effect of proposed changes in the GAFs.

The comparisons by region show that the change in capital payments per case from FY 2025 to FY 2026 for urban areas range from a 0.8 percent increase for the New England urban region to a 5.4 percent increase for the West North Central urban region. Meanwhile, the change in capital payments per case from FY 2025 to FY 2026 for rural areas range from a 1.3 percent increase for the East North Central rural region to a 5.2 percent increase for the West North Central rural region. Capital IPPS payments per case for hospitals located in Puerto Rico are projected to remain constant. These regional differences are primarily due to the proposed changes in the GAFs.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that voluntary hospitals as well as proprietary hospitals are expected to experience an increase in capital payments per case from FY 2025 to FY 2026 of 2.6 percent. Government hospitals are expected to experience an increase in capital payments per case from FY 2025 to FY 2026 of 3.1 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2026. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this proposed rule for FY 2026, we show the proposed average capital payments per case for reclassified hospitals for FY 2026. Urban reclassified hospitals are expected to experience an increase in capital payments per case of 2.7 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 2.6 percent. Rural reclassified hospitals as well as rural nonreclassified hospitals are expected to experience an increase in capital payments per case of 2.9 percent.

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE

FY 2025 payments compared to proposed FY 2026 payments	Number of hospitals	Average FY 2025 payments/case	Proposed average FY 2026 payments/case	Change
All Hospitals	3,038	1,184	1,216	2.7
By Geographic Location:				

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

FY 2025 payments compared to proposed FY 2026 payments	Number of hospitals	Average FY 2025 payments/case	Proposed average FY 2026 payments/case	Change
Urban hospitals	2,369	1,217	1,250	2.7
Rural hospitals	669	815	839	2.9
Bed Size (Urban):				
0–99 beds	643	903	933	3.3
100–199 beds	675	1,015	1,038	2.3
200–299 beds	405	1,115	1,141	2.3
300–499 beds	393	1,213	1,244	2.6
500 or more beds	251	1,451	1,494	3.0
Bed Size (Rural):				
0–49 beds	320	677	697	3.0
50–99 beds	182	780	798	2.3
100–149 beds	94	788	811	2.9
150–199 beds	42	888	914	2.9
200 or more beds	31	986	1,020	3.4
Urban by Region:				
New England	104	1,317	1,327	0.8
Middle Atlantic	274	1,366	1,398	2.3
East North Central	366	1,137	1,160	2.0
West North Central	156	1,138	1,199	5.4
South Atlantic	393	1,073	1,096	2.1
East South Central	142	1,002	1,042	4.0
West South Central	352	1,102	1,139	3.4
Mountain	180	1,220	1,258	3.1
Pacific	351	1,560	1,607	3.0
Rural by Region:				
New England	19	1,075	1,119	4.1
Middle Atlantic	50	934	953	2.0
East North Central	107	815	826	1.3
West North Central	74	801	843	5.2
South Atlantic	108	747	766	2.5
East South Central	128	733	757	3.3
West South Central	118	722	740	2.5
Mountain	41	864	900	4.2
Pacific	24	1,056	1,085	2.7
Puerto Rico:				
Puerto Rico Hospitals	51	608	608	0.0
By Payment Classification:				
Urban hospitals	1,609	1,116	1,146	2.7
Rural areas	1,429	1,236	1,269	2.7
Teaching Status:				
Nonteaching	1,765	964	989	2.6
Fewer than 100 residents	980	1,104	1,134	2.7
100 or more residents	293	1,603	1,646	2.7
Urban DSH:				
Non-DSH	334	1,006	1,036	3.0
100 or more beds	916	1,159	1,190	2.7
Less than 100 beds	359	829	851	2.7
Rural DSH:				
Non-DSH	91	1,121	1,141	1.8
SCH	231	840	866	3.1
RRC	858	1,284	1,318	2.6
100 or more beds	45	1,111	1,144	3.0
Less than 100 beds	204	685	703	2.6
Urban teaching and DSH:				
Both teaching and DSH	531	1,219	1,253	2.8
Teaching and no DSH	54	1,065	1,092	2.5
No teaching and DSH	744	1,016	1,040	2.4
No teaching and no DSH	280	972	1,004	3.3
Special Hospital Types:				
RRC	132	917	940	2.5
RRC with Section 401 Rural Reclassification	649	1,337	1,371	2.5
SCH	225	787	807	2.5
SCH with Section 401 Rural Reclassification	38	970	1,001	3.2
SCH and RRC	116	886	914	3.2
SCH and RRC with Section 401 Rural Reclassification	50	1,131	1,182	4.5
Type of Ownership:				
Voluntary	1,903	1,185	1,216	2.6
Proprietary	723	1,095	1,123	2.6
Government	412	1,293	1,333	3.1
Medicare Utilization as a Percent of Inpatient Days:				

TABLE III—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

FY 2025 payments compared to proposed FY 2026 payments	Number of hospitals	Average FY 2025 payments/case	Proposed average FY 2026 payments/case	Change
0–25	1,543	1,251	1,288	3.0
25–50	1,400	1,120	1,146	2.3
50–65	65	1,105	1,130	2.3
Over 65	14	932	995	6.8
Medicaid Utilization as a Percent of Inpatient Days:				
0–25	1,861	1,084	1,113	2.7
25–50	1,052	1,320	1,356	2.7
50–65	93	1,592	1,625	2.1
Over 65	31	1,357	1,380	1.7
FY 2026 Reclassifications:				
All Reclassified Hospitals	1,172	1,256	1,290	2.7
Non-Reclassified Hospitals	1,866	1,088	1,117	2.7
Urban Hospitals Reclassified	1,011	1,282	1,317	2.7
Urban Non-Reclassified Hospitals	1,371	1,115	1,144	2.6
Rural Hospitals Reclassified Full Year	280	831	855	2.9
Rural Non-Reclassified Hospitals Full Year	376	789	812	2.9
All Section 401 Rural Reclassified Hospitals	812	1,302	1,337	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	52	829	852	2.8

J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section XI. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2026. In the preamble of this proposed rule, we specify the statutory authority for the proposals that are presented, identify the proposed policies for FY 2026, and present rationales for our proposals as well as alternatives that were considered. In this section, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 328 LTCHs included in this impact analysis. We note that, although there are currently approximately 335 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2026 MS–LTC–DRG relative weights (discussed in section XI.B.3. of the preamble of this proposed rule). Moreover, in the claims data used for this proposed rule, one of the 328 LTCHs included in our impact analysis only had claims for site neutral payment rate cases and, therefore, does not affect our impact analysis for LTCH PPS standard Federal payment rate cases presented in Table IV (that is, the impact analysis presented in Table IV is based on the data for 327 LTCHs).

In the impact analysis, we used the proposed payment rate, factors, and policies presented in this proposed rule, the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2026.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high-cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases.

Based on the best available data for the 328 LTCHs in our database that were considered in the analyses used for this proposed rule, we estimate that overall LTCH PPS payments in FY 2026 will increase by approximately 2.5 percent (or approximately $61 million) based on the proposed rates and factors presented in section XI. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2024 LTCH cases that were used for the analysis in this proposed rule, approximately 10 percent of those cases were classified as site neutral payment rate cases (that is, 10 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). In section XI.B.3.b of the preamble, we outline how we considered the ending of the waiver of the application of the site neutral payment rate for LTCH cases under section 3711(b)(2) of the CARES Act when identifying site neutral payment rate cases based on the statutory patient criteria, admission date, and claim payment amounts. To estimate FY 2026 LTCH PPS payments for site neutral payment rate cases, we calculated the IPPS comparable per diem amounts using the proposed FY 2026 IPPS rates and factors along with other changes that would apply to the site neutral payment rate cases in FY 2026. We estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 8.5 percent (or approximately $9 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and factors reflected in our estimate of the IPPS comparable per diem amount, as well as an increase in estimated costs for these cases determined using the proposed charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this proposed rule. We note that we estimate payments to site neutral payment rate cases in FY 2026 will represent approximately 4.5 percent of estimated aggregate FY 2026 LTCH PPS payments.

Based on the FY 2024 LTCH cases that were used for the analysis in this proposed rule, approximately 90 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2026, and will be paid based on the LTCH PPS standard Federal payment rate. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2026 will increase approximately 2.2 percent (or approximately $52 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2026 is primarily due to the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate being partially offset by a projected 0.3 percent decrease in high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section.

Based on the 328 LTCHs that were represented in the FY 2024 LTCH cases that were used for the analyses in this proposed rule presented in this appendix, we estimate that aggregate FY 2026 LTCH PPS payments will be approximately $2.558 billion, as compared to estimated aggregate FY 2025 LTCH PPS payments of approximately $2.497 billion, resulting in an estimated overall increase in LTCH PPS payments of

approximately $61 million. We note that the estimated $61 million increase in LTCH PPS payments in FY 2026 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the proposed policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2025 is $49,383.26. For FY 2026, we are proposing to establish an LTCH PPS standard Federal payment rate of $50,728.77 which reflects the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate and the proposed budget neutrality factor for updates to the area wage level adjustment of 1.0012146 (discussed in section V.B.6. of the Addendum to this proposed rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are proposing to establish an LTCH PPS standard Federal payment rate of $49,739.90. This proposed LTCH PPS standard Federal payment rate reflects the proposed updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the proposed annual update of 2.6 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.5 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026, on average, for all LTCHs (Column 6). The estimated increase of 2.5 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 2.5 percent.

For FY 2026, we are proposing to update the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2022 which is the same data used for the FY 2026 IPPS wage index). In addition, we are proposing to establish a labor-related share of 73.1 percent for FY 2026, based on the most recent available data (IGI's fourth quarter 2024 forecast) of the relative importance of the labor-related share of operating and capital costs of the 2022-based LTCH market basket. We also are proposing to apply an area wage level budget neutrality factor of 1.0012146 to ensure that the proposed changes to the area wage level adjustment would not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2025 to FY 2026. Based on the FY 2024 LTCH cases that were used for the analyses in this proposed rule, we estimate that the FY 2025 high-cost outlier threshold of $77,048 (as established in the FY 2025 IPPS/LTCH PPS final rule) will result in estimated high-cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2025 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high-cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 8.2 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2025. Combined with our estimate that FY 2026 high-cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of estimated total LTCH PPS standard Federal payment rate payments in FY 2026, this will result in an estimated decrease in high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 0.3 percent between FY 2025 and FY 2026. We note that, in calculating these estimated high-cost outlier payments, we inflated charges reported on the FY 2024 claims by the proposed charge inflation factor described in section V.D.3.b. of the Addendum to this proposed rule. We also note that, in calculating these estimated high-cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

Table IV shows the estimated impact of the proposed payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2026 by comparing estimated FY 2025 LTCH PPS payments to estimated FY 2026 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases as discussed in section I.J.3. of this appendix.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments (for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases), and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 2.5 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This increase is primarily due to the combination of the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate for FY 2026, the proposed changes to the area wage level adjustment, and estimated changes in outlier payments. This estimated impact is based on the FY 2024 data for the 17 rural LTCHs (out of 327 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of the Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Proposed Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high-cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.1. of this appendix, we project an increase in aggregate LTCH PPS payments in FY 2026 of approximately $61 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $52 million and the projected increase in payments to site neutral payment rate cases of approximately $9 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

Consistent with prior years, Table IV only reflects proposed changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the proposed changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Proposed Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate

by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this proposed rule on different categories of LTCHs for FY 2026, it is necessary to estimate payments per discharge for FY 2025 using the rates, factors, and the policies established in the FY 2025 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2026 using the proposed rates, factors, and the policies in this proposed rule (as discussed in section XI. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our proposed policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Ownership control.
- Census region.
- Bed size.

c. Proposed Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2025 and proposed FY 2026 payments on a case-by-case basis using historical LTCH claims from the FY 2024 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2024 MedPAR files. For modeling FY 2025 LTCH PPS payments, we used the FY 2025 standard Federal payment rate of $49,383.26 (or $48,424.36 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the proposed FY 2026 LTCH PPS standard Federal payment rate, we used the proposed FY 2026 standard Federal payment rate of $50,728.77 (or $49,739.90 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable proposed adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2025 LTCH PPS payments, we used the current FY 2025 labor-related share (72.8 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2025 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2025 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $77,048 (as reflected in the FY 2025 IPPS/LTCH PPS final rule), and the FY 2025 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2025 nonlabor-related share (27.2 percent) for LTCHs located in Alaska and Hawaii.

Similarly, for modeling proposed FY 2026 LTCH PPS payments, we used the proposed FY 2026 LTCH PPS labor-related share (73.1 percent), the proposed FY 2026 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this proposed rule (which are available via the internet on the CMS website), the proposed FY 2026 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $91,247 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2026 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2026 nonlabor-related share (26.9 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2024 claims by the proposed charge inflation factors in section V.D.3.b. of the Addendum to this proposed rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2025 to FY 2026 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2025 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated proposed FY 2026 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2025 to FY 2026 due to the proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 due to the proposed changes to the area wage level adjustment (that is, the proposed updated hospital wage data and the proposed labor-related share) and the application of the corresponding proposed budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 (Column 4) to FY 2026 (Column 5) due to all proposed changes.

TABLE IV—IMPACT OF PROPOSED PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2026

[Estimated FY 2025 payments compared to estimated FY 2026 payments]

LTCH classification	Number of LTCHS	Number of LTCH PPS standard payment rate cases	Average FY 2025 LTCH PPS payment per standard payment rate	Average FY 2026 LTCH PPS payment per standard payment rate [1]	Change due to change to the annual update to the standard federal rate [2]	Percent change due to changes to area wage adjustment with wage budget neutrality [3]	Percent change due to all standard payment rate changes [4]
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)
ALL PROVIDERS	327	42,992	55,618	56,837	2.5	0.0	2.2
BY LOCATION:							
RURAL	17	1,323	44,169	45,270	2.5	−0.1	2.5
URBAN	310	41,669	55,981	57,205	2.5	0.0	2.2
BY OWNERSHIP TYPE:							
VOLUNTARY	53	4,983	59,899	61,587	2.5	0.5	2.8
PROPRIETARY	266	37,470	54,809	55,965	2.5	−0.1	2.1
GOVERNMENT	8	539	72,250	73,546	2.5	−0.7	1.8
BY REGION:							
NEW ENGLAND	10	1,329	49,702	50,751	2.6	0.8	2.1
MIDDLE ATLANTIC	20	2,966	64,256	66,532	2.5	0.6	3.5
SOUTH ATLANTIC	60	9,344	53,734	55,030	2.5	0.4	2.4
EAST NORTH CENTRAL	46	5,386	57,031	58,624	2.5	0.4	2.8
EAST SOUTH CENTRAL	32	3,243	49,350	50,806	2.5	0.6	3.0
WEST NORTH CENTRAL	21	2,342	51,228	52,866	2.5	1.2	3.2
WEST SOUTH CENTRAL	90	10,535	49,783	50,363	2.5	−0.7	1.2
MOUNTAIN	25	2,113	57,008	57,910	2.5	−0.5	1.6
PACIFIC	23	5,734	69,810	71,030	2.4	−0.8	1.7
BY BED SIZE:							
BEDS: 0–24	36	2,096	54,340	55,256	2.5	−0.1	1.7
BEDS: 25–49	152	16,712	49,714	50,809	2.5	0.2	2.2
BEDS: 50–74	75	10,521	56,893	58,344	2.5	0.2	2.6
BEDS: 75–124	44	8,407	63,364	64,759	2.5	−0.2	2.2
BEDS: 125+	20	5,256	59,958	60,946	2.5	−0.4	1.6

[1] Estimated FY 2026 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 due to the proposed annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 due to the proposed changes to the area wage level adjustment under § 412.525(c) (that is, the proposed updated hospital wage data and the proposed labor-related share) with budget neutrality.

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 (shown in Column 4) to FY 2026 (shown in Column 5), due to all of the proposed changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this proposed rule. We note that this column, which shows the percent change in estimated payments per discharge due to all proposed changes, does not equal the sum of the percent changes in estimated payments per discharge due to the proposed annual update to the LTCH PPS standard Federal payment rate (Column 6) and due to the proposed changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2024 LTCH cases (from 327 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the proposed LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to increase 2.2 percent, on average, for all LTCHs from FY 2025 to FY 2026 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 2.2 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2026 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed rule) to estimated FY 2025 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this appendix).

As stated previously, we are proposing an annual update to the LTCH PPS standard Federal payment rate for FY 2026 of 2.6 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a proposed budget neutrality factor for changes to the area wage level adjustment of 1.0012146 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section of the proposed rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.5 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2025 to FY 2026. We note our estimate of the changes in payments due to the proposed update to the LTCH PPS standard Federal payment rate also includes estimated payments for SSO cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit data under the requirements of the LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 3 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent increase in estimated payments per

discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 for all hospitals is 2.2 percent. Urban LTCHs are projected to experience an increase of 2.2 percent. Meanwhile, rural LTCHs are projected to experience an increase of 2.5 percent.

(2) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 2.1 percent. Voluntary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 of 2.8 percent. Government owned and operated LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 of 1.8 percent.

(3) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 are projected an increase from 1.2 percent in the West South Central region to 3.5 percent in the Middle Atlantic region. These regional variations are primarily due to the proposed changes to the area wage adjustment and estimated changes in outlier payments.

(4) Bed Size

LTCHs are grouped into five categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; and greater than 125 beds. We project that LTCHs with 50–74 beds will experience the largest increase in payments with 2.6 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 1.6 to 2.2 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2026 relative to FY 2025 of approximately $52 million (or approximately 2.2 percent) for the 328 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2026 relative to FY 2025 of approximately $9 million (or approximately 8.5 percent) for the 328 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2026 will represent approximately 4.5 percent of total estimated FY 2026 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2026 relative to FY 2025 of approximately $61 million (or approximately 2.5 percent) for the 328 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this proposed rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Proposed Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In sections X.C.3., X.C.4, and X.C.7. of the preamble of this proposed rule, we discuss the proposed requirements for hospitals reporting quality data under the Hospital IQR Program to receive the full annual percentage increase for the FY 2028 payment determination and subsequent years.

In the preamble of this proposed rule, we propose: (1) to modify the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) Following Acute Ischemic Stroke Hospitalization claims-based measure, beginning with the FY 2027 payment determination, associated with a July 1, 2023–June 30, 2025, performance period; (2) to modify the Hospital-Level, Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) claims-based measure beginning with the FY 2027 payment determination, associated with the April 1, 2023–March 31, 2025, performance period; (3) to modify the reporting requirements of the Hybrid Hospital-Wide Readmission (HWR) measure beginning with the FY 2028 payment determination, associated with a July 1, 2025–June 30, 2026, performance period; (4) to modify the reporting requirements of the Hybrid Hospital-Wide Mortality (HWM) measure beginning with the FY 2028 payment determination, associated with a July 1, 2025–June 30, 2026, performance period; (5) to remove the Hospital Commitment to Health Equity measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) to remove the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) to remove the Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination; and (8) to remove the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

As shown in the summary tables in section XIII.B.4.h. of the preamble of this proposed rule, we estimate a decrease of 627,027 hours at a savings of $16,116,129 in information collection burden associated with the proposed policies compared to the currently approved information collection burden estimates under OMB control number 0938–1022 (expiration date January 31, 2026). We also estimate a decrease of between 24,400 hours at a savings of $1,378,600 and 27,450 hours at a savings of $1,608,570 in information collection burden associated with the proposed policies compared to the currently approved information collection burden estimates and under OMB control number 0920–1317 (expiration date January 31, 2028).

In section X.C.7. of the preamble of this proposed rule, we propose to modify reporting requirements of the Hybrid HWR and HWM measures beginning with the FY 2028 payment determination. This modification would lower the submission thresholds for both the Hybrid HWR and HWM measures to allow for up to two missing laboratory results and up to two missing vital signs, reduce the core clinical data elements (CCDEs) submission requirement to 70 percent or more of discharges, and reduce the submission requirement of linking variables to 70 percent or more of discharges. While we are unable to quantify the associated impact, we believe these modifications would result in reducing the overall administrative burden required by hospitals to report these measures.

Regarding the remaining proposals, we do not anticipate any of these proposals would result in any additional economic impact beyond those discussed in section XIII.B.4. of the preamble of this proposed rule (Collection of Information).

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of the Hospital IQR Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years based on review of previous performance.

L. Effects of New Proposed Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section X.D. of the preamble of this proposed rule, we discuss proposed requirements for PPS-exempt cancer hospitals (PCHs) reporting quality data under the PCH Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In the preamble of this proposed rule, we proposed: (1) to remove the Hospital Commitment to Health Equity measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) to remove the Screening for Social Drivers of Health measure beginning with the CY 2024

reporting period/FY 2026 payment determination; and (3) to remove the Screen Positive Rate for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination. We also proposed to modify the public reporting requirements to allow for public reporting of the PCHQR Program on the Care Compare tool on *Medicare.gov* or a successor website in addition to current publication in the Provider Data Catalog.

As shown in the summary tables in section XIII.B.5.f. of the preamble of this proposed rule, we estimate a decrease of 107 hours at a savings of $2,921 in information collection burden associated with the proposed policies compared to the currently approved information collection burden estimates under OMB control number 0938–1175 (expiration date November 30, 2027). We do not believe any of these proposals would result in any additional economic impact beyond those discussed in section XIII.B.5. of the preamble of this proposed rule (Collection of Information).

M. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section X.E.3 of the preamble of this proposed rule, we are proposing to modify reporting requirements for the COVID–19 Vaccine: Percent of Patients/Residents Who are Up to Date measure to exclude patients who have expired in the LTCH beginning on October 1, 2026, for the FY 2028 LTCH QRP. In section X.E.4 of the preamble of this proposed rule, we are proposing to remove four standardized patient assessment data elements collected under the SDOH category from the LTCH QRP beginning with the FY 2028 LTCH QRP. Additionally, we propose to amend our reconsideration policy and process as described in section X.E.5 of the preamble of this proposed rule. Finally, in sections X.E.6 through X.E.8 of the preamble of this proposed rule, we seek public comment on several Requests for Information (RFIs), specifically: (1) future measure concepts for the LTCH QRP; (2) revisions to the data submission deadlines for assessment data collected for the LTCH QRP; and (3) advancing digital quality measurement (dQM) in the LTCH QRP.

The effect of these proposals for the LTCH QRP would be an overall decrease in burden for LTCHs participating in the LTCH QRP.

For the FY 2026 LTCH QRP, we estimate an increase in burden related to the proposal to amend the reconsideration request policy and process, as described in section X.E.4. of the preamble of this proposed rule. For LTCHs that seek to file an extension to file a request for reconsideration of a noncompliance determination, we estimate that this form will take LTCHs approximately 15 minutes to complete. We believe that this data would be entered by medical records specialists. However, LTCHs determine the staffing resources necessary.

For the purposes of calculating the costs we obtained median hourly wages from the U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates.[2] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table I.M.–01.

TABLE I.M.–01—U.S. BUREAU OF LABOR AND STATISTICS' MAY 2023 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation title	Occupation code	Median hourly wage ($/hr)	Other indirect costs and fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Medical Records Specialists	29–2072	$23.45	$23.45	$46.90

We estimate that the collection of this form will result in an additional 15 minutes, or 0.25 hours, per form. Based on the number of reconsiderations requests we have received in the previous 3 years, we estimate an average of 16 forms per year, for an additional 4 hours per year (0.25 hours × 16 forms per year) for all LTCHs. Given an estimated $46.90 hourly wage, we estimate an increase of $187.60 (4 hours × $46.90) for all LTCHs annually or $0.57 per LTCHs that submit reconsiderations.

For the FY 2028 LTCH QRP, as shown in summary table XII.B–09 in section XII.B.6. of the preamble of this proposed rule, we estimate a total information collection burden decrease for 330 eligible LTCHs of 7.98 hours per LTCH, or 2,633.51 hours for all LTCHs, for a total cost decrease of approximately −$180,016.80, or $545.51 per LTCH annually associated with our proposed policies and updated burden estimates for the FY 2028 program year compared to our currently approved information collection burden estimates. We refer readers to section XII.B.6. of the preamble of this proposed rule, where CMS has provided an estimate of the burden and cost to LTCHs, and note that it will be included in a revised information collection request for 0938–1163.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section X.F. of the preamble of this proposed rule, we discuss proposed requirements for eligible hospitals and critical access hospitals (CAHs) to report objectives and measures and electronic Clinical Quality Measures (eCQMs) under the Medicare Promoting Interoperability Program.

In the preamble of this proposed rule, we proposed to: (1) adopt a new optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange to a public health agency (PHA) that occurs using the Trusted Exchange Framework and Common Agreement (TEFCA), and where the eligible hospital or CAH meets certain additional requirements, beginning with the electronic health record (EHR) reporting period in CY 2026; (2) modify the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guides measure by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using the SAFER Guides published in January 2025 beginning with the EHR reporting period in CY 2026; (3) modify the Security Risk Analysis measure by adding a requirement for eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required under the HIPAA Security Rule beginning with the EHR reporting period in CY 2026; and (4) define the EHR reporting period in CY 2026 and subsequent years as a minimum of any continuous 180-day period within that CY for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program and to make corresponding revisions at 42 CFR 495.4.

As discussed in section XIII.B.7. of the preamble of this proposed rule, we estimate no change in information collection burden associated with our proposed policies and updated burden estimates for the EHR reporting period in CY 2026 and future years compared to our currently approved information collection burden estimates. We refer readers to section XIII.B.7. of the preamble of this proposed rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the Medicare Promoting Interoperability Program.

In section X.F.5. of the preamble of this proposed rule, we propose to adopt a new optional bonus measure under the Public Health and Clinical Data Exchange objective for health information exchange to a PHA that occurs using TEFCA, and where the eligible hospital or CAH meets certain additional requirements, beginning with the EHR reporting period in CY 2026. For eligible hospitals and CAHs that already report health information to a PHA using TEFCA, there will be no additional economic impacts if they elect to voluntarily attest to this optional bonus measure. For eligible hospitals and CAHs that are currently using another means for reporting data to a PHA and desire to attest to this optional bonus measure, there will be some non-recurring costs associated with the transition. In addition, eligible hospitals and CAHs may also incur some recurring costs associated with TEFCA connectivity depending on the nature of their agreement with the health IT vendors through which they participate in TEFCA. However, because each eligible

hospital, CAH, and health IT vendor is unique and we lack sufficient insight into the individual decisions of each, the extent of these costs is difficult to quantify.

In section X.F.4. of the preamble of this proposed rule, we propose to modify the SAFER Guides measure by requiring eligible hospitals and CAHs to attest ''yes'' to completing an annual self-assessment using the SAFER Guides that ASTP published in January 2025 beginning with the EHR reporting period in CY 2026. We do not believe this provision results in any additional economic impacts beyond those previously discussed in the FY 2022 IPPS/LTCH PPS and FY 2024 IPPS/LTCH PPS final rules (86 FR 45609 and 88 FR 59432 through 59433, respectively).

In section X.F.3. of the preamble of this proposed rule, we propose to modify the Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required under the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(B) beginning with the EHR reporting period in CY 2026. While we are proposing to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management, the costs associated with performing security risk management required under the HIPAA Security Rule are currently approved under OMB control number 0945–0003 (expiration date July 31, 2027). We do not believe this provision results in any additional economic impacts.

We do not believe the remaining provision results in any additional economic impact beyond those discussed in section XIII.B.7. of the preamble of this proposed rule (Collection of Information).

O. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered to the LTCH QRP Reporting Requirements

Regarding the proposal to remove item O0350, Patient's COVID–19 vaccination is up to date, on the LCDS with respect to patients who have expired in the LTCH, we believe this is responsive to LTCHs concerns and will help reduce assessment collection burden. We considered the alternative of continuing to collect this item with respect to patients who have expired in the LTCH but given the concerns from LTCHs and other interested parties about data collection challenges and increased provider burden in collecting immunization data, we believe maintaining this item is unwarranted. Regarding our proposal to remove four SDOH standardized patient assessment data elements, we considered keeping these items but decided not to because of the burden associated with these items at this time.

Regarding the proposal to amend the process by which an LTCH may request an extension to file a reconsideration request if the LTCH was affected by an extraordinary circumstance beyond the control of the LTCH, we considered the alternative of leaving the policy language unchanged. However, we found it important to clarify the definition of ''extraordinary'' and the process for requesting an extension to file a reconsideration request, we believe these proposals are responsive to providers' feedback.

2. Alternatives Considered for the Transforming Episode Accountability Model

In section XI.A. of the preamble of this proposed rule, we discuss the mandatory episode-based payment model called the Transforming Episode Accountability Model (TEAM). TEAM is designed to improve beneficiary care through financial accountability for episodes categories that begin with one of the following procedures: coronary artery bypass graft, lower extremity joint replacement, major bowel procedure, surgical hip/femur fracture treatment, and spinal fusion. TEAM will test whether financial accountability for these episode categories reduces Medicare expenditures while preserving or enhancing the quality of care for Medicare beneficiaries. We anticipate that TEAM would benefit Medicare beneficiaries through improving the coordination of items and services paid for through Medicare FFS payments, encouraging provider investment in health care infrastructure and redesigned care processes, and incentivizing higher value care across the inpatient and post-acute care settings for the episode.

Throughout this proposed rule, we have identified our proposed policies and alternatives that we have considered and provided information as to the effects of these alternatives and the rationale for each of the proposed policies. For example, we considered requiring new acute care hospitals that open in a mandatory core-based statistical areas (CBSA) to immediately participate in TEAM. However, we are concerned that requiring immediate participation while they are establishing their clinical and operational practices could make it challenging for new acute care hospitals to participate in the model.

We also considered multiple approaches to a low volume hospital policy, as discussed in section XI.A.2.c.(8) of the preamble of this proposed rule. While we have not proposed a low volume hospital policy, we recognize including a low volume hospital policy in TEAM would have a financial impact to TEAM's ability to save Medicare money. This is because all the options considered give some financial protection to the low volume hospital. We assessed the financial impact to TEAM by modeling the option that would result in the most cost to Medicare, specifically the option that would waive downside financial risk at the episode category level for TEAM participants that did not initiate at least 31 episodes in the baseline period. Using 2023 as a performance year and 2019–2021 as a baseline period, we simulated reconciliation results for the hospitals required to participate in TEAM. We found that applying a low volume policy where downside risk was waived for approximately 1.75% of the episodes in the model resulted in approximately $10.7 million in repayment amounts being waived. We also found that $5.8 million of the $10.7 million in repayment amounts were associated with safety net hospitals, that are already eligible to have downside risk waived if they choose to participate in Track 1 of the model. We note that our Medicare savings estimates from the FY 2025 IPPS/LTCH PPS final rule (89 FR 70026), that estimated a $481 million savings to Medicare, already assumed TEAM participants that are considered safety net hospitals, as defined at § 512.505, would have downside risk waived for the first three performance years of the model. Therefore, we anticipate the inclusion of a potential low volume hospital policy in TEAM would slightly reduce Medicare savings but would still yield overall positive savings to Medicare.

We solicit and welcome comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $4.0 billion in FY 2026, including operating, capital, and the effects of (1) new technology add-on payment changes, (2) the proposed changes to estimated uncompensated care payments and (3) the statutory expiration of the MDH program and the temporary changes to the low-volume hospital payment adjustment on October 1, 2025. The estimated change in operating payments and uncompensated care payments is approximately $3.95 billion (discussed in sections I.F of this Appendix). The estimated change in capital payments is approximately $0.21 billion (discussed in section I.I. of this Appendix). The estimated change in the combined effects of other proposed changes including new technology add-on payment changes and the statutory expiration of the temporary changes to the low-volume hospital payment adjustment on October 1, 2025, is approximately −$0.14 billion as discussed in sections I.F and I.G. of this Appendix. Totals may differ from the sum of the components due to rounding.

Table I. of section I.F. of this Appendix also demonstrates the estimated redistributional impacts of the proposed FY 2026 changes on IPPS payments relative to FY 2025.

We estimate that hospitals will experience a 2.7 percent increase in capital payments per case, as shown in Table III of section I.I. of this Appendix. We project that there will be an approximately $21 million increase in capital payments in FY 2026 compared to FY 2025.

The discussions presented in the previous pages, in combination with the remainder of this proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2026. In the impact analysis, we are using the rates, factors, and policies presented in this proposed rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY

2026. Accordingly, based on the best available data for the 328 LTCHs included in our analysis, we estimate that overall FY 2026 LTCH PPS payments would increase approximately $61 million relative to FY 2025, primarily due to the proposed annual update to the LTCH PPS standard Federal rate partially offset by an estimated decrease in high-cost outlier payments.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of this proposed rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 6,180 number of timely pieces of correspondence on the FY 2025 IPPS/LTCH proposed rule as our estimate for the number of reviewers of this proposed rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed rule is $106.42 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 15.22 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $1,619.71 (15.22 hours × $106.42). Therefore, we estimate that the total cost of reviewing this proposed rule is $10,009,807.80 ($1,619.71 × 6,180 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Table V. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the proposed changes to the IPPS presented in this proposed rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this Appendix, the net costs to the Federal Government associated with the policies in this proposed rule are estimated at $4.0 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2025 TO FY 2026

Category	Transfers
Annualized Monetized Transfers	$4.0 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers.

B. LTCHs

As discussed in section I.J. of this Appendix, the impact analysis of the payment rates and factors presented in this proposed rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2026 relative to FY 2025 of approximately $61 million based on the data for 328 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://www.reginfo.gov/public/jsp/Utilities/a-4.pdf*), in Table VI. of this Appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this proposed rule as they relate LTCHs. Table VI. of this Appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this proposed rule based on the data for the 328 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this Appendix, the net cost to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $61 million.

TABLE VI—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2025 LTCH PPS TO THE FY 2026 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$61 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this proposed rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the

provisions of this proposed rule relating to IPPS hospitals would have an economically significant impact on small entities as explained in this Appendix. Therefore, the Secretary has certified that this proposed rule is expected to have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,038 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2026,'' on average are expected to see increases in the range of 3.5 percent, primarily due to the proposed hospital rate update and proposed uncompensated care payments, as discussed in section I.F. of this Appendix. On average, the proposed rate update for these hospitals is estimated to be 2.4 percent and proposed uncompensated care payments are estimated to increase payments in FY 2026 by 1.3 percent for all hospitals.

The 328 LTCH PPS hospitals included in the impact analysis shown in ''Table IV: Impact of Proposed Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2026 (Estimated FY 2025 Payments Compared to Estimated Proposed FY 2026 Payments)'' on average are expected to see an increase of approximately 2.2 percent, primarily due to the proposed annual standard Federal rate update for FY 2026 (2.6 percent) being partially offset by a projected 0.3 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this Appendix.

This proposed rule contains a range of proposals. It provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. All alternatives considered apply to hospitals considered small businesses. The analyses discussed in this Appendix and throughout the preamble of this proposed rule constitutes our initial regulatory flexibility analysis. We are seeking public comments on our estimates and analysis of the impact of our proposals on small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.F. of this Appendix, rural IPPS hospitals with 0–49 beds (320 hospitals) are expected to experience an increase in payments from FY 2025 to FY 2026 of 2.3 percent and rural IPPS hospitals with 50–99 beds (182 hospitals) are expected to experience an increase in payments from FY 2025 to FY 2026 of 0.9 percent. These changes are primarily driven by the proposed hospital rate update and the increase in estimated uncompensated care payment offset by the statutory expiration of the MDH program. We refer readers to Table I. in section I.F. of this Appendix for additional information on the quantitative effects of the proposed policy changes under the IPPS for operating costs.

All rural LTCHs (17 hospitals) shown in Table IV. in section I.J. of this Appendix have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2025 to FY 2026 of 2.5 percent. This increase is primarily due to the combination of the proposed 2.6 percent annual update to the LTCH PPS standard Federal payment rate for FY 2026, as discussed in section I.J. of this Appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule would not mandate any requirements that meet the threshold for State, local, or Tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts state law, or otherwise has federalism implications. This proposed rule would not have a substantial direct effect on State or local governments, preempt states, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having Tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian Tribe or Tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this proposed rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act. We continue to engage in consultations with Tribal officials on IPPS issues of interest. We will use input received from these consultations, as well as the comments on the proposed rule, to inform this rulemaking.

VIII. Executive Order 14192

Executive Order 14192, titled ''Unleashing Prosperity Through Deregulation,'' was issued on January 31, 2025, and requires that ''any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations. This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. We estimate that this proposed rule would generate $17.5 million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024, over a perpetual time horizon.

Appendix B: Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this Appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2026, consistent with our approach for FY 2025, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2026

A. Proposed FY 2026 Inpatient Hospital Update

As discussed in section VI.B. of the preamble to this proposed rule, for FY 2026, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to 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 and 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 electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in this proposed rule, we are proposing to replace the 2018-based IPPS operating and capital market baskets with the rebased and revised proposed 2023-based IPPS operating and capital market baskets beginning in FY 2026.

In this FY 2026 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing to base the proposed FY 2026 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket rate-of-increase with historical data through third quarter 2024, which is estimated to be 3.2 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section VI.B. of the preamble of this FY 2026 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2024 forecast, we are proposing a productivity adjustment of 0.8 percentage point for FY 2026. We are also proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2026 market basket update and productivity adjustment for the FY 2026 IPPS/LTCH PPS final rule.

Therefore, based on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket percentage increase and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

FY 2026	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 IPPS Market Basket Rate-of-Increase	3.2	3.2	3.2	3.2
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.8	−0.8
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.4	0.0	−2.4
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.8	−0.8	−0.8	−0.8
Proposed Applicable Percentage Increase Applied to Standardized Amount	2.4	0.0	1.6	−0.8

B. Proposed FY 2026 SCH Update

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs is also subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act.

As discussed in section VI.F. of the preamble of this proposed rule, section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 extended the MDH program through FY 2025. Therefore, under current law, the MDH program will expire for discharges on or after October 1, 2025. We note that if the MDH program were to be extended by law into FY 2026, the proposed updates to the hospital-specific rates for SCHs as described in this section would also apply to the hospital-specific rates for MDHs for FY 2026. We refer readers to section V.E. of the preamble of this proposed rule for further discussion of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs.

C. Proposed FY 2026 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section VI.B.1. of the preamble of this proposed rule.

In addition, as discussed in section VI.B.2. of the preamble of this proposed rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that for FY 2024 and subsequent fiscal years, any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments).

Based on IGI's fourth quarter 2024 forecast of the proposed 2023-based IPPS market basket update with historical data through third quarter 2024, in this FY 2026 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing an IPPS market basket increase of 3.2 percent and a productivity adjustment of 0.8 percentage point. Therefore, for FY 2026, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing the following applicable percentage increases to the standardized amount for FY 2026 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 2.4 percent (that is, the FY 2026 estimate of the proposed IPPS market basket rate-of-increase of 3.2 percent less an adjustment of 0.8 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we are proposing an applicable percentage increase to the operating standardized amount of 0.0 percent (that is, the FY 2026 estimate of the proposed market basket rate-of-increase of 3.2 percent,

less an adjustment of 2.4 percentage point (the proposed IPPS market basket rate-of-increase of 3.2 percent × 0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2026 market basket percentage increase and the productivity adjustment for the FY 2026 IPPS/LTCH PPS final rule.

D. Proposed Update for Hospitals Excluded From the IPPS for FY 2026

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa). Section 1886(b)(3)(B)(ii) of the Act sets the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this proposed rule, we are proposing to use the percentage increase in the proposed 2023-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2026 and subsequent fiscal years. Accordingly, for FY 2026, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2026 percentage increase in the proposed 2023-based IPPS operating market basket. For this proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2026 is 3.2 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2026 IPPS operating market basket rate-of-increase for the FY 2026 IPPS/LTCH PPS final rule.

E. Proposed Update for LTCHs for FY 2026

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2026 by 2.6 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCH QR Program under section 1886(m)(5) of the Act, we are proposing to reduce the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are proposing to establish an update factor of 1.026 in determining the LTCH PPS standard Federal rate for FY 2026. For LTCHs that fail to submit quality data for FY 2026, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.6 percent (that is, the proposed annual update for FY 2026 of 2.6 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying a proposed update factor of 1.006 in determining the LTCH PPS standard Federal rate for FY 2026. (We note that, as discussed in section VII.D. of the preamble of this proposed rule, the update to the LTCH PPS standard Federal payment rate of 2.6 percent for FY 2026 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law plus 1.0 percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this Appendix. We are recommending that the same applicable percentage increases apply to SCHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.2 percent.

For FY 2026, consistent with policy set forth in section IX. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.6 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2026, we are recommending an annual update to the LTCH PPS standard Federal rate of 0.6 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2025 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended an update to the hospital inpatient rates by the amount specified in current law plus 1.0 percent. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law plus 1.0 percent in 2026 would generally be adequate to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to, if somewhat below, the cost of delivering high-quality care efficiently.

MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1.0 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends adding $4 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

We refer readers to the March 2025 MedPAC report, which is available for download at *https://www.medpac.gov/document-type/report/*. We look forward to working with Congress on these matters.

We are proposing an applicable percentage increase for FY 2026 of 2.4 percent as described in section 1886(b)(3)(B) of the Act, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this proposed rule.

We note that section 1886(d)(5)(F) of the Act provides for additional Medicare payment adjustments, called Medicare disproportionate share hospital (DSH) payments, for subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 1886(r) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall

pay each such subsection (d) hospital that is eligible for Medicare DSH payments an empirically justified DSH payment equal to 25 percent of the Medicare DSH adjustment they would have received under section 1886(d)(5)(F) of the Act if subsection (r) did not apply. The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments if subsection (r) of the Act did not apply, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and has uncompensated care. These additional payments are called uncompensated care payments. We refer readers to section V. of preamble of this proposed rule for a further discussion of Medicare DSH and uncompensated care payments.

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