DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 412, 495, and 512

Office of the Secretary

45 CFR Part 170

[CMS–1833–F and CMS–1808–F] RINs 0938–AV45, 0938–AV34, and 0955–AA06

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals (IPPS) and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year (FY) 2026 Rates; Changes to the FY 2025 IPPS Rates Due to Court Decision; Requirements for Quality Programs; and Other Policy Changes; Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization

AGENCY: Centers for Medicare & Medicaid Services (CMS) and Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC), Department of Health and Human Services (HHS).

ACTION: Final rules.

SUMMARY: This final rule revises the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; makes changes relating to Medicare graduate medical education (GME) for teaching hospitals; updates 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); updates and makes changes to requirements for certain quality programs; and makes other policy-related changes. We are also finalizing the provisions of the interim final action with comment period regarding the changes to the FY 2025 IPPS rates due to the court decision in *Bridgeport Hosp.* v. *Becerra.* Lastly, it finalizes certain updates to the ONC Health Information Technology (IT) Certification Program.

DATES: These final rules are effective on October 1, 2025. The incorporation by reference of certain material listed in this document is approved by the Director of the Federal Register as of October 1, 2025.

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.

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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

Ariel Cress, *Ariel.Cress@cms.hhs.gov*, Long-Term Care Hospital Quality Reporting Program—Administration Issues.

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)

Michael Lipinski, Office of Policy, Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ASTP/ONC), 202–690–7151.

SUPPLEMENTARY INFORMATION:

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2026 final 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 Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2026 final 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–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS final 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 final rule will 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 makes 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 final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. We are also making changes relating to Medicare graduate medical education (GME) for teaching hospitals.

In the Hospital Value-Based Purchasing (VBP) Program, we are finalizing modifications to the Hospital-Level Total Hip Arthroplasty/Total Knee Arthroplasty (THA/TKA) Complications measure beginning with the FY 2033 program year. We also provide notice of the technical update to the five National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) measures beginning with the FY 2029 program year, and the technical update to the six measures in the Clinical Outcomes domain beginning with the FY 2027 program year. We are finalizing removal of the Health Equity Adjustment (HEA) from the program's scoring calculations in the FY 2026 program year. We provide previously and newly established performance standards for FY 2027 through FY 2031 program years for the Hospital VBP Program.

In the Hospital-Acquired Condition (HAC) Reduction Program, we are also providing notice of the technical update to the five Centers for Disease Control and Prevention's (CDC) NHSN healthcare-associated infection (HAI) measures.

In the Hospital Readmissions Reduction Program, we are finalizing our proposal to add Medicare Advantage (MA) beneficiaries to the six Hospital Readmissions Reduction Program (HRRP) measures beginning with the FY 2027 program year; however, we are not finalizing our proposal to include payment data for MA beneficiaries in the calculation of aggregate payments for excess readmissions. We also are finalizing our proposal to reduce the applicable period from 3-years to 2-years beginning with the FY 2027 program year. We also provide notice of the technical update to remove the COVID–19 exclusion from all six readmission measures.

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

In the Hospital Inpatient Quality Reporting (IQR) Program, we are finalizing our proposals to modify four existing quality measures and to remove four existing measures. We also are finalizing our proposal, with modification, 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 with a modification.

In the Medicare Promoting Interoperability Program, we are finalizing our proposal 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 finalizing our proposal, with modifications, to revise the Security Risk Analysis measure beginning with the EHR reporting period in CY 2026. We are finalizing our proposal to modify the Safety Assurance Factors for EHR Resilience (SAFER) Guides measure beginning with the EHR reporting period in CY 2026. We are finalizing our proposal 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.

For the LTCH Quality Reporting Program (QRP), we are finalizing our proposal 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 also are finalizing our proposal to remove four Social Determinant of Health (SDOH) standardized patient assessment data elements from the LCDS. Next, we are finalizing our proposal to amend the reconsideration request process in the LTCH QRP. Finally, we include summaries of comments received in response to 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 final rule, we finalizing 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 broadening of the Skilled Nursing Facility (SNF) 3-Day Rule, and the removal of the Decarbonization and Resilience Initiative (DRI). Additionally, the policies in this final rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

The Secretary of Health and Human Services has delegated responsibilities to the Assistant Secretary for Technology Policy (ASTP)/Office of the National Coordinator for Health Information Technology (ONC) (collectively, ASTP/ONC [1]) for the implementation of certain provisions in Title IV of the 21st Century Cures Act (Public Law (Pub. L.)) 114–255, December 13, 2016) (Cures Act) that are designed to: advance interoperability; support the access, exchange, and use of electronic health information (EHI); and identify reasonable and necessary activities that do not constitute information blocking.[2] ASTP/ONC is also responsible for implementation of certain provisions of the Health Information Technology for Economic and Clinical Health Act (Pub. L. 111–5, Feb. 17. 2009) (HITECH Act) including: requirements that the National Coordinator perform duties consistent with the development of a nationwide

[1] 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).

[2] Reasonable and necessary activities that do not constitute information blocking, also known as information blocking exceptions, are identified in 45 CFR part 171 subparts B, C and D. ONC's official website, *HealthIT.gov*, offers a variety of resources on the topic of Information Blocking, including fact sheets, recorded webinars, and frequently asked questions. To learn more, please visit: *https://www.healthit.gov/topic/information-blocking/*.

health information technology infrastructure that allows for the electronic use and exchange of information and that promotes a more effective marketplace, greater competition, and increased consumer choice, among other goals; and requirements to keep or recognize a program or programs for the voluntary certification of health information technology.

Under various statutory authorities, we either discuss continued program implementation or 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 final 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 2017, 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 assess a hospital's performance relative to other hospitals with a similar proportion of beneficiaries who are dually eligible for both Medicare and full Medicaid benefits.
- 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 final rule. In general, these major provisions are being finalized 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 final rule is presented in section I.D. of the preamble of this final rule.

a. 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 final 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. We note, as discussed elsewhere, in this final rule we are finalizing the provisions of the interim final action with comment period (IFC) (89 FR 80405) (hereinafter referred to as the FY 2025 IFC), that implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those revisions, and made conforming changes to the hospital IPPS and LTCH PPS payment rates for FY 2025 to reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp.* v. *Becerra*.

For FY 2026 and subsequent fiscal years, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we are discontinuing the low wage index hospital policy and will 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 final rule, we are using 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 will be implemented in a budget neutral manner. This transitional exception policy will apply to hospitals that benefitted from the FY 2024 low wage index hospital policy and compares the hospital's FY 2026 wage index to the hospital's FY 2024 wage index. If the hospital's FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2026 for that hospital is 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 are making this policy budget neutral through an adjustment applied to the standardized amounts for all hospitals.

b. Update to the IPPS Labor-Related Share

As discussed in section IV. of the preamble of this final rule, we are finalizing our proposal 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 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we will use for discharges occurring on or after October 1, 2025. The 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 final 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 Readmissions Reduction Program

The Hospital Readmissions Reduction Program was established under section 1886(q) of the Act, as amended by section 15002 of the 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 or procedures. In this final rule, we are finalizing the following proposals, beginning with the FY 2027 program year: (1) Refine all six readmission measures to add Medicare Advantage patient cohort data; (2) reduce the applicable period from 3-years to 2-years and update codified regulation language; and (4) 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 with a modification. We also

provide notice of the technical update to remove the COVID–19 exclusion from all six readmission measures. We are not finalizing the proposal to include payment data for MA beneficiaries in the calculation of aggregate payments for excess readmissions..

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 final rule, we are making a technical update to the NHSN Healthcare Associated Infection (HAI) measures baseline. We are also finalizing our proposal 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 with a modification.

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 final rule, we are finalizing modifications to the THA/TKA Complications measure beginning with the FY 2033 program year. We also provide 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 2029 program year. We also are finalizing our proposal 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 with a modification. We are also finalizing our proposal to remove the Program's HEA adjustment in the FY 2026 program year. Lastly, we provide previously and newly established performance standards for FY 2027 through FY 2031 program years for the Hospital VBP Program.

f. 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 final rule, we are finalizing several changes to the Hospital IQR Program. We are finalizing modifications 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 finalizing the removal of 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 finalizing our proposal 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 with a modification. Additionally, we sought comments regarding measure concepts related to well-being and nutrition for future consideration. We also sought comments on the path forward for digital quality measurement and use of Fast Healthcare Interoperability Resources (FHIR).

g. 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 this final rule, we are finalizing our proposal 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 finalizing our proposals 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 program year. Lastly, we are finalizing our proposal 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 with a modification.

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

For the LTCH QRP, we are finalizing our proposal to remove one item from the LCDS with respect to patients who have expired in the LTCH. We also are finalizing our proposal to removal of four SDOH standardized patient assessment data elements from the LCDS. We are finalizing our proposal to amend the reconsideration request process in the LTCH QRP. Finally, we include a summary of comments received in response to 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.

i. 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. In this final rule, we are finalizing several changes to the Medicare Promoting Interoperability Program. Specifically, we are finalizing our proposals: (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.

j. Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this final rule, we discuss the changes we finalized and considered for 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 finalized 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) excluding Indian Health Service (IHS) hospitals from TEAM participation; (4) adding the Information Transfer Patient Reported Outcome-based Performance Measure (Information Transfer PRO–PM); (5) applying a neutral quality measure score for TEAM participants with insufficient quality data; (6) a methodology to construct target prices when there are coding changes; (7) reconstructing the normalization factor and prospective trend factor; (8) replacing the Area Deprivation Index (ADI) with the Community Deprivation Index (CDI); (9) using a 180-day lookback period and Hierarchical Condition Categories (HCC) version 28 for beneficiary risk adjustment; (10) eliminating downside financial risk for low volume hospitals; (11) aligning the date range used for episode attribution; (12) removing health equity plans and health related social needs data reporting; (13) broadening the Skilled Nursing Facility (SNF) 3-day rule waiver; (14) modifying the referral to primary care services requirement; and (15) removing the Decarbonization and Resilience Initiative (DRI).

k. ONC Health IT Certification Program Updates

In the Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability proposed rule (HTI–2 Proposed Rule) (89 FR 63498), which appeared in the **Federal Register** on August 5, 2024, ASTP/ONC proposed a wide-ranging set of updates to the ONC Health IT Certification Program. In the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit and Electronic Prior Authorization (HTI–4 final rule), which is being published as part of the FY 2026 IPPS/LTCH final rule, ASTP/ONC is finalizing a limited subset of the proposals in the HTI–2 proposed rule. In this section, ASTP/ONC describes the HTI–2 proposals it is finalizing in this rule.

(1) New and Revised Standards and Certification Criteria

(a) Minimum Standards Code Sets Updates

In section III.B.5 of the preamble of the HTI–2 Proposed Rule, ASTP/ONC proposed to adopt an updated baseline version of RxNorm, identified as a minimum standard code set, in 45 CFR 170.207(d) (Medications), and to reorganize the text of the regulation in 45 CFR 170.207(d). RxNorm is referenced in the ''electronic prescribing'' and ''real-time prescription benefit'' health IT certification criteria ASTP/ONC is also finalizing in this final rule. ASTP/ONC is finalizing these proposals in section XI.*B*.4.b.(2) of the preamble of this final rule, with modifications. Consistent with 45 CFR 170.555, health IT developers may use newer versions of the adopted baseline version of a standard identified as a minimum standard on a voluntary basis.

(b) Revised Electronic Prescribing Certification Criterion

As discussed in section XI.*B*.4.b.(3) of the preamble of this final rule, ASTP/ONC is finalizing proposed updates in the HTI–2 Proposed Rule to the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3), with modifications. ASTP/ONC is finalizing that, for technology certified to the criterion in 45 CFR 170.315(b)(3) subsequent to June 30, 2020, health IT developers must update the Health IT Module to use the National Council for Prescription Drug Programs (NCPDP) SCRIPT standard version 2023011 and provide that update to their customers in order to maintain certification of the Health IT Module, by January 1, 2028. For the time period up to and including December 31, 2027, ASTP/ONC is finalizing that developers certifying a Health IT Module to 45 CFR 170.315(b)(3) may use either the updated NCPDP SCRIPT standard version 2023011 or the NCPDP SCRIPT standard version 2017071. ASTP/ONC is also finalizing that any Health IT Modules for which a health IT developer seeks certification to the updated criterion using NCPDP SCRIPT standard version 2023011 would need to support electronic prior authorization transactions in accordance with the standard. Finally, ASTP/ONC is finalizing a series of additional updates to 45 CFR 170.315(b)(3)(ii), including removing transactions currently identified as optional for the certification criterion.

(c) New Real-Time Prescription Benefit Criterion

As discussed in section XI.*B*.4.b.(4) of the preamble of this final rule, ASTP/ONC is finalizing the proposal in the HTI–2 Proposed Rule to adopt a ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4), with modifications. Real-time prescription benefit tools empower providers and their patients to compare the patient-specific cost of a drug to the cost of a suitable alternative, compare prescription costs at different pharmacies, view information about out-of-pocket costs, and learn whether prior authorization for a specific drug is required. The certification criterion ASTP/ONC is finalizing is based on the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13. ASTP/ONC is also finalizing a proposal to include this certification criterion in the Base EHR definition in 45 CFR 170.102 after January 1, 2028. ASTP/ONC is finalizing these policies in order to implement section 119(b)(3) of Title I of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260).

(d) New Certification Criteria for Modular API Capabilities

As discussed in section XI.*B*.4.b.(5) of the preamble of this final rule, ASTP/ONC is finalizing two health IT certification criteria for ''modular API capabilities'' proposed in the HTI–2 Proposed Rule. Specifically, ASTP/ONC is finalizing certification criteria in 45 CFR 170.315(j)(20), ''Workflow triggers for decision support interventions,'' and 45 CFR 170.315(j)(21), ''Subscriptions—client,'' both of which are cross-referenced by other certification criteria ASTP/ONC is finalizing to support electronic prior authorization.

(e) New Certification Criteria for Electronic Prior Authorization

In section III.B.20 of the preamble of the HTI–2 Proposed Rule, ASTP/ONC proposed to adopt a ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34). ASTP/ONC also proposed to adopt a set of HL7® FHIR® implementation guides (IGs) in 45 CFR 170.215 for HHS use, including IGs referenced as part of the proposed criterion for electronic prior authorization and other IGs that support interoperable exchange of information between payers, providers, and patients.

In section XI.*B*.4.b.(5) of the preamble of this final rule, ASTP/ONC is finalizing three certification criteria in 45 CFR 170.315(g)(31), (32), and (33) for electronic prior authorization that are based on the requirements originally proposed in 45 CFR 170.315(g)(34), with modifications. ASTP/ONC is also finalizing adoption of the IGs proposed in section III.B.20 and incorporating these specifications by reference in 45 CFR 170.299.

ASTP/ONC is finalizing these criteria to make available Health IT Modules that can enable health care providers to conduct prior authorization transactions using payer APIs established by CMS in the Interoperability and Prior Authorization rule (89 FR 8758). Use of these Health IT Modules will also support providers and clinicians participating in the Promoting Interoperability programs and MIPS Promoting Interoperability performance category required to report on Electronic Prior Authorization measures.

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 final rule.

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Provision Description	Description of Costs, Transfers, Savings, and Benefits
Transition for the Discontinuation of the Low Wage Index Hospital Policy	As discussed in section III.F.7. of the preamble of this final rule, we are using 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 are making this policy budget neutral through an adjustment applied to the standardized amounts for all hospitals.
Update to the IPPS Labor-Related Share	As discussed in section IV. of the preamble of this final rule, we are rebasing and revising the 2018-based IPPS market basket to reflect a 2023 base year. In addition, using the cost category weights from the 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we will use for discharges occurring on or after October 1, 2025. The labor-related share of 66.0 percent is 1.6 percentage points lower than the current labor-related share of 67.6 percent. This change is budget neutral.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, acute care hospitals are estimated to experience an increase of approximately $5.0 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.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this final rule, based on the best available data for the 329 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum of this final rule, which reflect the 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 $83 million.
Changes to the Hospital Readmissions Reduction Program	We estimated that our changes for the Hospital Readmissions Reduction Program will result in no financial impact for the FY 2026 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.
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 2026 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 654,477 hours and $17,724,699 to the information collection burden for the FY 2026 payment determination or subsequent years.
Changes to the PCHQR Program	Across 11 PCHs, we estimated that our changes for the PCHQR Program will result in a decrease of 107 hours and $2,921 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.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Transforming Episode Accountability Model (TEAM)	We estimate for the TEAM proposals included in this final 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 $368 million across the 5 performance years.
HTI-2 (ASTP/ONC)	ASTP/ONC estimate that the total annual cost to developers of certified health IT and health IT purchasers for this final rule for the first year after it is finalized (including one-time costs), based on the cost estimates outlined above and throughout this RIA, would result in $50.3 million. The total undiscounted cost over a 10-year period for this final rule (starting in year two), based on the cost estimates outlined above, would result in $177.6 million. ASTP/ONC estimate the total costs to developers of certified health IT and health IT purchasers to be $228 million. ASTP/ONC estimate the total annual benefit across all entities for progress toward interoperability (progress initiated by adoption of the criteria and standards set forth in this final rule, then implemented with intermediate activities that connect such adoption with the generation of benefits) beginning in 2027, when the associated policies are required to be implemented and expected benefits to be realized, would be on average $1.0 billion. ASTP/ONC estimate the total benefits across all entities to be $19.2 billion. This benefits estimate is not comparable with the quantification of costs (totaling $228 million over ten years) because the cost of some intermediate activities has not been estimated and the cost of other intermediate activities has been attributed to other regulatory provisions, such as the ones finalized by CMS at 89 FR 8758.
FY 2025 IFC	In section XI.C. of the preamble of this final rule, we finalize the provisions of the FY 2025 IFC, which implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those revisions, and made conforming changes to the hospital IPPS payment rates for FY 2025. These changes reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp. v. Becerra.* That IFC also made conforming changes to IPPS rates and factors used to determine certain payments under the LTCH PPS for FY 2025. We estimate that acute care hospitals will experience an increase of approximately $41 million in FY 2025 due to the provisions of the FY 2025 IFC. This change is primarily due to the application of the non-budget neutral transitional payment exception policy

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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 Are Implemented in This Final 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. Issuance of a Notice of Proposed Rulemaking and Summary of the Proposed Provisions

The FY 2026 IPPS/LTCH PPS proposed rule appeared in the April 30, 2025, **Federal Register** (90 FR 18002). In the 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 proposed to make.

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

In section II. of the preamble of the proposed rule, we included 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 the proposed rule, we proposed 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 the proposed rule, we proposed to rebase and revise the IPPS market baskets to reflect a 2023 base year. In section IV.B.3. of the preamble of the proposed rule, using the cost category weights from the proposed 2023-based IPPS market basket, we proposed 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 the proposed rule, we discussed 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 the proposed rule, we discussed 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 discussed the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2026.

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 discussed 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 included 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 the 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 proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum of the proposed rule, we addressed 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 proposed 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 the 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 the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provided 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 addressed these recommendations in Appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2025 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*.

E. Public Comments Received in Response to the FY 2026 IPPS/LTCH PPS Proposed Rule

We received approximately 5,409 timely pieces of correspondence containing multiple comments on the proposed rule that appeared in the April 30, 2025 **Federal Register** (89 FR 18002) titled ''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'' (hereinafter referred to as the FY 2026 IPPS/LTCH PPS proposed rule). We note that some of these public comments were outside of the scope of the proposed rule. These out-of-scope public comments are not addressed with policy responses in this final rule. Summaries of the public comments that are within the scope of the proposed rule and our responses to those public comments are set forth in the various sections of this final rule under the appropriate heading.

II. 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).

Comment: A commenter summarized the statutory and regulatory history regarding the documentation and coding recoupment adjustments required under section (7)(b) of the TMA, Abstinence Education, and QI Programs Extension Act of 2007 (Pub. L. 110–90), as amended. The commenter reiterated its position that the total level of adjustments made by CMS under this section took back more than was authorized by Congress and stated that section 7(b)(2) of Public Law 110–90 requires CMS to increase the standardized amount by 0.9412% to avoid carrying over into FY 2026 the -3.9% reduction to the standardized amount that law required between FY 2013 and FY 2017.

Response: As of FY 2023, CMS completed the statutory requirements of section 7(b)(1)(B) of Public Law 110–90 as amended by section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112–240), section 404 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), and section 15005 of the 21st Century Cures Act (Pub. L. 114–255). As we discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44794 through 44795), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 through 58445) and in prior rules, we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. Those adjustments added up to +2.9488 percentage points, not +3.9 percentage points, and we see no evidence that Congress enacted that smaller adjustment schedule with the silent intent that CMS would later make a permanent 0.9412% payment adjustment to reach a total +3.9 percentage point adjustment. To the contrary, section 414 of MACRA instructs the agency to ''not make the adjustment (estimated to be an increase of 3.2 percent) that would otherwise apply for discharges occurring during fiscal year 2018 by reason of the completion of the adjustments required under clause (ii).'' Because the adjustment ''that would otherwise apply'' in fiscal year 2018 but for clause (1)(B)(iii) was +3.9%, the commenter's suggestion to complete making that adjustment now is inconsistent with the statute's text.

Subparagraph (b)(2) of Public Law 110–90 does not compel a contrary result. As the U.S. Court of Appeals for the D.C. Circuit has explained, that provision simply requires CMS ''to ignore recoupment adjustments'' when ''calculat[ing] and apply[ing] the annual 'percentage increase' '' to base rates provided for in the Medicare statute to account for inflation. *Fresno Community Hospital & Medical Center* v. *Cochran,* 987 F.3d 158, 163 (D.C. Cir. 2021). The Secretary has complied with that instruction. Similarly, the commenter's citations to statements the agency made in the **Federal Register** about its intent to unwind the reductions to the standardized amount the agency made between FY 2013 and FY 2017 were made before Congress passed clause (1)(B)(iii) and have been countermanded by that provision. We therefore decline the commenter's suggestion to read into section 7(b) of Public Law 110–90 implied authority to increase the standardized payment amount by 0.9412%.

C. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for 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 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.

Beginning with the MS–DRG classification change requests that are submitted for FY 2027 consideration, we plan to inform requestors via MEARIS™ if the MS–DRG classification change request is not able to be considered with the upcoming fiscal year rulemaking cycle. As in prior years, requests that may require more extensive analysis may include those involving multiple MS–DRGs, overlapping logic across multiple Major Diagnostic Categories (MDCs), special logic such as diagnosis codes combined with procedure codes, and/or complex logic including code clusters or multiple logic lists. Beginning with FY 2027 rulemaking, we will no longer summarize in the proposed and final rules those requests that are not able to be considered for the upcoming FY.

As noted previously, interested parties had to submit MS–DRG classification change requests for FY 2026 by October 20, 2024. As we have discussed in prior rulemaking and as previously noted, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. In the proposed rule, we noted those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking as summarized in the discussion that follows. We further noted 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 were not summarized or addressed in the discussion of the MS–DRG classification change requests received for FY 2026.

As discussed in the proposed rule, 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 do the following:

- 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.

In the proposed rule, we stated that we appreciated 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 also noted 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 noted 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 noted that, as discussed further in section II.C.5.c. of the preamble of the 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 proposed modifications. In addition, we stated that 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 noted in the proposed rule 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 the FY 2026 IPPS/LTCH PPS proposed rule, we also noted that we 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. We stated that in our review of the claims data to address that request we noted that a subset of the cases also reported procedure code XW0V0P7. As discussed in the proposed rule, 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. We stated that, for these reasons and those previously described, we believed additional time was needed to review and evaluate potential extensive modifications to the structure of these MS–DRGs.

In the proposed rule, we noted that 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 stated 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. We stated that additional time is needed to fully and accurately evaluate cases currently grouping to the MS–DRGs in MDC 15 to consider if restructuring the current MS–DRGs would better recognize the clinical distinctions of these patient populations.

Comment: A commenter (the manufacturer) thanked CMS for consideration of its request to reassign 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 and expressed their understanding that resources are limited such that not every request may be considered each cycle. However, the commenter stated they were hopeful that CMS would move forward with their recommendations, so that hospitals supporting these case types in FY 2026 would be compensated appropriately. The commenter provided additional information and analyses for CMS' consideration, including analyses with the proposed diagnosis code logic changes for MS–DRGs 456, 457, and 458, and stated its findings reinforce that the reassignment request for FY 2026 involving MS–DRGs 426, 427, and 428; MS–DRGs 456, 457, and 458; and MS–DRGs 447 and 448 to maintain payment accuracy and protect access to care for Medicare beneficiaries requiring advanced sacropelvic fixation is warranted, given the significant cost differences reported for these cases compared to all other cases in related MS–DRGs.

Several commenters (members of an international society for spine surgery) suggested that CMS finalize the requested reassignment of cases reporting a sacroiliac joint fusion or pelvic fixation procedure with another spinal fusion procedure code from the lower severity level to the higher severity level spinal fusion MS–DRG in FY 2026 IPPS rulemaking. The commenters stated that in comparison to standard spinal fusion cases, procedures that include sacroiliac joint fusion and pelvic fixation represent a substantial increase in surgical complexity, operative time, and instrumentation cost. According to the commenters, the addition of both sacroiliac joint fusion and pelvic fixation adjunctive to spinal fusion introduces a level of surgical intensity that is not currently accounted for in the existing MS–DRG assignments. The commenters encouraged CMS to recognize the added clinical burden and cost associated with these cases and assign them to MS–DRGs that appropriately reflect their complexity.

A commenter stated that CMS should reconsider its rejection of the request to reassign cases reporting procedures describing sacroiliac joint and pelvic internal fixation devices using a tulip connector. Another commenter stated that while there is an increased cost in performing pelvic fixation, its use dramatically lowers the risk of failure and reoperation, both of which lead to extraordinary cost escalation for care of these patients. The commenter also stated that long-term sustainability of the health care landscape depends on CMS incentivizing and supporting better care for these spinal patients through reassigning these higher cost cases to the higher paying MCC MS–DRG in the relevant MS–DRG grouping.

In response to the discussion regarding the request to reassign cases reporting procedure code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) from the lower severity level to the highest (with MCC) severity level MS–DRG among MS–DRGs 463, 464, and 465; MS–DRGs 466, 467, and 468; and MS–DRGs 492, 493, and 494, a commenter (the manufacturer) expressed concern that CMS did not act on its request and deferred the requested changes. The commenter stated its belief that without action on its request, the payment outlook for cases reporting procedure code XW0V0P7 for bone infection will result in underpayment and suppress hospital adoption and patient access to improved clinical outcomes. Additionally, the commenter stated that CMS' reasoning to defer decision making on claims reporting procedure code XW0V0P7 was based on the procedures non-O.R. designation and it was confusing to them as most treatments of bone infection with the antibiotic-eluting bone void filler (code XW0V0P7) are performed in the O.R. The commenter further stated that CMS should reconsider its FY 2026 decision to postpone action on the MS–DRG modification request to reassign cases reporting procedure code XW0V0P7 and clarify the criteria for how procedures are assigned O.R. versus non-O.R. status, as well as whether having O.R. status for a procedure code is essential for the code to potentially influence the MS–DRG assignment in the GROUPER. The commenter provided additional information and analyses for CMS' consideration and stated that cases

reporting procedure code XW0V0P7 show a compelling discrepancy in resource use that should not be ignored.

With respect to our discussion regarding the request to modify the GROUPER logic of MS–DRG 794, a commenter specifically stated they appreciate CMS' ongoing examination of the GROUPER logic for the MS–DRGs in MDC 15 (Newborns and Other Neonates with Conditions Originating in Perinatal Period) to determine if restructuring the current MS–DRGs would better recognize the clinical distinctions of these patient populations.

Response: We thank the commenters for sharing their feedback on these requests. As discussed in the proposed rule, 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 the relevant data for evaluating a potential change.

With respect to the comments received in response to our proposed rule discussion of the request to modify the GROUPER logic of MS–DRGs 426, 427, and 428, MS–DRGs 456, 457, and 458, and MS–DRGs 447 and 448, while many commenters stated their belief that a modification to the logic of these MS–DRGs is warranted for FY 2026, we note that we did not propose a change to the logic for FY 2026, nor did we state the request was specifically rejected. Rather, we noted in the proposed rule that we will continue to consider this request in connection with future rulemaking. We appreciate the analysis that the commenter (the manufacturer) performed and the findings it shared, including with the proposed changes to the diagnosis code logic for MS–DRGs 456, 457, and 458; however, as discussed in the proposed rule, the proposed changes for MS–DRGs 456, 457, and 458 involving diagnosis code logic were only one of several considerations as to why additional time is needed to evaluate the reassignment request (90 FR 18012). We note that the logic for case assignment to MS–DRGs 456, 457, and 458 is also defined by extensive fusions. In addition, MS–DRGs 426, 427, 428, 447, and 448 (that is, multiple level spinal fusions) recently became effective October 1, 2024 which we are continuing to monitor. The data analysis necessary to examine the intricate logic within the spinal fusion MS–DRGs outlined in the request is complex and requires additional time for careful consideration of case redistribution and potential relative weight impacts, in connection with other related spinal fusion procedure requests that may be discussed in future rulemaking.

With respect to the comment we received in response to our proposed rule discussion of the request to reassign cases with ICD–10–PCS code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) among MS–DRGs 463, 464, and 465; MS–DRGs 466, 467, and 468; and MS–DRGs 492, 493, and 494, while the commenter stated that CMS should reconsider the decision to postpone action on the request to modify the MS–DRG logic for the aforementioned MS–DRGs for FY 2026, we note that we did not propose a change to the logic for FY 2026. Rather, we noted in the proposed rule that we will continue to consider this request in connection with future rulemaking. We appreciate the analysis that the commenter (the manufacturer) performed and the findings it shared; however, we note that in addition to assessing impacts in association with other MS–DRG requests being considered, there are various types of bone void fillers and additional data analysis would also need to be performed to assess cases reporting the procedure codes describing those alternative products for comparison. While we did not propose a change to the assignment of these cases for FY 2026, we noted in our proposed rule discussion that we will continue to consider this request in connection with future rulemaking.

As previously discussed, we will continue to consider these issues in connection with future rulemaking. As we develop and refine our analysis of the claims data with respect to MS–DRGs in MDC 01, MDC 08, and MDC 15, we welcome 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 the FY 2026 IPPS/LTCH PPS proposed rule we provided 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 the proposed rule. We noted that this test software reflected the proposed GROUPER logic for FY 2026. Therefore, it included 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 the 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 the proposed rule. Those tables were not published in the Addendum to the 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 the 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 made 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 had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were 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 were also 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. In the proposed rule we also noted that, 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. As such, we made 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.*

We noted in the proposed rule that 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. We also stated that 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.

In association with the proposed rule, we made available the test version of the ICD–10 MS–DRG GROUPER Software, Version 43, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 43, the draft version of the Definitions of Medicare Code Edits Manual, Version 43, and the supplemental mapping files in Tables 6P.1a and 6P.1b of the FY 2025 and FY 2026 ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes which are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Comment: Commenters expressed appreciation that we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 43, along with mapping files to assist with analysis, however, the commenters stated that this version essentially only allows for a case-by-case analysis and a minimal batch analysis. The commenters stated that it would be more beneficial to have a Batch z/OS version of the test GROUPER so that it could be better utilized for broader and more meaningful analysis purposes. The commenters requested that availability of a Batch z/OS version of the test GROUPER be made publicly available for all future rulemaking.

Response: We appreciate the commenters' feedback and will take the suggestion into consideration.

Following are the changes that we proposed to the MS–DRGs for FY 2026. We invited 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 the FY 2026 IPPS/LTCH PPS proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. As discussed in the 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 referred to these claims data as the ''September 2024 update of the FY 2024 MedPAR file.''

As explained in previous rulemaking (76 FR 51487), 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 Number	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs NonCC
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 ≥ 3.0 for the three-way split within the base MS-DRG	R2 ≥3.0 for the two-way 1_23 split within the base MS-DRG	R2 ≥ 3.0 for the two-way 12_3 split within the base MS-DRG

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 the 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 2 years of data. This analysis includes 2 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.

We are making the FY 2026 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 43, the ICD–10 MS–DRG Definitions Manual files Version 43 and the Definitions of Medicare Code Edits Manual Version 43 available to the public on our CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*.

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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18015 through 18017), we discussed a request we received 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 stated in the proposed rule that we appreciated 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. As discussed 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 noted 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 referred the reader to the discussion in section II.D. of the 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.

As discussed in the proposed rule, with respect to the requestor's suggestion that a modification to the title of Pre-MDC MS–DRG 018 be proposed, we noted that the requestor did not provide a specific recommendation for FY 2026 consideration; however, we acknowledged 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 stated that 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 stated 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 proposed rule discussion, 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 noted in the proposed rule 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. We noted that 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 noted in the proposed rule 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 noted in the proposed rule 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 noted in the proposed rule 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 noted in the proposed rule 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 referred the reader to section II.C.11. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule for additional information regarding the ICD–10 C&M Committee meeting process.

As discussed in the proposed rule, 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 referred 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.

We stated that 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.

We stated that our analysis of the September 2024 update of the FY 2024 MedPAR file yielded zero cases reporting the administration of eladocagene exuparvovec; therefore, we believed it would be premature to consider the creation of a new neurosurgical gene therapy MS–DRG at this time. We also stated we appreciated

the detailed clinical information that the requestor provided and acknowledged that cases involving neurosurgery are technically complex and that patients undergoing these procedures tend to be critically ill, many with rare diseases.

We noted 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 note that procedure code 00H033J (Insertion of infusion device into brain, temporary, percutaneous approach) that describes the procedure that uses the Smartflow® Neuro Cannula was approved and finalized as reflected in the FY 2026 ICD–10–PCS code update files that were made publicly available on the CMS website on June 6, 2025 at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes*.

We also noted, 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.

Comment: A commenter (the requestor) expressed appreciation for the clarification CMS provided regarding the submission of comments related to coding requests presented during the Spring ICD–10 Coordination and Maintenance Committee Meeting and that comments submitted after the Spring meeting will be shared with the groups responsible for considering MS–DRG mappings. The commenter stated that while some stakeholders may have the resources and expertise to review meeting materials, infer potential requested mappings for all therapies requesting new codes and submit mapping comments accordingly, many stakeholders will not. The commenter stated that if an applicant is requesting an MS–DRG mapping as part of the ICD–10–PCS process, this should be made explicitly public in the meeting materials, even if it is not discussed in the meeting itself. The commenter also stated that CMS should not ask or expect all stakeholders to know enough about clinical care and CMS' mapping processes to be able to suggest an alternative mapping for a code, if required. The commenter reiterated its request for CMS to introduce a process by which stakeholders can review requested MS–DRG mappings as part of, or in parallel to, the ICD–10–PCS code request process. The commenter also requested that CMS utilize its established process to review and reconsider MS–DRG assignment when stakeholders raise concerns about CMS' assignment instead of expecting stakeholders to propose alternative mappings.

Response: We thank the commenter for the feedback. In response to the commenter's assertion that not all stakeholders may have the resources and expertise to review meeting materials, infer potential requested mappings for all therapies requesting new codes and submit mapping comments accordingly, we note that we have made all of the information and materials necessary to conduct those actions publicly available via the CMS website. Specifically, the ICD–10 Coordination and Maintenance Committee Meeting materials are available at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials*, and the meeting process is summarized in the annual rulemakings available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*. In addition, the ICD–10 MS–DRG Definitions Manual is made publicly available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*.

In response to the commenter's statement that if an applicant is requesting an MS–DRG mapping as part of the ICD–10–PCS process it should be made public in the meeting materials even if it is not discussed in the meeting itself, we note that, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, the purpose of the ICD–10 Coordination and Maintenance 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, we disagree that the information should be included in the meeting materials. We underscore that the focus of the ICD–10 Coordination and Maintenance Committee meetings is on updates and maintenance to the ICD–10 code sets and not about how a potential new code may be designated or assigned under the IPPS, which is addressed through rulemaking. These are two separate and distinct processes, each with their own objectives and timelines.

In response to the commenter's statement that CMS should not ask or expect all stakeholders to know enough about clinical care and CMS' mapping processes to be able to suggest an alternative mapping for a code, if required, we note that under our established process, we consider requests for MS–DRG classification changes on an annual basis that are submitted via MEARIS™ at: *https://mearis.cms.gov/public/home* by the designated October 20 deadline for the upcoming fiscal year. If a proposal is subsequently put forth in rulemaking and members of the public submit comments expressing disagreement with that proposal (for example, proposed new MS–DRG(s), proposed reassignment of diagnosis and/or procedure codes, or their designation), the public comments routinely provide the rationale behind the disagreement as well as alternative suggestions) for our consideration, which we may be able to further evaluate. With respect to the mapping process, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, under our established process, when a new procedure code is finalized, 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.

Comment: A commenter (the requestor) expressed appreciation that CMS shared the types of concerns and questions raised by stakeholders about the rationale for mapping new ICD–10–PCS codes for novel therapies into Pre-MDC MS–DRG 018; however, the commenter requested that CMS discuss

the rationale for mapping Orca-T allogeneic T-cell immunotherapy to Pre-MDC MS–DRG 018.

Response: We thank the commenter for the feedback. The procedure code proposal for Orca-T allogeneic T-cell immunotherapy was discussed at the March 19–20, 2024 ICD–10 Coordination and Maintenance Committee meeting. We refer the reader to the meeting materials on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials* for additional information regarding the request. ICD–10–PCS codes XW033BA (Introduction of Orca-T allogeneic T-cell immunotherapy into peripheral vein, percutaneous approach, new technology group 10) and XW043BA (Introduction of Orca-T allogeneic T-cell immunotherapy into central vein, percutaneous approach, new technology group 10) became effective October 1, 2024, for FY 2025. Under our established process, we reviewed the predecessor code assignments. The predecessor codes for Orca-T allogeneic T-cell immunotherapy (hereafter referred to as Orca-T) are procedure codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) that are designated as non-O.R. and do not affect MS–DRG assignment. We then reviewed other factors associated with Orca-T. Notably, Orca-T is a precision-engineered allogeneic stem cell and T-cell immunotherapy biologic (that is, a combination therapy comprised of immune cells, including regulatory T-cells (Tregs) and conventional T-cells (Tcons), and stem cells) that is in clinical trials and regulated under FDA section 351 of the Public Health Service Act (PHSA) as a biologic.

Allogeneic hematopoietic stem cell transplant (alloHSCT) can provide a curative therapy for many patients with advanced hematologic malignancies. Unfortunately, despite advancements in identifying matching donors and medical care, patients can experience a variety of post-transplant complications including Graft Versus Host Disease (GvHD), infection and organ failure. GvHD is a condition in which the donated cells attack the recipient's tissues which can lead to end organ damage.

Orca-T is derived from an HLA matched donor and combines progenitor stem cells along with highly purified T-cells in the form of regulatory T-cells (Tregs, a specialized CD4+ T cell subset) and conventional T-cells (Tcons). Because of its purified nature, the Tregs can proliferate and exist in a patient's tissues in a fashion not normally possible. While the stem cells serve to build a long term immune system in the recipient, the Tregs act to protect the patient's tissues and organs from GvHD and other toxicities. The Tcons component is designed to accelerate the reconstitution of a patient's immune system, mediating the graft-versus-leukemic effect, graft-versus-infection and the inflammatory responses, providing protection against infection.

Establishment of a successful allograft requires an approach that balances an enhancement of the graft-vs-tumor and graft-vs-infection effects while avoiding or limiting GvHD. While some immunotherapeutic agents treat an active disease process, the specialized cells in Orca-T are intended to immunologically mitigate significant post allograft complications such as GvHD and infection.

We note that both CAR T-cell therapy and Orca T-cell therapy are forms of immunotherapies that are indicated for patients diagnosed with acute lymphoblastic leukemia (ALL), among other types of cancer. One of the challenges experienced to date with the treatment of ALL is GvHD, which is what Orca-T is formulated to address. We also note that there are other procedure codes describing both allogeneic CAR T-cell and non-CAR T-cell immunotherapy currently assigned to MS–DRG 018. Therefore, we believe the assignment of Orca T-cell immunotherapy to Pre-MDC MS–DRG 018 is appropriate.

Comment: A commenter stated that the procedure code describing valoctocogene roxaparvovec is listed in Table 6B in association with the proposed rule and a proposed mapping to Pre-MDC MS–DRG 018, but CMS did not discuss any rationale for this proposal in the rule text. The commenter stated that the title of Pre-MDC MS–DRG 018 is Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies, and valoctocogene roxaparvovec is an off-the-shelf in vivo gene therapy that is neither a CAR–T nor an immunotherapy. Additionally, according to the commenter, it does not require the same types of complex and specialized clinical resources to administer as the other therapies assigned to Pre-MDC MS–DRG 018. The commenter further stated that, as a result, and without any discussion or explanation from CMS about why its medical advisors have proposed this, they assume that this proposed assignment is simply based on the manufacturer's request to assign its product to Pre-MDC MS–DRG 018 as part of the ICD–10–PCS code request application. The commenter stated that CMS' acceptance of this requested mapping is concerning as it seems that resource homogeneity is the only factor being relied upon. The commenter stated its understanding is that CMS has always discussed the importance of balancing both clinical and resource homogeneity when considering MS–DRG assignments for new therapies. The commenter provided an example stating that CMS assigned several hematopoietic stem cell gene therapies to autologous transplant MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC and without CC/MCC, respectively) based on the clinical similarity of the services being provided to the patient, rather than basing assignment on price point. According to the commenter, if the latter had been deemed more critical at the time of those assignments, then CMS would have assigned the therapies to Pre-MDC MS–DRG 018 as well. The commenter also stated that CMS did not propose to map eladocagene exuparvovec to MS–DRG 018 after denying its request for a new MS–DRG (as discussed later in this section), though eladocagene exuparvovec has a similar price point. The commenter stated it cannot determine any consistent logic guiding the variation in recent mapping proposals and decisions.

The commenter requested that CMS not finalize the proposed mapping of valoctocogene roxaparvovec to Pre-MDC MS–DRG 018 due to differences in clinical complexity and resource use. The commenter stated that CMS should use its established mapping process and input from its clinical advisors to assign valoctocogene roxaparvovec to a more clinically appropriate MS–DRG.

Response: In response to the commenter's request that CMS not finalize the proposed mapping of valoctocogene roxaparvovec to Pre-MDC MS–DRG 018 because it is neither a CAR–T nor an immunotherapy and does not require the same types of complex and specialized clinical resources to administer as the other therapies assigned to Pre-MDC MS–DRG 018, we note that, as discussed in prior rulemaking, consideration is given to the similarities and differences in resource utilization among patients in each MS–DRG and we strive to ensure that resource utilization is relatively consistent across patients in each MS–DRG. However, some variation in resource intensity will remain among the patients in each MS–DRG because

the definition of the MS–DRG is not so specific that every patient is identical, rather the average pattern of resource intensity of a group of patients in an MS–DRG can be predicted. We note that historically, in the development of the DRGs, the initial step in the determination of the DRG had been the assignment of the appropriate MDC based on the principal diagnosis, however, beginning with the eighth version of the GROUPER (CMS 8.0), the initial step in DRG assignment was based on the procedure being performed, thus the creation of the Pre-MDC DRGs, where the patient is assigned to these DRGs independent of the MDC of the principal diagnosis. Therefore, the logic for case assignment to Pre-MDC MS–DRG 018 does not preclude the assignment of other therapies indicated in the treatment of patients with different diagnoses. In our review of the MS–DRG assignment of valoctocogene roxaparvovec, we recognized that this technology is defined as a gene therapy. We also note that similar to the discussions in prior rulemaking with respect to the difficulty in predicting what the associated costs will be in the future for CAR T-cell and other immunotherapies that remain under development (87 FR 48806), it is also difficult to predict what the associated costs will be in the future for cell and gene therapies that remain under development or in clinical trials.

In response to the commenter's assertion that CMS did not use its established mapping process and input from its clinical advisors to assign valoctocogene roxaparvovec to a more clinically appropriate MS–DRG, as discussed in the preamble of the proposed rule (90 FR 18016) and this final rule, and as noted in prior rulemaking, 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. As noted previously and in prior rulemaking, 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.). We note that the proposal to create new procedure codes that describe the administration of valoctocogene roxaparvovec was discussed at the September 10, 2024 ICD–10 Coordination and Maintenance Committee meeting. The predecessor codes to describe the administration of valoctocogene roxaparvovec are ICD–10–PCS codes 3E033GC (Introduction of other therapeutic substance into peripheral vein, percutaneous approach) and 3E043GC (Introduction of other therapeutic substance into central vein, percutaneous approach) which are designated as non-O.R. and do not impact MS–DRG assignment. 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 code request, including a recording of the discussion and the related meeting materials. We also note that the procedure codes to describe the administration of valoctocogene roxaparvovec were approved and finalized as reflected in Table 6B.—New Procedure Codes associated with the proposed rule and this final rule (and available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*) as well as reflected in the FY 2026 ICD–10–PCS code update files that were made publicly available on the CMS website on June 6, 2025 at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes.* As discussed in section II.C.11. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee meeting process that have been finalized after the review of public comments. As also discussed in the preamble of the proposed rule (90 FR 18067) and this final rule, we proposed 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 associated with the proposed rule. Therefore, the public has the opportunity to comment and provide feedback on the proposed assignments for CMS' consideration, which is subsequently included in the final rule with a summary of the comments and feedback and CMS' response, as is reflected in the discussion in this section of this final rule.

In response to the commenter's statement that valoctocogene roxaparvovec does not require the same types of complex and specialized clinical resources to administer as other therapies assigned to Pre-MDC MS–DRG 018, we note that valoctocogene roxaparvovec is indicated in the treatment of Hemophilia A, an X-linked genetic disorder that results in a dysfunction in the gene encoding for Factor VIII which is essential for proper coagulation. Patients may have varying degrees of functional activity of Factor VIII with severe activity (< 1IU per deciliter) resulting in spontaneous hemorrhage. This can result in life threatening hemorrhages into the brain or lead to debilitating hemorrhages in the soft tissues or joints leading to chronic pain or arthropathy. While prophylactic regimens may improve outcomes, they do not address the underlying dysfunctional gene encoding for Factor VIII. Valoctocogene roxaparvovec is a one-time therapy that uses an adeno-associated virus (AAV5) to deliver a functional copy of the F8 gene which is responsible for the production of Factor VIII.

Valoctocogene roxaparvovec is similar to other gene based therapies currently assigned to Pre-MDC MS–DRG 18 such as prademagene zamikeracel (Zevaskyn™) and CAR T-cell therapy in that these treatments involve introduction of genetic material into a patient's cells to treat a disease process. CAR T-cell therapy uses a patient's genetically modified T-cells to treat cancer while prademagene zamikeracel and valoctocogene roxaparvovec introduce functional deoxyribonucleic acid (DNA) copies into a patient's skin and liver, respectively, to correct an inherited genetic dysfunction. While they are similar in character to the hematopoietic stem cell gene therapies assigned to autologous transplant MS–DRGs 016 and 017 (Autologous Bone Marrow Transplant with CC/MCC and without CC/MCC, respectively), resource utilization differs. Prademagene zamikeracel and valoctocogene roxaparvovec involve introduction of genetic material into mature cells while hematopoietic gene therapy involves introduction of genetic material into stem cells which require a level of resource utilization more akin to other therapies in MS–DRGs 016 and 017.

In response to the commenter's assumption that the manufacturer requested assignment to Pre-MDC MS–DRG 018 in association with its procedure code request, we note that it did not. We also take this opportunity to emphasize that, as has been discussed in prior rulemaking with respect to gene therapies, 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 also note that valoctogene roxaparvovec is primarily administered in the outpatient setting (for example, hemophilia treatment centers). However, in rare instances when the therapy is administered in the inpatient setting or the patient must be transferred to the inpatient setting, providers are equipped with a specific procedure code to report its use in connection with a predictable payment mechanism under the IPPS.

Comment: A commenter stated they support appropriate and ongoing refinement of the MS–DRG system and greater clarity with respect to how CMS renders decisions regarding ICD–10–PCS codes mapped to Pre-MDC MS–DRG 018. Another commenter recommended that CMS dedicate space in each IPPS proposed rule to identify relevant ICD–10–PCS codes that might be assigned to Pre-MS–DRG 018, along with preliminary rationales for these potential assignments.

Response: We appreciate the commenters' feedback. We note that while the establishment of Pre-MDC MS–DRG 018 has presented unique operational considerations under the IPPS, there are also over 700 other MS–DRGs that warrant continued review for ongoing refinements. In response to how CMS renders decisions regarding the mapping of procedure codes to a Pre-MDC MS–DRG, as discussed in the preamble of the proposed rule (90 FR 18068) and in this final rule, 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 or treatment of the condition. As previously noted, 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.

Comment: A commenter stated it is unclear why discussion of the request to create a new MS–DRG to describe neurosurgical gene therapies was included under the Pre-MDC MS–DRG 018 section of the proposed rule instead of under MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) where prior discussions of eladocagene exuparvovec have been included. The commenter indicated that if CMS placed this discussion in the Pre-MDC MS–DRG 018 section in an effort to seek comments about whether Pre-MDC MS–DRG 018 should be broadened to include eladocagene exuparvovec and other gene therapies that it be made explicit what information the agency is seeking from stakeholders in advance of the FY 2027 IPPS/LTCH PPS rulemaking cycle. The commenter also stated that if CMS intends for Pre-MDC MS–DRG 018 to be the primary Pre-MDC MS–DRG for all cell and gene therapies until further modifications can be made, the agency should propose to rename the MS–DRG and be consistent with mapping practices and rationale. The commenter further remarked that CMS' proposed rule analysis stated no cases reporting eladocagene exuparvovec were found, however, according to the commenter, because the product was not approved until November 2024, cases would not be expected to appear in the data.

Response: As stated in the preamble of the proposed rule (90 FR 18016), 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, which we believe was appropriately placed and discussed in that section of the preamble of the proposed rule. As also explicitly stated in the preamble of the proposed rule (90 FR 18017), 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, therefore, we believe that our intentions were clearly stated. In response to the commenter's suggestion that a proposal to revise the title for Pre-MDC MS–DRG 018 should be put forth if CMS aims to temporarily designate Pre-MDC MS–DRG 018 as the primary Pre-MDC MS–DRG for all cell and gene therapies, we note that, as also stated in the preamble of the proposed rule, (90 FR 18016), 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 stated we will continue to review additional feedback and suggestions in connection with future rulemaking. In response to the commenter's remarks that CMS' proposed rule analysis stated no cases were found to report the administration of eladocagene exuparvovec and because the product was not approved until November 2024, cases would not be expected to appear in the data, we note that procedure code XW0Q316 (Introduction of eladocagene exuparvovec into cranial cavity and brain, percutaneous approach, new technology group 6) that describes the administration of eladocagene exuparvovec became effective October 1, 2020 (FY 2021) and a single case was previously identified in the data in MS–DRG 829 (Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Other Procedures with CC/MCC) with an average length of stay of 2 days and average costs of $1,544, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48854). We further note that, as also discussed in prior rulemaking, the creation of a code to describe a technology that is utilized in the performance of a procedure or service does not require FDA approval of the technology nor is the proposed and final assignment of a procedure code to an MS–DRG dependent upon a product's FDA approval (86 FR 44806).

Several commenters provided general feedback on the subject of cell and gene therapies for CMS' consideration in association with the Pre-MDC MS–DRG 018 proposed rule discussion. Notably, commenters suggested that CMS: (1) issue a Request for Information (RFI) to obtain additional insight on provider experiences, including information on the therapies under development and expected to become available in the near future, as well as features of their administration and the affected patient populations, (2) develop a payment model or long-term solution for appropriate payment that also accounts for products whose new technology add-on payment is expiring, and (3) ensure transparency in the refinement process by collaborating with stakeholders.

We appreciate the commenters' recommendations and feedback as we continue to examine the complexities involved with these therapies under the IPPS. We intend to address any potential modifications to the MS–DRGs through future notice and comment rulemaking.

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

a. Logic for MS–DRGs 023 Through 027

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18017

through 18025), 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 final 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.

We noted in the proposed rule that 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 (Craniotomy with Acute Complex CNS Principal Diagnosis with MCC or Antineoplastic Implant). 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, as discussed in the proposed rule, we reviewed the GROUPER logic for MS–DRGs 023 and 024 (Craniotomy with Acute Complex CNS Principal Diagnosis without MCC). We noted in the proposed rule that 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

We stated that 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, we noted 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 Responsive Neurostimulation (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.

As discussed in the preamble of the proposed rule, 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 stated we reviewed the claims data, and did 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. We stated that 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, 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 did not propose 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 did 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 in the proposed rule, 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, in the proposed rule we stated 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 was 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 the FY 2026 IPPS/LTCH PPS proposed rule to ensure clinical coherence between these cases and the other cases with which they would 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

In the proposed rule we stated that 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 stated 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 noted in the proposed rule 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 stated 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 proposed 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 also proposed 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.

Comment: Commenters supported the proposals to add procedure codes 00H001Z, 00H005Z, 00H031Z, and 00H041Z to the ''Chemotherapy Implant'' logic list in MS–DRGs 023 and 024 and to change the description of the logic list in MS–DRGs 023 and 024 from ''Chemotherapy Implant'' to ''Antineoplastic Implant'', effective October 1, 2025, for FY 2026.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add procedure codes 00H001Z, 00H005Z, 00H031Z, and 00H041Z to the ''Chemotherapy Implant'' logic list in MS–DRGs 023 and 024, without modification, effective October 1, 2025, for FY 2026. We are also finalizing the change of the description of the logic list in MS–DRGs 023 and 024 from ''Chemotherapy Implant'' to ''Antineoplastic Implant''.

As mentioned previously, and as discussed in the 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.''

We stated in the proposed rule that 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 percent 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.

We stated in the proposed rule that 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, as discussed in the proposed rule, 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 stated that 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 noted in the proposed rule 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 the 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 stated 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.

In the proposed rule, we stated we reviewed the claims data, and the data did 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. We stated 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 stated 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 did not propose 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 did 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, we stated 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 stated 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 the 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, as discussed in the proposed rule, 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).

In the proposed rule, we stated 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 in the proposed rule 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. We further noted that 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.

In the proposed rule, we stated 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final rule (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.

As discussed in the proposed rule, 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 noted in the proposed rule 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 stated 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.

As discussed in the proposed rule, 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 noted in the proposed rule 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 stated 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 stated we did 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 stated 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 noted in the proposed rule 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 did 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, we stated in the proposed rule that 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 did 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, we stated 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.

As discussed in the proposed rule, we reviewed these issues and noted 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, we stated that 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 stated 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 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**

In the proposed rule we stated we reviewed these data and did 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 noted in the proposed rule 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 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 stated in the proposed rule 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.

As discussed in the proposed rule, 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.'' We noted in the proposed rule that 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 the 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 intracranial vascular procedures and the 66 diagnosis codes describe a diagnosis of intracranial hemorrhage, in the proposed rule we stated 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 proposed to add the 57 procedure codes to the ''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.

As discussed in the proposed rule, in reviewing the claims data from the September 2024 update of the FY 2024 MedPAR file and examining the clinical considerations, we stated 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 stated 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.

In the proposed rule, we stated 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 stated that 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 proposed 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 also proposed 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 the 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 proposed 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, as discussed in the proposed rule, 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 Cost
020	All Cases	2,322	12.5	$71,916
	-- 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**

In the proposed rule, we stated 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. We stated that 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 proposed 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 also proposed 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 also proposed to delete the ''Major Device Implant,'' ''Epilepsy Principal Diagnosis,'' ''Neurostimulator'' logic lists from MS–DRGs 023 and 024. Lastly, for consistency, we proposed 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,'' proposed 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 proposed 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.

Comment: Commenters supported the proposal to add the 57 procedure codes to the ''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.

Response: We appreciate the commenters' support.

Comment: Several commenters supported our proposal 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. A few commenters expressed gratitude to CMS for its thorough analysis and fully supported the proposal, urging CMS to finalize it in its current form. A

commenter specifically stated that this proposal supports their longstanding goal of providing more appropriate payment levels for hospitals furnishing intracranial vascular procedures that are assigned to MS–DRGs 020, 021, and 022 after multiple years of payment declines. Another commenter stated that the proposal recognizes the similarities in clinical characteristics associated with deep brain stimulators for Parkinson's disease, essential tremor, epilepsy, and dystonia and stated that the proposed reassignments better represent the resource utilization associated with inserting a full deep brain stimulator system.

Many other commenters expressed their concerns with the proposals. Some commenters noted that procedure code 00H004Z (Insertion of radioactive element, cesium-131 collagen implant into brain, open approach) is included in the Chemotherapy Implant logic list of MS–DRG 023 and suggested that this assignment does not accurately reflect the increased resources required to perform procedures involving the insertion of radioactive implants. Several commenters stated that with CMS' proposed reassignment of neurostimulator cases out of MS–DRG 023, these procedures involving the insertion of radioactive implants will be grouped with acute complex central nervous system (CNS) procedures, and this grouping is clinically inconsistent, as the majority of acute CNS cases describe conditions treated without implanted devices. Other commenters stated that while procedures involving the insertion of radioactive implants and procedures involving the introduction of chemotherapy both involve the delivery of either radiation or chemotherapy directly after tumor resection, the overall care pathway and resources associated with the episodes of care are dramatically different. These commenters stated that procedures involving the insertion of radioactive implants are more aligned with major device implant procedures than with the acute complex CNS cases that will remain in MS–DRG 023. Another commenter stated they performed their own analysis and stated that they found that procedures involving the insertion of radioactive implants have consistently demonstrated higher resource use than antineoplastic chemotherapy implant cases across two consecutive years of MedPAR data and are more closely aligned with cases assigned to MS–DRGs 020, 021 and 022. These commenters recommended that cases reporting procedure code 00H004Z, such as cases involving GammaTile®, which is a surgically implanted brachytherapy device used to treat patients with malignant brain tumors, be assigned to MS–DRGs 020, 021, and 022.

Other commenters expressed concerns with the proposal to reassign 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) with a principal diagnosis of epilepsy from MS–DRG 023 to MS–DRGs 020, 021, and 022. These commenters stated that this proposal would have devastating impacts on hospital payment, which in turn would impact the ability of hospitals to continue to offer the RNS® neurostimulator to Medicare beneficiaries. While thanking CMS for continuing to explore solutions to better align the resource utilization of epilepsy with neurostimulator cases, some commenters stated the proposed reassignment would result in a greater misalignment of hospital costs, resulting in a significant reduction in hospital payment for the vast majority of epilepsy with neurostimulator cases. A commenter specifically stated that they performed their own analysis and found that most epilepsy with neurostimulator cases do not report a secondary diagnosis designated as an MCC, therefore reassigning these cases to MS–DRGs 020, 021, and 022 without maintaining the ''Epilepsy Principal Diagnosis,'' ''Neurostimulator'' logic lists in these MS–DRGs will have the opposite effect and will decrease hospital payments even further. Many commenters requested that CMS modify its current proposal and assign all 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) with a principal diagnosis of epilepsy to MS–DRG 020 even if there is no MCC reported.

Response: We appreciate the commenters' feedback and thank the commenters for sharing their concerns.

In response to the commenters' concerns that finalizing our proposal could adversely affect cases reporting procedure code 00H004Z and 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, we performed additional analysis of these cases. As discussed in the preamble of the proposed rule, MS–DRGs 023 and 024 contain a logic list referred to as ''Chemotherapy Implant.'' This logic list includes four ICD–10–PCS codes: 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), and 3E0Q705 (Introduction of other antineoplastic into cranial cavity and brain, via natural or artificial opening). In our analysis discussed in the proposed rule, we 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 ''Chemotherapy Implant'' logic list in MS–DRG 023.

To evaluate the commenters' concerns regarding cases involving the insertion of radioactive implants, we further 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 procedure code 00H004Z specifically. The following table shows our findings:

MS-DRG 023	Number of Cases	Average Length of Stay	Average Costs
All cases	12,136	10	$51,132
Cases reporting procedure code 00H004Z	111	5.5	$53,666

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 111 cases reporting procedure

code 00H004Z with an average length of stay of 5.5 days and average costs of $53,666.

Because all cases reporting a procedure code included in the logic list referred to as ''Chemotherapy Implant'' are assigned to the higher severity level (with MCC) MS–DRG 023 and there is a three-way split within MS–DRGs 020, 021, and 022, we next analyzed the 111 cases reporting a procedure code 00H004Z in MS–DRG 023 for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
023	Cases reporting procedure code 00H004Z with a secondary diagnosis code designated as an MCC	77	6.5	$57,820
	Cases reporting procedure code 00H004Z with a secondary diagnosis code designated as a CC	23	3.5	$46,741
	Cases reporting procedure code 00H004Z without a secondary diagnosis code designated as a CC or an MCC	11	2.1	$39,075

We then examined claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRGs 020, 021, and 022. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
020	2,322	12.5	$71,916
021	642	7.8	$48,421
022	385	2.4	$28,243

As shown in the table, the data analysis performed indicates that the 77 cases in MS–DRG 023 reporting procedure code 00H004Z with a secondary diagnosis code designated as an MCC have a shorter average length of stay (6.5 days versus 12.5 days) and lower average costs ($57,820 versus $71,916) when compared to all the cases in MS–DRG 020. The 23 cases in MS–DRG 023 reporting procedure code 00H004Z with a secondary diagnosis code designated as an CC have a shorter average length of stay (3.5 days versus 7.8 days) and lower average costs ($46,741 versus $48,421) when compared to all the cases in MS–DRG 021. The 11 cases in MS–DRG 023 reporting procedure code 00H004Z without a secondary diagnosis code designated as an CC or an MCC have a shorter average length of stay (2.1 days versus 2.4 days) and higher average costs ($39,075 versus $28,243) when compared to all the cases in MS–DRG 022. These data reflect when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC, the 111 cases in MS–DRG 023 reporting procedure code 00H004Z have lower average costs and shorter lengths of stay than the cases in the FY 2024 MedPAR file for MS–DRGs 020 and 021 while having higher average costs and shorter lengths of stay than the cases in MS–DRG 022.

While the 111 cases reporting procedure code 00H004Z have average costs that are higher than the average costs of all cases in their currently assigned MS–DRG 023 ($53,666 versus $51,132), we do not believe it would be appropriate to reassign the cases reporting procedure code 00H004Z to MS–DRG 020, 021, and 022 as the cases are not clinically coherent with regard to resource utilization as reflected in the difference in average costs when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC.

We then performed a similar analysis for 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® neurostimulator) and a principal diagnosis of epilepsy. As discussed in the proposed rule, for MS–DRG 023, 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) and a principal diagnosis of epilepsy with an average length of stay of 2.4 days and average costs of $66,303. Because all 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 are assigned to the higher severity level (with MCC) MS–DRG 023 and there is a three-way split within MS–DRGs 020, 021, and 022, next we analyzed the 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) and a principal diagnosis of epilepsy in MS–DRG 023 for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC).

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
023	Cases with a principal diagnosis of epilepsy and a secondary diagnosis code designated as an MCC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	9	4.6	$66,945
	Cases with a principal diagnosis of epilepsy and a secondary diagnosis code designated as a CC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	23	2.6	$76,648
	Cases with a principal diagnosis of epilepsy without a secondary diagnosis code designated as a CC or an MCC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	36	1.8	$59,534

The data analysis performed indicates that the 9 cases in MS–DRG 023 reporting a principal diagnosis of epilepsy and a secondary diagnosis code designated as an MCC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have a shorter average length of stay (4.6 days versus 12.5 days) and lower average costs ($66,945 versus $71,916) when compared to all the cases in MS–DRG 020. The 23 cases in MS–DRG 023 reporting a principal diagnosis of epilepsy and a secondary diagnosis code designated as a CC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have a shorter average length of stay (2.6 days versus 7.8 days) and higher average costs ($76,648 versus $48,421) when compared to all the cases in MS–DRG 021. The 36 cases in MS–DRG 023 reporting a principal diagnosis of epilepsy without a secondary diagnosis code designated as a CC or an MCC with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have a shorter average length of stay (1.8 days versus 2.4 days) and higher average costs ($59,534 versus $28,243) when compared to all the cases in MS–DRG 022.

As shown in the table, when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC, the 68 cases in MS–DRG 023 reporting a principal diagnosis of epilepsy with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have higher average costs and shorter lengths of stay than the cases in the FY 2024 MedPAR file for MS–DRGs 021 and 022 while having lower average costs and shorter lengths of stay than the cases in MS–DRG 020. We note, similar to the commenters' analysis, our analysis using the September 2024 update of the FY 2024 MedPAR file reflects that the majority of the cases (36) 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 do not also report secondary diagnoses designated as CCs or MCCs.

While the 68 cases reporting a principal diagnosis of epilepsy with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have average costs that are higher than the average costs of all cases in their currently assigned MS–DRG 023 ($66,303 versus $51,132), the data indicate that the difference in average costs is $12,382 ($71,916 − $59,534 = $12,382) for the majority of the cases which describe 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 without reporting a secondary diagnosis code designated as a CC or an MCC in MS–DRG 023 when compared to all the cases in MS–DRG 020. We do not believe it would be appropriate to reassign all cases reporting a principal diagnosis of epilepsy with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into the brain to the highest severity level (with MCC) MS DRG 020 as the majority of the cases are not clinically coherent with regard to resource utilization as reflected in the difference in average costs.

After consideration of the public comments we received, and for the reasons discussed, we believe that further analysis of cases reporting the insertion of a radioactive element into the brain and 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 prior to generally finalizing further reassignment of these cases to ensure clinical and resource coherence between these cases and the other cases with which they may potentially be grouped. Accordingly, we believe it would be appropriate to take additional time to examine the relevant clinical factors and similarities in resource consumption in order to best represent these subsets of patients within the MS–DRG classification and improve the overall accuracy of the IPPS payments.

CMS appreciates the comments submitted in response to our proposal as discussed in the FY 2026 IPPS/LTCH PPS proposed rule. We continue to be attuned to the requestors' and the commenters' concerns about payment for cases reporting procedure codes describing the insertion of the RNS® neurostimulator, the implantation of a DBS system, or the insertion of antineoplastic implants and note that our work in this area is ongoing. As stated in prior rulemaking, we recognize the logic for MS–DRGs 020 through 027 has grown more complex over the years and continue to believe there is an opportunity for further refinement. As discussed in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58661 through 58667), we have begun to analyze the ICD–10 coded claims data to determine if the patients' diagnoses, the objective of the procedure performed, the specific anatomical site where the procedure is performed or the surgical approach used (for example, open, percutaneous, percutaneous endoscopic, among others) demonstrates a greater severity of illness and/or increased treatment difficulty as we consider where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to MS–DRGs 020 through 027, including how to better

align the clinical indications with the performance of specific intracranial procedures. CMS will continue to monitor and analyze the claims data with respect to MS–DRGs 020 through 027 as we further examine the logic for case assignment to the craniotomy MS–DRGs and we will continue to consider these issues as we develop potential future rulemaking proposals. Feedback and other suggestions on what other factors should be considered in a potential restructuring of these MS–DRGs may continue to be directed to MEARIS™, discussed in section II.C.1.b. of the preamble of this final rule at: *https://mearis.cms.gov/public/home*.

In summary, for FY 2026, after consideration of the public comments we received and for the reasons discussed, we are generally not finalizing our proposed changes to the assignment of the cases reporting the insertion of an intracranial neurostimulator implant, other than the changes described in more detail in the discussion that follows.

For FY 2026, 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 will be maintained in MS–DRG 023. We are not finalizing our proposal to add 114 procedure code combinations to a ''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. Accordingly, the ''Major Device Implant,'' ''Epilepsy Principal Diagnosis,'' ''Neurostimulator'' logic lists will be maintained in MS–DRGs 023 and 024 for FY 2026.

We are also not finalizing our proposals 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,'' 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,'' or 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.''

As discussed earlier in this section, we noted that 36 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, in MS–DRG 023 and 024, 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. As discussed in the proposed rule, our analysis indicated 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 then examined the data to determine how the resources for the subset of cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain compared to cases in MS–DRGs 023 and 024, and similarly found that the cases reporting the insertion of a single array generator and insertion of neurostimulator lead into brain have average costs that are higher and an average length of stay that is shorter than all cases in MS–DRGs 023 and 024. In the FY 2026 proposed rule we stated 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. While we continue to believe that reassigning 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 not fully address the difference in resource utilization in these cases, we believe that adding the 36 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 to the ''Major Device Implant'' logic list under MS–DRGs 023 and 024 for FY 2026 would better reflect hospital resource utilization and appropriately group these cases describing single array stimulator generator combinations with those cases describing multiple array generator combinations consistent with our proposal. Therefore, for the reasons discussed, we are finalizing the addition of the 36 ICD–10–PCS procedure code combinations 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 to the ''Major Device Implant'' logic list in MS–DRGs 023 and 024. We refer the reader to Table 6P.2b associated with this FY 2026 IPPS/LTCH PPS final rule (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 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 that are being added to the ''Major Device Implant'' logic list in MS–DRGs 023 and 024.

We also note that as discussed earlier in this section, after consideration of the public comments we received, we are finalizing our proposal to add procedure codes 00H001Z, 00H005Z, 00H031Z, and 00H041Z to the ''Chemotherapy Implant'' logic list in MS–DRGs 023 and 024, without modification, effective October 1, 2025, for FY 2026. We are also finalizing the change of the description of the logic list in MS–DRGs 023 and 024 from ''Chemotherapy Implant'' to ''Antineoplastic Implant''. Therefore, for consistency with our finalized changes to the logic list, we are finalizing a change to 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 Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Antineoplastic Implant or Epilepsy with Neurostimulator.''

Comment: Several commenters noted that in Table 6P.2c associated with the FY 2026 IPPS/LTCH PPS proposed rule, which contains the list of the 57 ICD–10–PCS procedure codes that were inadvertently excluded from the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022, ICD–10–PCS codes 057L3DZ (Dilation of intracranial vein with intraluminal device, percutaneous approach) and 057L4DZ (Dilation of intracranial vein with intraluminal device, percutaneous endoscopic approach) were included. These commenters noted that ICD–10–PCS code 057L0DZ (Dilation of intracranial vein with intraluminal device, open approach) was not also included in the list and recommended CMS consider also adding procedure code 057L0DZ to the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022, as this code also describes dilation of an intracranial vein with an intraluminal device, differing only in approach. Several commenters specifically stated that they were unclear on the rationale for not including ICD–10–PCS code 057L0DZ (Dilation of Intracranial Vein with Intraluminal Device, Open Approach) to the logic list of MS–DRGs 020, 021, and 022.

Response: We appreciate the commenters' feedback. In the ICD–10 MS–DRGs Version 42.1, ICD–10–PCS procedure codes 057L3DZ and 057L4DZ are currently assigned to MS–DRGs 023, 024, 025, 026, and 027. As we noted in the proposed rule, during our review of MS–DRGs 020, 021, and 022, we identified 57 ICD–10–PCS procedure codes describing intracranial vascular procedures that were inadvertently excluded from the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022. We note that we identified the 57 procedure codes by comparing the logic lists in MS–DRGs 023, 024, 025, 026, and 027 to the logic list of MS–DRGs 020, 021, and 022.

ICD–10–PCS procedure code 057L0DZ (Dilation of intracranial vein with intraluminal device, open approach) is currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System) MS–DRGs 252, 253 and 254 (Other Vascular Procedures with MCC, with CC, without MCC respectively) and therefore was not identified in our initial review. We agree with the commenters that ICD–10–PCS code 057L0DZ describes an intracranial vascular procedure and should be added to the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022, consistent with our proposal to add the ICD–10–PCS procedure codes describing intracranial vascular procedures that were inadvertently excluded from the ''Intracranial Vascular Procedures'' logic list.

During our review of this issue identified by the commenters, we further examined the GROUPER logic that would determine the assignment of a case to MS–DRGs 020, 021, and 022. Specifically, we reviewed the ICD–10–PCS classification to determine if there were other ICD–10–PCS codes describing dilation of an intracranial vein that were not listed in the logic for MS–DRGs 020, 021, and 022. We identified the following three procedure codes.

ICD-10-PCS Code	Description
057L0ZZ	Dilation of intracranial vein, open approach
057L3ZZ	Dilation of intracranial vein, percutaneous approach
057L4ZZ	Dilation of intracranial vein, percutaneous endoscopic approach

ICD–10–PCS codes 057L0ZZ, 057L3ZZ, and 057L4ZZ are also currently assigned to MS–DRGs 252, 253 and 254 in the ICD–10 MS–DRGs Version 42.1. In response to the commenters that stated they were unclear on the rationale for not including ICD–10–PCS code 057L0DZ in the list of procedure codes proposed to be added to the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022, we have identified that the disparate MS–DRG assignments of the six ICD–10–PCS procedure codes that describe the dilation of an intracranial vein are a result of a replication error in transitioning to ICD–10. We determined it may be helpful to provide the comparable translations under ICD–9–CM for commenters to better understand how these six procedures were initially grouped to the ICD–10 MS–DRGs as a result of replication during the conversion from ICD–9 to ICD–10 based MS–DRGs. We refer the reader to Table 6P.2f associated with this FY 2026 IPPS/LTCH PPS final rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the findings from our analysis of the six procedure codes, which indicates how these procedures were classified under ICD–10–PCS based on the comparable translations under ICD–9–CM resulting in the current MS–DRG assignments.

We reviewed ICD–10–PCS codes 057L0DZ, 057L0ZZ, 057L3ZZ, and 057L4ZZ and note these codes describe intracranial vascular procedures that are consistent with the existing procedure codes included in the logic for case assignment to MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027. Accordingly, because procedure codes 057L0DZ, 057L0ZZ, 057L3ZZ, and 057L4ZZ that describe dilation of an intracranial vein were not assigned to MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027 as a result of replication in the transition from ICD–9 to ICD–10 based MS–DRGs, and are consistent with the existing procedure codes that also describe dilation of an intracranial vein currently included in the logic for these MS–DRGs, we believe that consistent with our proposal to add the other ICD–10–PCS procedure codes describing intracranial vascular procedures that were inadvertently excluded from the ''Intracranial Vascular Procedures'' logic list, procedure codes 057L0DZ, 057L0ZZ, 057L3ZZ, and 057L4ZZ should be assigned to MS–DRGs 020, 021, 022, 023, 024, 025, 026, and 027 in MDC 01, effective FY 2026.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to add the 57 procedure codes to the ''Intracranial Vascular Procedures'' logic list, and the 66 diagnosis codes to the ''Hemorrhage

Principal Diagnosis'' logic list of MS–DRGs 020, 021, and 022, with modification, effective October 1, 2025, for FY 2026. Specifically, we are also adding ICD–10–PCS codes 057L0DZ, 057L0ZZ, 057L3ZZ, and 057L4ZZ that also describe dilation of an intracranial vein to the list of procedure codes in the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022. The list of ICD–10–PCS procedure codes describing intracranial vascular procedures that we are finalizing to add to the ''Intracranial Vascular Procedures'' logic list of MS–DRGs 020, 021, and 022 are shown in Table 6P.2c associated with this final rule and available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*. In addition, we are also finalizing the assignment of ICD–10–PCS codes 057L0DZ, 057L0ZZ, 057L3ZZ, and 057L4ZZ to MS–DRGs 023, 024, 025, 026, and 027 in MDC 01 effective FY 2026.

These finalizations as discussed are reflected in the final version of ICD–10 MS–DRG Definitions Manual, Version 43 that contains the complete documentation of the GROUPER logic for MS–DRGs 020 through 027 for FY 2026 and is available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*.

b. Hypertensive Encephalopathy

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18026 through 18028, 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.

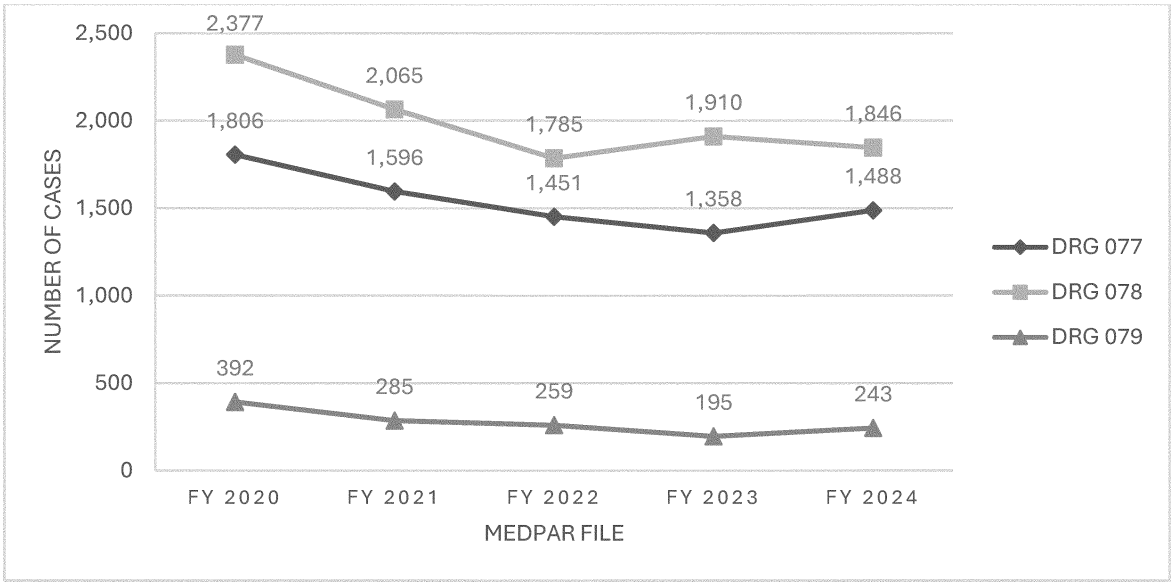
To begin our analysis, as discussed in the proposed rule, we reviewed the ICD–10–CM Tabular List of Diseases and Injuries. We stated that the requestor is correct a ''use additional code'' instructional note was added under diagnosis code I16.1 (Hypertensive emergency) in the ICD–10–CM Tabular List of 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 to be sequenced first followed by the manifestation. Wherever such a combination exists there is an '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 noted in the proposed rule 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. We stated 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 noted in the proposed rule 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

We stated in the proposed rule 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 noted in the proposed rule 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 stated 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.

As discussed in the proposed rule, 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 noted in the proposed rule that the majority of the listed MS–DRGs are assigned to MDC 01 with one exception: Pre-MDC 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 stated 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 stated 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 stated 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 in the proposed rule 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 and discussed in the proposed rule, 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.

We stated in the proposed rule 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 stated 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.

As discussed in the proposed rule, 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 stated 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 stated we believe it is appropriate to propose to revise the titles of these MS–DRGs for consistency.

In this final rule, we are amending our previous statement as the titles of MS–DRGs 067 and 068 are ''Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC'', respectively, in the ICD–10 MS–DRG Definitions Manual Version 42.1. The title of MS–DRG 069 is ''Transient Ischemia without Thrombolytic'' and was inadvertently referenced in our proposed rule discussion in connection with MS–DRGs 067 and 068.

In summary, for FY 2026, we proposed to delete MS–DRGs 077, 078, and 079. Additionally, we proposed 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 also proposed 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.

Comment: Commenters supported the proposals to delete MS–DRGs 077, 078, and 079, 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, to change the titles of MS–DRGs 067, 068, and 069 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 to ''Other Cerebrovascular Disorders with MCC, with CC, and without CC/MCC, respectively''. Some commenters stated that they supported the proposal based on CMS' data analysis, which indicates a general decline in the number of cases reporting hypertensive encephalopathy as a principal diagnosis in these MS–DRGs over the past 5 years.

Several commenters, while supporting the proposals, stated that they disagree with CMS' statement that since no ''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, the sequencing of the diagnosis codes depends on the circumstances of the encounter when hypertensive emergency and hypertensive encephalopathy are documented. These commenters stated that they do not believe this is a correct interpretation of the ICD–10–CM instructional notes. In their interpretation, when both an etiology and manifestation are documented, and a ''use additional code'' note appears at the ICD–10–CM code for the etiology, the manifestations listed in that note must be sequenced as secondary diagnosis codes, regardless of whether a corresponding ''code first'' note appears at the codes listed in the ''use additional code'' note. A commenter stated that since they question the interpretation of the instructional notes as discussed in the proposed rule, additional data analysis should be performed based on the ICD–10–CM Tabular List instructions.

Response: We appreciate the commenters' support and thank them for sharing their interpretation of the ICD–10–CM instructional notes. As noted in section II.C.11. of the preamble of this final rule, the Centers for Disease Control and Prevention's (CDC's) National Center for Health Statistics (NCHS) has lead responsibility for the diagnosis codes and CMS has lead responsibility for the ICD–10–PCS procedure codes. We note that after review of the commenters' interpretation of the ICD–10–CM Tabular List instructions, we consulted with the staff at the CDC/NCHS and NCHS confirmed that they would consider further review of the classification, including review of the Tabular List instructions for hypertensive emergency and hypertensive encephalopathy and other instances in the classification where a ''code first'' note does not appear at the manifestation code. Additionally, as we noted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38012), coding advice is issued independently from payment policy. While we collaborate with the American Hospital Association (AHA) through the Coding Clinic for ICD–10–CM and ICD–10–PCS to promote proper coding as one of the Cooperating Parties for ICD–10, the AHA is the official U.S. clearinghouse on medical coding. We recommend that an entity seeking coding guidance on reporting hypertensive emergency and hypertensive encephalopathy submit any questions to the AHA's Central Office on ICD–10 at *https://www.codingclinicadvisor.com/*.

In response to the suggestion that CMS perform additional analysis based on the commenters' interpretation of the ICD–10–CM Tabular List instructions, we note that as discussed in the proposed rule, the GROUPER logic for MS–DRGs 077, 078, and 079 is defined by only diagnosis code I67.4 listed under the heading of ''Principal Diagnosis'' in the ICD–10 MS–DRG Definitions Manual. As the GROUPER logic for MS–DRGs 077, 078, and 079 is

defined by only one diagnosis code, it is unclear how the interpretation of the ICD–10–CM Tabular List instructions would factor into our data analysis, as cases reporting a different principal diagnosis code would not be assigned to MS–DRGs 077, 078, and 079. We further note our proposal to delete MS–DRGs 077, 078, and 079 was based on our review of the findings indicating a general decline in the number of cases reporting hypertensive encephalopathy as a principal diagnosis in the inpatient setting over the past few years and in consideration of the intent of the MS–DRGs.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to delete MS–DRGs 077, 078, and 079. Additionally, we are finalizing our proposal 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. We are also finalizing our proposal 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'', without modification, effective October 1, 2025, for FY 2026.

Lastly, as discussed previously, in the ICD–10 MS–DRG Definitions Manual Version 42.1, the titles of MS–DRGs 067 and 068 are ''Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC'', respectively, and MS–DRG 069 was inadvertently referenced in our discussion in the proposed rule. Therefore, after consideration of the public comments we received, for the reasons discussed, we are finalizing our proposal with modification. Specifically, we are finalizing our proposal to change the titles of MS–DRGs 067 and 068 from ''Nonspecific CVA and Precerebral Occlusion without Infarction with MCC and without MCC'', respectively, to ''Precerebral Occlusion without Infarction with MCC and without MCC'', respectively, effective October 1, 2025. Under this finalization, the title of MS–DRG 069 will be maintained as ''Transient Ischemia without Thrombolytic'' for FY 2026.

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

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18028 through 18029), 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

As discussed in the proposed rule, 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 stated we believe that code 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 noted in the proposed rule 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.

In the proposed rule we stated 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 proposed 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 also proposed 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).

Comment: Commenters supported the proposal to assign ICD–10–CM codes Z45.31, Z45.320, Z45.321, and Z45.328 to MDCs that better describe the indication of the implanted devices of the special senses the diagnosis codes describe.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to reassign ICD–10–CM diagnosis code Z45.31 from MDC 01 MS–DRGs 091, 092, and 093 to MDC 02 MS–DRG 123 (Neurological Eye Disorders). We are also finalizing our proposal 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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18029 through 18032), we discussed a request we received 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.[3] 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.[4] [5] [6] The requestor also stated that occluding the internal iliac artery can result in significant hip and/or 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.[7] [8] 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.[9]

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.

[3] 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.

[4] 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.

[5] 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.

[6] 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.

[7] 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.

[8] 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.

[9] 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.

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, as discussed in the proposed rule, 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.

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.

We stated in the proposed rule that 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 agreed that patients who have aortoiliac and iliac aneurysms are a more complex population to treat, contributing to increased resource utilization.

Additionally, in the proposed rule we stated that, 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.

We stated we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule. We noted that, as shown in the table that follows, a three-way split of the 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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. In the proposed rule we stated we applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups. We noted 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 noted 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 proposed 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-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed MS-DRG 213	1,064	3.0	$51,784

Comment: Commenters supported the proposal to create proposed new MS–DRG 213 to differentiate resource use between standard EVAR to treat AAA and EVAR to treat AAA extending into the iliac artery. The commenters stated that they appreciated CMS' thorough analysis of the request in exploring mechanisms to address resource use of these procedures. The commenters agreed with CMS' findings that the cases reporting EVAR using an abdominal aortic aneurysm (AAA) endoprosthesis with an IBE utilize greater resources compared to the cases reporting standard EVAR using an AAA endoprosthesis and that patients who have aortoiliac and iliac aneurysms are a more complex population to treat, contributing to increased resource utilization. The commenters also acknowledged that the criteria were not met to subdivide the proposed new MS–DRG 213 further. However, the commenters stated that given that CMS' data support that patients who have EVAR procedures using an AAA endoprosthesis with an IBE are a more complex population to treat and contribute to increased resource utilization, they requested CMS reconsider the proposed relative weight of proposed new MS–DRG 213. The

commenters stated that, as reflected in Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2026 Proposed Rule, the proposed new MS–DRG 213 relative weight of 5.7834 is lower than the FY 2026 proposed relative weight of MS–DRG 268 (6.9027) and that MS–DRG 268 is the ''with MCC'' MS–DRG. A commenter who supported the proposal also encouraged CMS to continue to track the costs of these cases in future years to assess if CC subgroups would be supported.

Response: We thank the commenters for their support and feedback. The commenters are correct that in Table 5., made publicly available in association with the proposed rule at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*, the proposed relative weight for MS–DRG 213 is shown as 5.7834 and the proposed relative weight for MS–DRG 268 is shown as 6.9027. As summarized in the analysis provided in the preamble of the proposed rule (90 FR 18031) and this final rule, a total of 2,519 cases were identified in MS–DRG 268 and a total of 10,108 cases were identified in MS–DRG 269. Among the 2,519 cases in MS–DRG 268, we found 193 cases that reported EVAR using an AAA endoprosthesis with an IBE, with an average length of stay of 8.2 days and average costs of $68,145. Of the 10,108 cases in MS–DRG 269, we found 871 cases that reported EVAR using an AAA endoprosthesis with an IBE, with an average length of stay of 1.8 days and average costs of $48,159. Because most of the cases reporting EVAR using an AAA endoprosthesis with an IBE are derived from MS–DRG 269 compared to MS–DRG 268 (871 versus 193), and the cases from MS–DRG 269 have lower average costs compared to MS–DRG 268 ($48,159 versus $68,145), the data from MS–DRG 269 have a greater influence on the structure and composition of the proposed new MS–DRG 213. Alternatively, among the 2,519 cases found in MS–DRG 268, 1,500 cases reported standard EVAR using an AAA endoprosthesis with average costs of $63,877, and among the 10,108 cases in MS–DRG 269, we found 8,655 cases that reported standard EVAR using an AAA endoprosthesis with average costs of $38,562. Since the higher volume of cases in MS–DRG 268 is reflected by the cases reporting standard EVAR using an AAA endoprosthesis compared to the cases reporting EVAR using an AAA endoprosthesis with an IBE (1,500 compared to 193), the cases reporting standard EVAR using an AAA endoprosthesis have a greater influence on the revised structure and composition of MS–DRG 268, thus, the higher proposed relative weight for MS–DRG 268 compared to the proposed relative weight for the proposed new MS–DRG 213.

After consideration of the public comments we received, we are finalizing our proposal, without modification, to create new base MS–DRG 213 (Endovascular Abdominal Aorta and Iliac Branch Procedures) for FY 2026. We will continue to monitor the data for this new MS–DRG to determine if future revisions are warranted.

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 continue 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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18032 through 18035), 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.''

As discussed in the proposed rule, 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, as discussed in the proposed rule, 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 the 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.

As discussed in the proposed rule, 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 stated 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, we stated that the data do not indicate cases reporting an open valve procedure and an open surgical ablation procedure without a procedure code describing the performance of a cardiac catheterization utilize similar resources when compared to the cases assigned to MS–DRGs 216, 217, and 218. We stated that 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 noted in the proposed rule 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 stated 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. We stated our claims analysis for the 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.

We stated that 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 proposed to maintain the structure of MS–DRGs 216, 217, and 218 for FY 2026. We also proposed 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.

Comment: Commenters expressed support for the proposal to maintain the structure of MS–DRGs 216, 217, and 218 in MDC 05 for FY 2026. A commenter specifically stated that they support CMS' decision and rationale for maintaining the current structure of MS–DRGs 216, 217, and 218. Another commenter stated they acknowledge CMS' assessment that current data do not support moving these cases for the upcoming fiscal year and stated they believe that updated data will continue to reflect the greater resource utilization

of cases reporting cardiac valve procedures with surgical ablation compared to other cases in the respective MS–DRGs, and respectfully requested that CMS continue to monitor the relevant data and reassess the impact of concomitant surgical ablation in future rulemaking cycles.

Some commenters stated while they appreciate CMS' continued review of this issue and understand CMS' reasoning for proposing to maintain the current structure of MS–DRGs 216, 217, and 218 for FY 2026, the measures taken by CMS, such as revisions to the surgical hierarchy in FY 2022 and the creation of MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) in FY 2024, have not effectively addressed the increased resource demands of cases involving a single open surgical valve procedure combined with open surgical ablation despite repeated analyses over the years recognizing the higher costs associated with these procedures. A few commenters suggested that CMS should consider alternative methods of addressing the increased costs associated with cases where a single open surgical valve procedure is performed with any of the other concomitant procedures, such as the creation of new MS–DRGs, to ensure clinical coherence and more accurately reflect resource utilization. A commenter suggested that CMS amend the definition of MS–DRG 212 to address cases where a single open surgical valve procedure is performed with any of the other concomitant procedures from MDC 05 that are included in the GROUPER logic of MS–DRG 212, while another commenter suggested that CMS carefully review all concomitant procedures with higher hospital resource utilization, given the important patient care benefits and efficiencies associated with performing certain procedures concomitantly in a single encounter rather than staging separate procedures.

Response: We thank the commenters for their support, and we appreciate the commenters sharing their concerns and feedback on this proposal. While the data do not support creating a new MS–DRG for cases reporting an open valve procedure and an open surgical ablation procedure and instead suggest that cases are suitably grouped to MS–DRGs 216, 217, 218, 219, 220, and 221 where they are currently assigned based on the similarities in resource utilization compared to all the cases in their respective MS–DRG, we will continue to monitor the claims data for cases reporting an open valve procedure and an open surgical ablation procedure to determine if additional refinements may be warranted in the future. We note that we would address any proposed modifications to the existing logic in future rulemaking.

Comment: Another commenter suggested that if CMS finalizes its proposal to maintain the structure of MS–DRGs 216, 217, and 218 for FY 2026, CMS should consider partially mitigating the impact of this finalization on advanced AF patients by designating ICD–10–CM diagnosis codes I48.11 (Longstanding persistent atrial fibrillation) and I48.21 (Permanent atrial fibrillation) as MCCs on its own initiative for FY 2026 to better align appropriate resources to treat the most complex subset of patients with atrial fibrillation. This commenter stated they performed their own analysis and found that data indicate that the presence of longstanding persistent atrial fibrillation and permanent atrial fibrillation results in significant costs differences compared to other admissions.

Response: We appreciate the commenters' feedback. While we consider this comment to be outside the scope of the proposal included in the FY 2026 IPPS/LTCH PPS proposed rule as we did not examine a potential change to the severity level designations for the diagnosis codes that describe longstanding persistent atrial fibrillation and permanent atrial fibrillation, we encourage individuals with comments about the severity level designations of ICD–10–CM diagnosis codes to submit these comments no later than October 20th of each year, via MEARIS™ at: *https://mearis.cms.gov/public/home*, so that they can be considered for possible inclusion in the annual proposed rule. We refer the commenter to section II.C.8. of the preamble of this FY 2026 IPPS/LTCH PPS final rule for discussion related to our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to maintain the structure of MS–DRGs 216, 217, and 218 for FY 2026, without modification. We are also finalizing our proposal 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. As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18035 through 18038), 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, comprised 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.

As discussed in the proposed rule, 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 FY 2023 Final MedPAR data. The requestor stated they found the cases reporting a diagnosis of aortic regurgitation in MS–DRG 266 and 267 have 20 percent 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 percent versus AS = 5.82 percent) 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). As we discussed in the proposed rule, 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 noted in the proposed rule 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. We stated 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 noted in the proposed rule 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).

As discussed in the proposed rule, 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, we stated 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, in the proposed rule we stated 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. We stated 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 acknowledged that if not treated AR can gradually worsen and lead to left ventricular enlargement and eventually heart failure, we stated 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 proposed to maintain the GROUPER logic for MS–DRGs 266 and 267 for FY 2026. We also proposed to maintain the title of MS–DRGs 215 as ''Other Heart Assist System Implant'' for FY 2026.

Comment: Commenters supported the proposal to maintain the GROUPER

logic for MS–DRGs 266 and 267 for FY 2026. A commenter stated they believe the request to reassign cases reporting TAVR procedures for aortic regurgitation from MS–DRGs 266 and 267 was premature, as valve treatments and the data associated with these procedures are limited. This commenter further stated that as more data are available, CMS will be better able to evaluate appropriate assignment of endovascular cardiac valve therapies in the future. Another commenter stated that patients requiring heart assist devices tend to present with more severe illnesses and require greater resource utilization and longer lengths of stay than those patients undergoing TAVR for aortic regurgitation, therefore reassigning cases reporting TAVR procedures for aortic regurgitation to MS–DRG 215 would not be clinically coherent. Other commenters stated that upon review of the data analysis that CMS described in the proposed rule, it appears the reassignment may not be appropriate at this time and encouraged CMS to continue to monitor the data for these cases and consider if any MS–DRG modifications may be warranted in the future.

Response: We appreciate the commenters' support.

Comment: Other commenters stated CMS should reconsider its proposal to maintain the GROUPER logic for MS–DRGs 266 and 267 for FY 2026 and should reassign cases reporting TAVR procedures for aortic regurgitation from MS–DRGs 266 and 267 to a more clinically and cost cohesive MS–DRG. Several commenters noted that CMS' analysis of cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation included ICD–10–CM diagnosis code I35.2 (Nonrheumatic aortic (valve) stenosis with insufficiency). These commenters stated that code I35.2 inadvertently identifies patients with mixed valvular heart disease and predominant aortic stenosis and including this code in the analysis does not allow an understanding of the resource utilization required to treat patients with predominant aortic regurgitation. These commenters encouraged CMS to refine our analysis to exclude cases with aortic stenosis by analyzing the cases reporting a principal or secondary diagnosis of aortic regurgitation, without including ICD–10–CM code I35.2 and, if the data supports, assign these cases to a more clinically and cost cohesive MS–DRG. Another commenter (the requestor) stated the inclusion of ICD–10–CM code I35.2 inadvertently analyzed a very different patient population from the population they identified in their initial request, which they asserted truly identified patients who were treated with TAVR for aortic regurgitation. This commenter stated that it was impossible for more than 8,000 TAVR procedures to have been performed for patients with aortic regurgitation since there is no FDA-approved valve for this indication and noted that the ALIGN–AR trial (a single-arm, prospective, multicenter study designed to evaluate the efficacy and safety of the JenaValve Trilogy transcatheter heart valve in patients with symptomatic, greater-than-moderate native aortic regurgitation who were deemed high risk for surgery) only treated 180 patients in 2023. The commenter requested that CMS analyze the MedPAR data again using ICD–10–CM diagnosis codes I06.1 (Rheumatic aortic insufficiency) or I35.1 (Nonrheumatic aortic (valve) insufficiency) as principal or secondary diagnosis only, to accurately identify the costs and lengths of stay for patients treated for aortic regurgitation.

Response: We appreciate the commenters sharing their concerns and feedback. We agree with commenters that diagnosis code I35.2 describes nonrheumatic mixed aortic valve disease (MAVD), a condition where the aortic valve is affected by both aortic stenosis and aortic regurgitation. As discussed in the proposed rule and earlier in this section, the requestor identified TAVR for aortic regurgitation with ICD–10–CM diagnosis code I35.1 (Nonrheumatic aortic (valve) insufficiency) only. In reviewing this request, we identified five additional diagnosis codes in the ICD–10–CM classification that also describe aortic regurgitation, including code I35.2, and therefore included these codes in our analysis to avoid unintended consequences or missed opportunities in most appropriately capturing the resource utilization and clinical coherence for cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation.

To examine the recommendations that CMS (1) analyze cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation, while excluding cases reporting a principal or secondary diagnosis of ICD–10–CM code I35.2 (Nonrheumatic aortic (valve) stenosis with insufficiency), and (2) analyze cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of ICD–10–CM codes I06.1 (Rheumatic aortic insufficiency) or I35.1 (Nonrheumatic aortic (valve) insufficiency) only, we further examined claims data from the September 2024 update of the FY 2024 MedPAR file for MS–DRG 266 and 267. 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 excluding cases reporting ICD-10-CM diagnosis code I35.2	2,019	6.5	$57,724
	Cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation by reporting ICD-10-CM diagnosis codes I06.1 or I31.1 only	264	7.0	$61,433
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 excluding cases reporting ICD-10-CM code I35.2	2,038	1.7	$40,153
	Cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation by reporting ICD-10-CM diagnosis codes I06.1 or I31.1 only	262	1.6	$40,937

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 2,019 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation, excluding cases reporting ICD–10–CM diagnosis code I35.2, with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 266 ($57,724 compared to $55,402) and a longer average length of stay (6.5 days compared to 4.5 days). Additionally, there were 264 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation by reporting ICD–10–CM diagnosis codes I06.1 or I31.1 only, with average costs higher than the average costs in the FY 2024 MedPAR file for MS–DRG 266 ($61,433 compared to $55,402) and a longer average length of stay (7.0 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 2,038 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation, excluding cases reporting ICD–10–CM diagnosis code I35.2, with average costs lower than the average costs in the FY 2024 MedPAR file for MS–DRG 267 ($40,153 compared to $43,282) and a longer average length of stay (1.7 days compared to 1.5 days). Additionally, there were 262 cases reporting a procedure code describing TAVR with a principal or secondary diagnosis of aortic regurgitation by reporting ICD–10–CM diagnosis codes I06.1 or I31.1 only, with average costs lower than the average costs in the FY 2024 MedPAR file for MS–DRG 267 ($40,937 compared to $43,282) and a longer average length of stay (1.6 days compared to 1.5 days).

We reviewed these data and note that the original request was to reassign cases reporting TAVR procedures for aortic regurgitation from MS–DRGs 266 and 267 to what the requester described as a more clinically and cost cohesive MS–DRG such as MS–DRG 215 (Other Heart Assist System Implant). We continue to 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 compared to cases reporting codes describing TAVR for aortic regurgitation, even when excluding cases with a principal or secondary diagnosis of ICD–10–CM code I35.2 or when considering cases reporting a principal or secondary diagnosis of ICD–10–CM codes I06.1 or I35.1 only. We also note that the claims data reflect variance with regard to average length of stay and average costs for these cases when considering which principal or secondary ICD–10–CM diagnosis codes are reported to describe aortic regurgitation. The claims data also clearly show that the cases reporting secondary diagnoses designated as MCCs are more resource intensive compared to other cases reporting codes describing TAVR for aortic regurgitation. As such, we believe it is premature to propose changes to the MS–DRG assignment of cases reporting TAVR procedures for aortic regurgitation. Further analysis is needed, particularly focusing on the diagnosis codes reported, and also giving consideration as to whether other factors, such as the reporting of secondary MCC and CC diagnoses, may be contributing to the average costs prior to proposing any reassignment of these cases to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. Furthermore, it is also difficult to predict what the associated costs and resource utilization will be in the future for TAVR devices that remain under development or in clinical trials as research continues to refine TAVR techniques, evaluate long-term outcomes, develop new devices, and expand clinical indications. We expect in future years we will have additional data that can be used to evaluate the potential reassignment of cases reporting TAVR procedures. We will continue to monitor the claims data in consideration of any future modifications to the MS–DRGs for which TAVR procedures may be reported.

Therefore, after consideration of the public comments we received, we are finalizing our proposal to maintain the GROUPER logic for MS–DRGs 266 and 267 for FY 2026, without modification. We are also finalizing our proposal 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 IVL, 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 rulemaking (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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18038 through 18042), 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.

As discussed in the proposed rule, 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
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 noted in the proposed rule 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 stated 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.

As discussed in the proposed rule, 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 stated in the proposed rule 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. We stated that 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 rulemaking (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 stated 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).

As discussed in the proposed rule, 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. We stated 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 proposed 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, as discussed in the proposed rule, 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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 percent difference in average costs between the CC and NonCC subgroup.

Proposed New MS-DRGs	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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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	3,307	5.1	$31,886
Without MCC	3,134	2.5	$20,889

As discussed in the proposed rule, 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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 noted in the proposed rule 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 proposed 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 proposed 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 also proposed to create a new base MS–DRG for cases describing percutaneous or percutaneous endoscopic coronary atherectomy without an intraluminal device. The 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 the 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 proposed to define in the logic for each of the proposed new MS–DRGs. We noted that discussion of the surgical hierarchy for the proposed modification is discussed in section II.C.10. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule.

Comment: Many commenters expressed support for CMS' proposal to create new MS–DRGs for cases describing percutaneous or percutaneous endoscopic coronary atherectomy. Commenters stated they appreciate CMS' recognition of the greater resources required to perform percutaneous or percutaneous endoscopic coronary atherectomy. These commenters stated that they agree that the new MS–DRGs will appropriately reflect the higher resource use and longer hospital stays associated with these complex procedures and applauded CMS for recognizing the increased resources required and for undertaking the detailed analysis.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to create new MS–DRG 359 (Percutaneous Coronary Atherectomy with Intraluminal Device with MCC), new MS–DRG 360 (Percutaneous Coronary Atherectomy with Intraluminal Device without MCC) and new MS–DRG 318 (Percutaneous Coronary Atherectomy without Intraluminal Device) for cases reporting percutaneous or percutaneous endoscopic coronary atherectomy, without modification, for FY 2026.

We refer the reader to Table 6P.4a and Table 6P.4b associated with this FY 2026 IPPS/LTCH PPS final 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 finalizing to define in the logic for each of the new MS–DRGs. We note that discussion of the surgical hierarchy for the finalized modification is discussed in section II.C.10. of the preamble of this FY 2026 IPPS/LTCH PPS final rule.

e. Complex Aortic Arch Procedures

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18042 through 18047), 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 final 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 noted in the proposed rule 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 stated 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 noted in the proposed rule 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 final rule for a discussion regarding the 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'', in the proposed rule we stated 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.

As discussed in the proposed rule, 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 stated 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 stated 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, and discussed in the proposed rule, 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.

As discussed in the proposed rule, in analyzing this request, we noted 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). We stated 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 final rule for a discussion regarding the 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 stated in the proposed rule that 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.

In the proposed rule, we stated we reviewed these data and noted 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 stated we 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 stated we do not believe the data adequately supports a potential reassignment of these cases to MS–DRGs 216, 217, and 218, respectively.

We also stated we 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 noted in the proposed rule 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 stated 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 stated 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 noted in the proposed rule that, 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 proposed 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 did not propose 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 proposed 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 the 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 proposed to define in the logic for the proposed new MS–DRG. We note that the surgical hierarchy for the proposed modification is discussed in section II.C.10. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule.

Comment: Many commenters expressed support for the proposal to create new base MS–DRG 209 for cases reporting complex aortic arch procedures in MDC 05. Commenters stated that the creation of MS–DRG 209 would ensure better alignment with resource use and clinical needs, allowing appropriate payment and improved access to care for patients undergoing these complex surgeries. Several commenters agreed patients undergoing complex aortic arch procedures reflect a complex patient population that require increased resource utilization associated with their care. A commenter stated that the new MS–DRG would account for new technologies, resulting in a more tailored and appropriate payment to providers, which will inevitably result in better patient care and wider access to these complex aortic arch procedures. Another commenter specifically stated they appreciate the creation of the new MS–DRG and stated the proposed placement of MS–DRG 209 in the surgical hierarchy of MDC 05 will ensure that this group of complex patients will be clinically coherent and will appropriately account for the increased resource use and complexity required to care for them.

Response: We appreciate the commenters' support.

Comment: Another commenter disagreed with the proposal to create new MS–DRG 209 for cases reporting complex aortic arch procedures in MDC 05 and suggested that CMS delay the creation of the new MS–DRG to allow more time to analyze cost and length of stay data. This commenter stated that the current volume of cases is too small to justify a new MS–DRG and stated that more data is needed to assess the impact of concomitant comorbidities on resource use. While acknowledging that aortic arch repair procedures can be resource-intensive, the commenter

asserted that the impact of other concomitant comorbidities in exacerbating resource use has not adequately been assessed, and these cases should be more thoroughly evaluated before establishing a new MS–DRG. This commenter performed their own analysis and stated that they found that cases reporting a diagnosis of atrial fibrillation with procedure codes describing complex aortic arch procedures have higher average costs and longer average lengths of stay. The commenter stated that the disparity of resource use for complex aortic procedures may partially be due to the presence of comorbid diagnoses, such as atrial fibrillation, and should be evaluated in further detail. Lastly, the commenter expressed concern that the new MS–DRG could negatively affect the surgical hierarchy in MDC 05, particularly with regard to MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures). Specifically, the commenter noted that for FY 2026, CMS proposed to place new MS–DRG 209 in the highest position in the proposed Version 43 surgical hierarchy for MDC 05, ahead of MS–DRG 212. The commenter stated that MS–DRG 212 is defined by the performance of three cardiac procedures and asserted the complexity of performing three cardiac procedures is significant and should be reflected in the surgical hierarchy.

Response: We thank the commenter for their feedback and for sharing their concerns. In response to the suggestion that CMS delay implementation of proposed new MS–DRG 209 for complex aortic arch procedures, we reviewed the commenters' concern and do not agree that a delay is necessary or appropriate. As stated earlier, the data analysis clearly shows that when performed, complex aortic arch procedures are clinically different when compared to all cases in MS–DRGs 216, 217, 218, 219, 220, and 221 in terms of technical complexity and hospital resource use. For these reasons, we proposed to create a new MS–DRG for cases reporting complex aortic arch procedures. We continue to believe that a new base MS–DRG in MDC 05 will better differentiate these cases reporting complex aortic arch procedures from other cases in their currently assigned MS–DRGs.

In response to the commenters' concern that the disparity of resource use for complex aortic procedures may partially be due to the presence of comorbid diagnoses and therefore should be evaluated in further detail, as discussed in the proposed rule and earlier in this section, our data analysis indicated that the average costs of 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 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 higher than the average costs of all cases in MS–DRG 216, which is the highest severity level ''with MCC'' MS–DRG. For the cases reporting these 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 did not propose to subdivide the proposed new MS DRG for complex aortic arch procedures into severity levels for FY 2026. We believe that over time the volume of cases reporting complex aortic arch procedures in MS–DRG 209 may increase and we could consider subdividing the proposed new MS DRG for complex aortic arch procedures into severity levels in the future.

In response to the concern regarding the surgical hierarchy for MDC 05, we continue to believe our proposed revisions to the surgical hierarchy account for the resources expended to address these complex procedures and do not believe any modifications are warranted at this time. We believe the sequencing as discussed in the proposed rule appropriately reflects resource utilization when the assigned cardiac procedures are performed and will result in the most suitable MS–DRG assignments. We will continue to review the surgical hierarchy, consistent with our annual rulemaking, to determine if other modifications are warranted in the future.

Comment: A commenter (the manufacturer of the GORE® TAG® TBE) stated they reviewed the ICD–10–PCS classification for other procedure code combinations that would describe a ''complex aortic arch procedure'' by reporting a procedure code reporting the endovascular restriction of the thoracic aorta with a branched or fenestrated intraluminal device with an ICD–10–PCS code describing a Zone 0 (innominate artery), Zone 1 (left common carotid), or Zone 2 (left subclavian artery) aortic arch procedure to ensure continued access to care for Medicare beneficiaries undergoing this treatment and better alignment of resource use, costs, and clinical complexity of these aortic arch procedures. This commenter identified the following nine ICD–10–PCS codes and requested that these codes be added to definition (logic) of new MS–DRG 209 when reported with code 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach).

ICD-10-PCS Code	Description
031209K	Bypass innominate artery to left extracranial artery with autologous venous tissue, open approach
03120AK	Bypass innominate artery to left extracranial artery with autologous arterial tissue, open approach
03120JK	Bypass innominate artery to left extracranial artery with synthetic substitute, open approach
03120KK	Bypass innominate artery to left extracranial artery with nonautologous tissue substitute, open approach
03L40CZ	Occlusion of left subclavian artery with extraluminal device, open approach
03L40ZZ	Occlusion of left subclavian artery, open approach
03L43DZ	Occlusion of left subclavian artery with intraluminal device, percutaneous approach
03L44CZ	Occlusion of left subclavian artery with extraluminal device, percutaneous endoscopic approach
03L44ZZ	Occlusion of left subclavian artery, percutaneous endoscopic approach

Response: We appreciate the commenters' feedback. As discussed previously and in the proposed rule, Zone 0 of the aortic arch 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. We note

that Zone 2 of the aortic arch refers to the segment of the aortic arch located between the left common carotid artery and the left subclavian artery. This zone is a common location for aortic tears, aneurysms, and dissections and is a critical area for surgical and endovascular interventions. We agree with the commenter that the nine ICD–10–PCS codes as reflected in the previous table describe Zone 0, Zone 1, or Zone 2 aortic arch procedures, and when reported with code 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach), would describe complex aortic arch procedures and should be added to the list of ICD–10–PCS procedure codes in the logic for assignment of cases for the proposed new MS–DRG that describe complex aortic arch procedures when reported with code 02VX3EZ.

During our review of this issue, we further examined the GROUPER logic that would determine assignment of a case to proposed new MS–DRG 209. Specifically, we reviewed the ICD–10–PCS classification to determine if there were other ICD–10–PCS codes describing Zone 0, Zone 1 or Zone 2 aortic arch procedures that could describe complex aortic arch procedures when reported with code 02VX3EZ that were inadvertently not listed in the proposed GROUPER logic for MS–DRG 209. We identified the following 11 procedure codes.

ICD-10-PCS Code	Description
03120ZK	Bypass innominate artery to left extracranial artery, open approach
03L40DZ	Occlusion of left subclavian artery with intraluminal device, open approach
03L43CZ	Occlusion of left subclavian artery with extraluminal device, percutaneous approach
03L43ZZ	Occlusion of left subclavian artery, percutaneous approach
03L44DZ	Occlusion of left subclavian artery with intraluminal device, percutaneous endoscopic approach
03LJ0BZ	Occlusion of left common carotid artery with bioactive intraluminal device, open approach
03LJ0DZ	Occlusion of left common carotid artery with intraluminal device, open approach
03LJ3CZ	Occlusion of left common carotid artery with extraluminal device, percutaneous approach
03LJ3ZZ	Occlusion of left common carotid artery, percutaneous approach
03LJ4BZ	Occlusion of left common carotid artery with bioactive intraluminal device, percutaneous endoscopic approach
03LJ4DZ	Occlusion of left common carotid artery with intraluminal device, percutaneous endoscopic approach

We reviewed the 11 ICD–10–PCS codes as reflected in the previous table and note that when reported with code 02VX3EZ (Restriction of thoracic aorta, ascending/arch with branched or fenestrated intraluminal device, one or two arteries, percutaneous approach), these procedure code combinations also describe complex aortic arch procedures. As these procedure code combinations also describe complex aortic arch procedures, we believe these 11 ICD–10–PCS procedure codes should also be added to the list of ICD–10–PCS procedure codes that describe complex aortic arch procedures when reported with code 02VX3EZ in the logic for assignment of cases for proposed new MS–DRG 209.

Therefore, after consideration of the public comments received, and for the reasons discussed, we are finalizing our proposal to create new MS–DRG 209 (Complex Aortic Arch Procedures), with modification, effective October 1, 2025, for FY 2026. Specifically, we are adding the 20 ICD–10–PCS codes listed previously to the list of procedure codes that describe other complex aortic arch procedures when reported with ICD–10–PCS code 02VX3EZ in the logic for the new MS–DRG 209. Conforming changes to the GROUPER logic are also are shown in Table 6P.5a associated with this final rule and available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* and also as reflected in the final version of ICD–10 MS–DRG Definitions Manual, version 43, available in association with this final rule and available via the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*. We note that discussion of the surgical hierarchy for the finalized modification is discussed in section II.C.10. of the preamble of this FY 2026 IPPS/LTCH PPS final rule.

Comment: A commenter noted that a code proposal requesting new procedure codes to identify bypass procedures from the innominate artery to a subclavian artery or an axillary artery was displayed in association with the Spring 2025 ICD–10 Coordination and Maintenance Committee Update. The commenter suggested that any new procedure codes finalized in association with the Spring 2025 ICD–10 Coordination and Maintenance Committee Update that identify bypass procedures from the innominate artery to a subclavian artery or an axillary artery should be assigned to the GROUPER logic of MS–DRG 209 when coded with procedure code 02VX3EZ, as these procedure code combinations would describe ''complex aortic arch procedures'' as well.

Response: We thank the commenter for their feedback. We note that the proposal requesting new procedure codes to identify bypass procedures from the innominate artery to a subclavian artery or an axillary artery that was displayed in association with the Spring 2025 ICD–10 Coordination and Maintenance Committee Update was approved and five new procedure codes to identify bypass procedures from the innominate artery to a subclavian artery or an axillary artery were finalized as reflected in the FY 2026 ICD–10–PCS Code Update files that were made publicly available on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10* on June 6, 2025. We note that the new procedure codes are also reflected in Table 6B.—New Procedure Codes, in association with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, including the MS–DRG assignments for these new codes for FY 2026.

We agree that when coded with procedure code 02VX3EZ, these procedure code combinations would also describe complex aortic arch procedures and therefore should be assigned to new MS–DRG 209 along with other procedure codes describing complex aortic arch procedures. As reflected in Table 6B.—New Procedure Codes in association with this final rule, we note that the five procedure codes describing bypass procedures from the innominate artery to a subclavian artery or an axillary artery are assigned to new MDC 05 MS–DRG 209 and MS–DRGs

252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) for FY 2026. This assignment is reflected in the final V43 GROUPER logic. We refer the reader to section II.C.13. of the preamble of this final rule for further information regarding the table.

f. Deep Vein Thrombophlebitis

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18047), we stated that 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. We noted that 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.

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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

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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 noted in the proposed rule 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.

We stated in the proposed rule that based on our analysis and review of the cases grouping to MS–DRGs 294 and 295, we believed 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 proposed 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.

Comment: Several commenters supported the proposal 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.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to delete MS–DRGs 294 and 295 and reassign the 35 diagnosis codes describing deep vein thrombophlebitis listed previously that are currently assigned to MS–DRGs 294 and 295 to MS–DRGs 299, 300, and 301 for FY 2026.

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

a. Hip or Knee Procedures With Periprosthetic Joint Infection

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18049 through 18052), we discussed a request we received 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.[10] 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 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:

[10] 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.

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 that was made publicly available in association with the proposed rule and is available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* 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
	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).

We stated in the proposed rule that, based on our review and analysis of the data, we disagreed with the request to reassign PJI cases from the lower severity ''without CC/MCC'' level MS–DRG to the higher severity ''with CC'' level MS–DRG suggested by the requestor as the average costs of the PJI cases in the ''without CC/MCC'' level are not comparable and do not align with the average costs of all the cases at the ''with CC'' level. 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 stated 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.

We stated we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule. We noted 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final 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. Therefore, we 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 proposed to create new MS–DRGs 403 and 404 (Hip or Knee Procedures with Principal Diagnosis of Periprosthetic Joint Infection with MCC and without MCC, respectively). The following table reflects a simulation of the proposed new MS–DRGs.

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

Comment: Several commenters supported the proposal to create proposed new MS–DRGs 403 and 404. A commenter stated it was pleased that CMS is taking note of the resource intensiveness required to thoroughly treat periprosthetic joint infections (PJI). According to the commenter, PJIs have become more prevalent in recent years and are now the leading cause of revision surgery in both Total Knee Arthroplasty (TKA) and Total Hip Arthroplasty (THA) procedures. The commenter stated that according to the American Joint Replacement Registry, PJIs account for over 20 percent of hip revisions and 28 percent of knee revisions annually. The commenter expressed agreement with CMS' statement in the proposed rule that there are multiple MS–DRGs to which these cases are assigned dependent on treatment type. The commenter stated that given the wide variability of cost among the cases in the MS–DRGs analyzed, they appreciate that CMS proposed to assign these cases to

proposed new MS–DRGs based on a principal diagnosis of PJI. The commenter stated its belief that these proposed new MS–DRGs will provide more accurate and appropriate payment for the treatment of PJI commensurate with the complexity of these cases. The commenter also stated that as this epidemic of PJI is growing, they want to ensure that individuals facing challenges with treatment of PJI have access to a quality health care system which is primarily based on a set of organizational structures to ensure rapid diagnosis and appropriate treatment, and this proposed change is a significant positive step in that direction. Another commenter who expressed support for the proposal recommended that CMS and other stakeholders take caution and closely monitor these proposed new MS–DRGs if finalized, to observe how the proposed new structure may alter referral patterns, utilization, or site of service for unanticipated effects. This commenter also suggested that CMS identify the party requesting reassignment and stated that in the interest of transparency in public programs, when CMS addresses a reclassification request in the annual proposed rulemakings, it should be clear to the public which parties are requesting the changes so that stakeholders can take that into account when commenting to CMS.

Response: We appreciate the commenters' support. In response to the commenter's recommendation that any finalized policy should continue to be closely monitored, we thank the commenter for the feedback and note that we review the MS–DRGs for changes in treatment patterns and resource utilization on an annual basis. With respect to the request that CMS identify the party requesting reassignment for transparency, we will consider this suggestion for future rulemaking.

Comment: A commenter who expressed support for the creation of proposed new MS–DRGs 403 and 404 stated it encountered inconsistencies with case volumes when grouping cases using the Version 43 test GROUPER that was made publicly available in association with the FY 2026 IPPS/LTCH PPS proposed rule on the CMS website: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.* The commenter stated it reviewed CMS' analysis findings summarized in the proposed rule and the accompanying After Outliers Removed and Before Outliers Removed (AOR/BOR) file that shows the case volume and MS–DRG shifts between the Version 42.1 GROUPER and Version 43 test GROUPER and identified differences in case volume shifts among the MS–DRGs that were analyzed for proposed new MS–DRGs 403 and 404. The commenter indicated that it was challenging to understand the rationale for some of the shifts in case volume among the MS–DRGs when comparing the AOR/BOR file to the proposed rule findings. The commenter stated it validated that the data appropriately reflected declining volume in MS–DRGs 463, 464, 465, 474, 475, 476, 480, 481, and 482 as CMS outlined in the analysis as the cases shifted to proposed new MS–DRGs 403 and 404. The commenter also validated that CMS' analysis excluded MS–DRGs 485, 486, and 487 and these MS–DRGs reflected zero cases shifting as CMS outlined in the preamble of the proposed rule (90 FR 18051) and in the AOR/BOR file that was made publicly available in association with the proposed rule at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.* However, the commenter stated that the AOR/BOR file shows a decline (that is, shift) in case volume for MS–DRG 466 (243 cases), MS–DRG 467 (406 cases), and MS–DRG 468 (48 cases), resulting in a total decline of 699 cases while the proposed rule analysis identified a total of 1,567 cases reporting a principal diagnosis of PJI with a hip or knee procedure among those MS–DRGs (MS–DRG 466 (460 cases); MS–DRG 467 (947 cases); and MS–DRG 468 (160 cases)). The commenter also stated that in the proposed rule analysis, CMS noted that it excluded MS–DRGs 466, 467, and 468 from further consideration because it believed those cases were grouping appropriately in their current MS–DRG assignment.

The commenter stated that they reviewed the list of procedure codes analyzed by CMS, which was made publicly available in Table 6P.6a in connection with the proposed rule, as well as the list of procedure codes in the logic for MS–DRGs 466, 467, and 468 included in the Draft Version 43 ICD–10 MS–DRG Definitions Manual and noted an overlap of approximately 52 procedure codes. The commenter provided the example of procedure code 0SRB0EZ (Replacement of left hip joint with articulating spacer, open approach) and stated this procedure code is included in both lists. The commenter stated it recognized that logically the surgical hierarchy would result in the assignment of MS–DRG 403 or 404 versus MS–DRGs 466, 467, or 468, however, the commenter expressed concern regarding the case shift for 699 of the 1,567 cases from MS–DRGs 466, 467, and 468 into the proposed new MS–DRGs 403 and 404 and that the shift was not acknowledged nor explained in the proposed rule. The commenter stated their belief that the shifts should have been included within the proposed rule and explained for data transparency. According to the commenter, the lack of detail in the proposed rule made it unclear if the cases shifted because of the procedure code overlap or because of programming within the Version 43 test GROUPER. The commenter requested CMS provide an explanation for the decline in case volume among MS–DRGs 466, 467, and 468.

The commenter stated that during its review of the shift in case volume among MS–DRGs 466, 467, and 468, it identified inconsistencies in the assignment of cases to proposed new MS–DRGs 403 and 404 utilizing the Version 43 test GROUPER. The commenter provided examples of eight different test cases that included procedure codes from the list in Table 6P.6a that was made available in association with the proposed rule. According to the commenter's review, all eight cases should have resulted in assignment to the proposed new MS–DRGs 403 and 404; however, using the Version 43 test GROUPER, only four of the test cases grouped to proposed new MS–DRGs 403 and 404 while the remaining four test cases grouped to current MS–DRGs 463 or 464. The commenter stated that proposed new MS–DRGs 403 and 404 are proposed to be sequenced higher in the surgical hierarchy than existing MS–DRGs 463 and 464, therefore, the commenter requested an explanation regarding the accuracy of the Version 43 test GROUPER and the impact on the AOR/BOR file. The commenter requested additional transparency with regard to the MS–DRG groupings, the Version 43 test GROUPER, and the AOR/BOR file. Additionally, the commenter stated that if the findings demonstrate inaccuracies, corrected versions should be made available. The commenter suggested that for future rulemaking CMS consider including further insight, rationale and transparency regarding any shifts in volume that may result from proposed changes to MS–DRG logic.

Response: We appreciate the commenter's support and feedback. The commenter is correct that there is a redistribution (or shift) in cases among the MS–DRGs that were analyzed and discussed in the proposed rule (466, 467, and 468). We note that under the

GROUPER software program some collections of ICD–10–PCS procedure codes have a different set of attributes, independent of those of the codes that make them up (that is, their ''components''). These collections of ICD–10–PCS procedure codes are called clusters. A routine program in the GROUPER, upstream of the MS–DRG assignment logic, searches the claim for clusters. When a cluster is found, it is added to the list of procedures found on the claim. Clusters may be ''restricted'' by Major Diagnostic Category (MDC) and a restricted cluster inhibits the use of its procedure code component attributes for the MDC's MS–DRG assignment logic. For example, procedure code cluster 0SPC0JZ (Removal of synthetic substitute from right knee joint, open approach) and 0SRT0JZ (Replacement of right knee joint, femoral surface with synthetic substitute, open approach) may be recognized on a claim if both codes appear (in any order). The reporting of these codes creates a new procedure code cluster ''@0045''. The cluster @ 0045 has a different set of attributes than either code 0SPC0JZ or 0SRT0JZ by itself and is further ''restricted'' for MDC 08. When the GROUPER logic determines that the MDC is 08, it ignores the attributes of procedure codes 0SPC0JZ and 0SRT0JZ individually, only using those of @0045. This logic results in assignment of the claim to MS–DRGs 466, 467, and 468 (Revision of Hip or Knee Replacement with MCC, with CC, and without CC/MCC, respectively) rather than 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). If the principal diagnosis reported is not assigned under MDC 08, the cluster would not restrict the interpretation of the component codes and their individual attributes could be relevant as well as those of @0045.

Following publication of the proposed rule, we identified that the intended grouping of cases to the proposed new MS–DRGs was impacted because of these cluster restrictions under MDC 08, therefore we removed the restrictions and performed additional analysis. As a result of removing the restrictions, and due to the existing overlapping procedure code logic among a subset of the MDC 08 MS–DRGs, our analysis showed that further redistribution of the cases under MDC 08 occurs, impacting the remaining number of cases in MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, such that, those MS–DRGs no longer satisfy the criteria for a 3-way split. Under our established process for applying the criteria to create subgroups within a base MS–DRG, existing MS–DRGs 466, 467, and 468 would be deleted and a new base MS–DRG for Revision of Hip or Knee Replacement would be established. Additionally, under this established process, existing MS–DRGs 485, 486, and 487 would be deleted and new MS–DRGs (2-way split) for Knee Procedures with Principal Diagnosis of Infection with and without MCC, respectively, would be established. Because these findings were not identified until after publication of the proposed rule, we believe it is appropriate to further consider the creation of proposed new MS–DRGs 403 and 404, along with the removal of the MDC 08 restrictions on the procedure code clusters and the potential implications for existing MS–DRGs 466, 467, and 468 and MS–DRGs 485, 486, and 487, as well as the creation of new MS–DRGs, in addition to having an updated test Grouper that reflects these potential changes. We also note that any future proposed MS–DRG changes may also impact the surgical hierarchy.

After consideration of the public comments we received, and for the reasons described, we are not finalizing our proposal 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) for FY 2026. As noted, we may further consider these potential MS–DRG changes for future rulemaking.

b. Arthroscopy

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18052 through 18054), we stated that 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. We noted that 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 orthopedic 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.

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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
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

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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 noted 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 stated 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

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
513	1,335	5.0	$14,219
514	317	2.6	$9,556

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
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 stated that 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 proposed to do the following:

- Reassign the 8 procedure codes describing arthroscopy of the shoulder or elbow joint to MS–DRGs 510, 511, and 512 (Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures with MCC, with CC, and without CC/MCC, respectively).
- Reassign the 10 procedure codes describing arthroscopy of the hand or wrist joint to MS–DRGs 513 and 514 (Hand or Wrist Procedures, Except Major Thumb or Joint Procedures with CC/MCC and without CC/MCC, respectively).
- Reassign the 29 procedure codes describing arthroscopy of various vertebral joints and other

musculoskeletal joints to MS–DRGs 515, 516, and 517 (Other Musculoskeletal System and Connective Tissue O.R. Procedures with MCC, with CC, and without CC/MCC, respectively).

We refer the reader to Table 6P.7a made publicly available in association with the proposed rule and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* for the detailed list of procedure codes with the proposed MS–DRG reassignments.

Comment: Commenters supported our proposal to delete MS–DRG 509 and to reassign the 47 procedure codes describing arthroscopy of various anatomic sites to the proposed clinically appropriate MS–DRGs.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to delete MS–DRG 509 and to reassign the 47 procedure codes describing arthroscopy of various anatomic sites to clinically appropriate MS–DRGs, as reflected in Table 6P.7a in association with this final rule and available at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*.

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

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18054 through 18056), 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 titled ''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 titled ''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 titled ''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 titled ''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 titled ''Spinal Curvature/Malignancy/Infection'' there are a subset of diagnosis codes describing spinal infections. We stated in the proposed rule that 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.

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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

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

Comment: Commenters supported our proposal to add the previously listed 47 diagnosis codes to the logic list titled ''Spinal Curvature/Malignancy/Infection'' in MS–DRGs 456, 457, and 458, and our proposal to delete the eight previously listed diagnosis codes from the logic list titled ''Spinal Curvature/Malignancy/Infection'' in MS–DRGs 456, 457, and 458.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to add the previously listed 47 diagnosis codes to the logic list titled ''Spinal Curvature/Malignancy/Infection'' in MS–DRGs 456, 457, and 458, effective October 1, 2025 for FY 2026. We are also finalizing, without modification, our proposal to remove the eight previously listed diagnosis codes from the logic list titled ''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 proposed to move the cases reporting the procedures and/or principal diagnosis codes described in this section of this 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.

a. Control of Bleeding in the Genitourinary Tract

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18056 through 18057), 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.

As noted in the proposed rule, 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 stated in the proposed rule 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 in the proposed rule that 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 stated 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 proposed 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.

Comment: Commenters supported the proposal to add ICD–10–PCS procedure codes 0W3R0ZZ, 0W3R3ZZ, 0W3R4ZZ, 0W3R7ZZ, and 0W3R8ZZ to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders).

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure codes 0W3R0ZZ, 0W3R3ZZ, 0W3R4ZZ, 0W3R7ZZ, and 0W3R8ZZ to MDC 16, without modification, for FY 2026. Under this finalization, cases reporting a procedure code describing the control of bleeding in the genitourinary tract with a principal diagnosis of a hemorrhagic disorder due to extrinsic circulating anticoagulants (diagnosis code D68.32) in MDC 16 would group to MS–DRGs 802, 803, and 804.

b. Removal of Infusion Device From Peritoneal Cavity

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18057 through 18058), 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. In the proposed rule, we included the following table, listing the three ICD–10–PCS procedure codes reviewed, and indicating current assignment to MDCs 06 and 21:

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

In this final rule, we are correcting this display to reflect that ICD–10–PCS code 0WPG33Z is not currently assigned to MDC 21. We note that, in ICD–10 MS–DRGs Definitions Manual Version 42.1, ICD–10–PCS codes 0WPG03Z and 0WPG43Z are assigned to MDC 21 MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively). ICD–10–PCS code 0WPG33Z is assigned to MDC 06 MS–DRGs 356, 357 and 358 (Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively). We list in the following table the ICD–10–PCS procedure codes describing the removal of an infusion device from the peritoneal cavity and their corresponding MS–DRG assignments in the ICD–10 MS–DRGs Definitions Manual Version 42.1.

ICD-10-PCS Code	Description	MDC	MS-DRG	Description
0WPG03Z	Removal of infusion device from peritoneal cavity, open approach	06	356-358	Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively
		21	907-909	Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively
0WPG33Z	Removal of infusion device from peritoneal cavity, percutaneous approach	06	356-358	Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively
0WPG43Z	Removal of infusion device from peritoneal cavity, percutaneous endoscopic approach	06	356-358	Other Digestive System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively
		21	907-909	Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively

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.

As discussed in the proposed rule, 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 stated 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 later in this section.

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 the following 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

As discussed in the proposed rule, 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 lengths of stay are shorter than for cases in MS–DRGs 907, 908, and 909. However, we stated 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, we stated it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we proposed to add the three procedure codes listed previously to MDC 21. We stated that under this proposal, cases reporting a procedure code describing the removal of an infusion device from the peritoneal cavity with a principal diagnosis of an infection and inflammatory reaction due to peritoneal dialysis catheter, initial encounter (diagnosis code T85.71XA) in MDC 21 would group to MS–DRGs 907, 908, and 909.

Comment: Commenters supported the proposal to add procedure codes describing the removal of an infusion device from the peritoneal cavity to MDC 21 (Injuries, Poisonings and Toxic Effects of Drugs).

Response: We appreciate the commenters' support.

As discussed previously, in ICD–10 MS–DRGs Definitions Manual Version 42.1, ICD–10–PCS codes 0WPG03Z and 0WPG43Z are already assigned to MDC 21 MS–DRGs 907, 908, and 909 (Other O.R. Procedures for Injuries with MCC, with CC, and without CC/MCC, respectively). Therefore, after consideration of the public comments we received, for the reasons discussed, we are finalizing our proposal with modification. Specifically, we are finalizing our proposal to add ICD–10–PCS code 0WPG33Z to MDC 21 for FY 2026. Under this finalization, cases reporting procedure code 0WPG33Z (Removal of infusion device from peritoneal cavity, percutaneous approach) 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, as discussed in the proposed rule, 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 stated 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 will 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 stated 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 stated we did not identify any cases for reassignment. Therefore, for FY 2026 we did not propose to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Comment: Commenters expressed support for CMS' proposal to not move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to not 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 final 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 M–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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18059 through 18060), we stated 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 stated 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.

Comment: Commenters supported CMS' plan to continue to conduct the comprehensive, systematic review of the ICD–10–PCS codes and to evaluate their current O.R. and non-O.R. designations. These commenters expressed that they were supportive of CMS' decision to continue to develop our process and methodology. A commenter stated they agreed that the revolution in medical procedures in recent years may render the performance of a procedure in an O.R. a less critical distinction in driving payment policy and stated that because of technological advances, sophisticated, resource-intensive procedures are no longer confined to the O.R. setting and noted that in their observation, bi-plane radiology interventional suites and cardiac catheterization labs used for procedures such as mechanical thrombectomy or endovascular coiling for aneurysms can utilize more advanced equipment and supplies than a basic operating room with minimal installed equipment. This commenter recommended that CMS provide detailed impact files prior to the adoption of changes to the designation of procedure codes in the ICD–10–PCS classification and stated that they look forward to commenting on CMS' data analysis and methodology in the future.

As part of the broader and continuing conversation about the designations of procedures in the ICD–10–PCS classification system, a commenter recommended that CMS work closely with physician specialty societies and industry stakeholders to identify the most important drivers of complexity and resource use in the hospital setting. Another commenter specifically recommended that CMS include nurse representatives when reviewing methodologies for determining the designation of procedure codes in the ICD–10–PCS classification system and noted that nurses are an integral part of the healthcare team, work closely with physicians in the operating room and have firsthand knowledge and experience to know what hospital resources are needed for procedures. This commenter further stated that omitting nurses only serves to discount their perspectives and could result in decision making that does not fully capture the hospital resources needed.

Response: We thank the commenters for their support. We also thank commenters for sharing their views and their willingness to provide feedback and recommendations as to what factors to consider in evaluating O.R. versus non-O.R. designations. We agree with commenters and believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. While CMS has already convened an internal team comprised of clinicians, consultants, coding specialists and other policy analysts, as well as provided the opportunity for interested parties to provide feedback as to what factors to consider in evaluating O.R. versus non-O.R. designations, we look forward to further input and feedback from interested parties, including nurses. As discussed in the proposed rule, we are considering the feedback received to date 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. As part of this comprehensive review of the procedure codes, we are also considering renaming the designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment (that is, ''O.R. procedures'', ''non-O.R. procedures'', or ''non O.R. affecting the MS–DRG'') for consistency. As discussed in prior rulemaking and earlier in this section of the preamble of this final rule, we have signaled that 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 encourage the public to continue to submit comments and feedback on any other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for procedures within the ICD–10 MS–DRGs under the IPPS.

As discussed in the 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 final rule, as we did in the proposed rule, we summarize and respond to those requests. In this section of the preamble of this final rule, we also discuss the proposal we made 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 final 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 proposed to change the designation of procedure codes from non-O.R. procedures to O.R. procedures, we also proposed 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 made based on our internal review and analysis in the proposed rule and in this section of the preamble of this FY 2026 IPPS/LTCH PPS final 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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18060 through 18061), 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 the 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 in the proposed rule, we stated we 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 proposed to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9T0ZZ and 0N9V0ZZ.

Comment: A commenter opposed CMS' proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9T0ZZ (Drainage of right mandible, open approach), and 0N9V0ZZ (Drainage of left mandible, open approach) and stated when performed in the inpatient setting, these procedures often involve complex infectious disease cases requiring significant resources. This commenter stated that their analysis and clinical experience suggest that these procedures, when performed on hospitalized patients, are substantially different and more complex when compared to routine outpatient drainage procedures and more closely align with other O.R.-designated procedures in terms of resource utilization. The commenter further stated that the infectious nature of these cases specifically requires additional resources beyond the procedure itself, including extended antimicrobial therapy, infectious diseases consultation and potential management of sepsis or other systemic complications.

Response: We thank the commenter for their feedback.

We reviewed the commenter's concerns and continue to support maintaining the current non-O.R. designation of the procedure codes describing open drainage of the mandible and disagree that the procedures describing the open drainage of the mandible typically require the resources of an operating room. 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.

In response to the issues raised by this commenter, we examined claims data from the September 2024 update of the FY 2024 MedPAR file for cases reporting 0N9T0ZZ or 0N9V0ZZ. Our findings are shown in the following table.

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MS-DRGs Reporting Procedure Codes 0N9T0ZZ or 0N9V0ZZ					
MS-DRG	**Description**		**Number of Cases**	**Average Length of Stay**	**Average Costs**
012	Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with CC	All cases	1,294	9.8	$38,637
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	11	$69,077
157	Dental and Oral Diseases with MCC	All cases	1,598	6.1	$15,737
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	2	4	$6,798
158	Dental and Oral Diseases with CC	All cases	2,725	3.5	$8,424
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	13	3.6	$10,745
159	Dental and Oral Diseases without CC/MCC	All cases	503	2.5	$6,686
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	6	$19,745
356	Other Digestive System O.R. Procedures with MCC	All cases	6,122	10.2	$38,574
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	3	$37,175
516	Other Musculoskeletal System and Connective Tissue O.R. Procedures with CC	All cases	10,522	5.0	$18,832
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	4	$10,908
554	Bone Diseases and Arthropathies without MCC	All cases	8,807	3.5	$7,800
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	3	$4,352
603	Cellulitis without MCC	All cases	55,341	3.8	$8,045
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	2	$2,437
853	Infectious and Parasitic Diseases with O.R. Procedures with MCC	All cases	75,711	12.3	$42,737
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	17	$39,483
856	Postoperative or Post-Traumatic Infections with O.R. Procedures with MCC	All cases	6,497	12.1	$38,696
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	4	$11,471
871	Septicemia or Severe Sepsis without MV >96 Hours with MCC	All cases	540,907	6.4	$17,468
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	2	10	$17,971
872	Septicemia or Severe Sepsis without MV >96 Hours without MCC	All cases	98,684	4.2	$9,413
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	4	$15,260
908	Other O.R. Procedures for Injuries with CC	All cases	6,625	4.8	$17,938
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	9	$11,475
920	Complications of Treatment with CC	All cases	10,257	3.7	$9,330
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	4	$13,263
983	Extensive O.R. Procedures Unrelated to Principal Diagnosis without CC/MCC	All cases	1,831	2.6	$15,837
		Cases reporting 0N9T0ZZ or 0N9V0ZZ	1	1	$4,117
		All cases reporting 0N9T0ZZ or 0N9V0ZZ	**29**	**4.9**	**$14,758**

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As shown in the table, we found a total of 29 cases reporting procedure codes 0N9T0ZZ or 0N9V0ZZ across the MS–DRGs, demonstrating that procedures that describe open drainage of the mandible are infrequently performed in the inpatient setting. Our data findings also demonstrate, generally, the cases reporting procedures describing the open drainage of the mandible have average costs that are lower than the average costs of all cases in their respective MS–DRGs, while the average lengths of stay are shorter.

Therefore, after consideration of the public comments we received, for the reasons stated, we are finalizing our proposal to maintain the current non-O.R. designation of ICD–10–PCS procedure codes 0N9T0ZZ and 0N9V0ZZ, without modification, for FY 2026.

In our review of this issue, in the proposed rule, we stated 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 stated 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 open drainage of the 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. In the proposed rule we stated we agree that procedures that describe open drainage of the 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 proposed 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.

Comment: Commenters supported CMS' proposal to remove procedure code 0W950ZZ 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.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure code 0W950ZZ (Drainage of lower jaw, open approach) from O.R. procedure to non-O.R. procedure, without modification, effective October 1, 2025. Under this finalization, this procedure code 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

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18061 through 18062), we again 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.

In the proposed rule, we noted that 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 noted 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 noted 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 stated in the proposed rule that we continue to disagree with designating the procedure to deliver paclitaxel to a coronary vessel as identified by any one of the previously listed 16 procedure codes as O.R. procedures. 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 referred the reader to the ICD–10 MS–DRG Definitions Manual, Version 42.1 available in association with the 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 proposed to maintain the designation of the 16 procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology as non-O.R. for FY 2026.

Comment: Some commenters agreed with the proposal to maintain the designation of the 16 procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology as non-O.R. for FY 2026.

Response: We thank the commenters for their support.

Comment: A commenter (the manufacturer) urged CMS to change the designation of the procedure codes that describe the AGENT™ Paclitaxel-Coated Balloon Catheter technology from non-O.R. to O.R. for FY 2026. The commenter stated that patients scheduled for a procedure that uses the AGENT™ Paclitaxel-Coated Balloon Catheter technology have a principal diagnosis of ISR, and introduction of the AGENT™ implant is the principal procedure to address the ISR. The commenter stated that the AGENT™ implant represents the therapeutic intent of the intervention, drives associated resource requirements, and is not performed incident to vessel preparation. The commenter stated that other services provided during the same operative session as the AGENT™ implant are for the purpose of vessel dilation or plaque modification in preparation for effective therapeutic drug delivery. According to the commenter, the specific approach and rigor to vessel preparation technique(s) are dictated by the physician's decision to treat the lesion with the AGENT™ implant and are therefore secondary to the AGENT™ implant. The commenter stated the secondary procedures may include balloon angioplasty for vessel dilation, and atherectomy, lithotripsy, and/or cutting balloon for plaque modification. In addition, the commenter stated that intravascular ultrasound (IVUS) and/or optical coherence tomography (OCT) may be used for enhanced vessel visualization.

The commenter provided a table comparing clinical functions associated with percutaneous coronary interventions as follows:

Clinical Function	Procedure	Technologies
Vessel Dilation	Angioplasty	Compliant Low-Pressure Dilation Balloon Semi-Compliant Low- Pressure Dilation Balloon Non-Compliant High- Pressure Dilation Balloon
Lesion Modification *(fragmentation, extirpation)*	Atherectomy Intravascular Lithotripsy	Cutting and Scoring Balloons Rotational and Orbital Atherectomy Laser Fiber Catheter Sonic Wave Balloon Catheter
Lesion Treatment *(insertion, supplement)*	Stent Placement Localized Drug Implant	Bare Metal Stent (BMS) Drug Eluting Stent (DES) Drug Coated Balloon (DCB)

The commenter also stated that the primary role of the AGENT™ implant is supported by ICD–10–PCS Guidelines which instruct to sequence the procedure performed for definitive treatment most related to the principal diagnosis as principal procedure. The commenter included the FDA labeling language that was referenced in the preamble of the proposed rule (90 FR 18062) and stated that because patients who are admitted for a procedure to deliver the AGENT™ implant have a principal diagnosis of ISR, the AGENT™ implant is the principal procedure from a coding perspective and is the primary procedure that represents the therapeutic intent of the intervention.

The commenter asserted that the AGENT™ DCB therapy is consistent with drug-eluting stent (DES) therapy in terms of diagnostic methods, intra-operative procedure steps, complexity and risk, therefore, consistent with DES and other procedure codes for percutaneous coronary interventions (PCI), the codes for the AGENT™ DCB should be designated as O.R. codes. The commenter stated that the procedure involving the AGENT™ implant is most clinically similar to a DES procedure because both are PCI procedures, performed only by physicians experienced in PCI, involve a surgical implant within the coronary artery, involve the transfer of therapeutic substances to a lesion and are targeted localized therapies as opposed to systemic treatments. The commenter added that the procedural steps to prepare a vessel for the AGENT™ implant is consistent with that required for a DES including obtaining percutaneous arterial access, positioning a guide catheter in the heart, advancing a guide wire across the coronary artery stenosis, preparing the vessel for the AGENT™ implant using specialized catheters and devices as needed (for example, angioplasty balloon, cutting balloon, lithotripsy, atherectomy), and using angiographic imaging to visualize the heart and IVUS or OCT to guide the procedure.

The commenter stated that in addition to the clinical similarities between the AGENT™ DCB and a DES, the procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology in ICD–10–PCS Table XW0 (Introduction, Anatomical Regions) closely mirror the procedure codes describing use of a DES, in ICD–10–PCS Table 027, Dilation of Heart and Great Vessels because both sets of codes account for treatment of multiple coronary arteries and the use of multiple devices. The commenter asserted that since the procedure codes describing a DES and all other PCI procedure codes are classified as surgical, the AGENT™ Paclitaxel-Coated Balloon Catheter technology should be similarly classified as surgical. The commenter stated that the 16 procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology should be designated as O.R. procedures regardless of whether there is immediate impact to the MS–DRG assignment.

Other commenters expressed appreciation that CMS reviewed the request to reconsider the MS–DRG assignment of the sixteen procedure codes describing use of the AGENT™ Paclitaxel-Coated Balloon Catheter technology from non-O.R. to O.R. however, the commenters disagreed with the proposal to maintain the DCB placement as a non-O.R. procedure. According to the commenters, because the vessel preparation techniques discussed to allow placement of the AGENT™ Paclitaxel-Coated Balloon Catheter are O.R. services, it would only be consistent for the AGENT™ Paclitaxel-Coated Balloon Catheter service itself to also be designated as an O.R. service. The commenters stated that, from a similar perspective, just as drug-eluting intraluminal device procedures (drug-eluting stents) are considered alongside non-drug-eluting intraluminal devices (stents); the AGENT™ Paclitaxel-Coated Balloon Catheter service should be categorized in the same manner as other dilation of coronary artery procedures (that is, angioplasty).

Response: We appreciate the commenters' feedback. We disagree with the commenter's (the manufacturer) statement that the vessel preparation technique(s) are secondary to delivery of the AGENT™ implant (that is, paclitaxel). While the delivery of paclitaxel via the AGENT™ Paclitaxel-Coated Balloon Catheter is the intended therapeutic intervention to treat ISR, it cannot occur in the absence of the initial vessel preparation procedure (for example, angioplasty for vessel dilation, and atherectomy, lithotripsy, and/or cutting balloon for plaque modification). In response to the commenter's statement that the primary role of the AGENT™ implant is supported by ICD–10–PCS sequencing guidelines for the principal procedure, we note that the ICD–10–PCS Guidelines regarding sequencing of the principal procedure have no direct correlation on MS–DRG assignment or whether a procedure code is designated as O.R. or non-O.R. We also note that the sequencing of the procedure on the claim does not have an effect on MS–DRG assignment. Rather, the MS–DRG assignment is based on the O.R. or non-O.R. designation of the procedure code.

While we agree that there are some procedural similarities between delivery of the AGENT™ implant and the insertion of a DES, we note that a major distinction is that the objective of the AGENT™ Paclitaxel-Coated Balloon Catheter is to deliver a targeted anti-proliferative drug dose, without introducing an extra layer of metal that is intended to remain permanently. We disagree with the commenter that the procedure involving the AGENT™ implant should be designated as an O.R. procedure. Although the FDA

designated the AGENT™ Paclitaxel-Coated Balloon as an implant for Pre-Market Approval (PMA) purposes, (that is, per FDA guidance, the drug component is considered a permanent implant because it remains in the body for greater than 30 days), delivery of a drug (or therapeutic agent) is not equivalent to the insertion of an intraluminal device (that is, stent) under the ICD–10–PCS classification. Notably, unlike a device, a drug cannot become dislodged from its location nor can it be removed.

Designating a procedure code that is identified as one component of a multi-component procedure, service, or therapy as O.R. when that component would not be performed independently and is not FDA approved to be performed independently in the absence of another component (that is, two components are necessary for reporting to accurately reflect the entire procedure) would not be appropriate and is also not necessary when the other component has an existing O.R. designation. Specifically, it would not be appropriate to only report a procedure code describing the introduction of the AGENT™ Paclitaxel-Coated Balloon Catheter technology and arrive at one of the requested MS–DRG assignments in the absence of a procedure code describing an angioplasty, lithotripsy, or atherectomy procedure being reported. To encourage proper coding and reporting, as well as to ensure appropriate MS–DRG assignment, both the AGENT™ Paclitaxel-Coated Balloon Catheter technology and one of the procedure codes describing an angioplasty, lithotripsy, or atherectomy must be reported. We also note that under ICD–10–PCS, PCI procedures such as angioplasty performed for the treatment of blocked arteries with one or more intraluminal devices (that is, stents) that remain in the patient are coded to ''Dilation with intraluminal device''. The AGENT™ Paclitaxel-Coated Balloon Catheter technology does not involve a stent; rather, the drug (paclitaxel) is deployed and the balloon catheter is removed. The procedure codes describe the administration or transfer of the drug via the delivery mechanism of the balloon catheter. The intended outcomes or benefits of altering the designation of the procedure codes for the AGENT™ Paclitaxel-Coated Balloon Catheter technology from non-O.R. to O.R. remain unclear, as the MS–DRG assignment is determined by the vessel preparation procedure, which is classified as an O.R. procedure. As discussed in section II.C.7 of the preamble of the proposed rule (90 FR 18059) and this final rule, each ICD–10–PCS procedure code has a designation that determines whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment.

After consideration of the public comments received and for the reasons previously described, we are finalizing our proposal to maintain 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

As discussed in the proposed rule (90 FR 18062 through 18063), 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 stated 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 proposed 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).

Comment: Commenters supported the proposal to change the designation of procedure codes 0T9680Z, 0T9780Z, and 0T9880Z from non-O.R. procedures to O.R. procedures.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to change the designation of procedure codes 0T9680Z, 0T9780Z, and 0T9880Z from non-O.R. procedures to O.R. procedures, without modification, effective October 1, 2025.

8. 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 believed 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.

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.

Comment: A commenter stated that they applaud the inclusion of the guiding principles that recognize organ system instability or failure, chronic illness with susceptibility to exacerbations, conditions requiring higher levels of care, and systemic impact. This commenter stated that these principles appropriately capture the resource intensity associated with managing complex infectious diseases. This commenter also urged CMS to expedite the comprehensive CC/MCC analysis, paying particular attention to diagnoses that describe infectious conditions, and recommended that CMS consider additional factors specific to infectious disease management such as antimicrobial resistances, factors related to immunocompromised hosts and the role of antimicrobial stewardship when reviewing these conditions.

Response: We thank the commenter for their support and appreciate their feedback. We continue to welcome feedback regarding the guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We will examine these suggestions as we continue the comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18064), we did not receive any requests to change the severity level designations of specific ICD–10–CM diagnosis codes. We stated 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 did not propose any severity designation changes for FY 2026.

Comment: Commenters supported the decision to not propose any severity designation changes for FY 2026. A commenter stated that they appreciate CMS' commitment to refining the MS–DRG system to better reflect hospital resource use.

Response: We appreciate the commenters' support.

Comment: Several commenters stated that they appreciate that CMS finalized changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC in the FY 2020 IPPS/LTCH PPS final rule. These commenters stated that they continue to support these designations and encouraged CMS to clarify that all current and future ICD–10–CM diagnosis codes describing antimicrobial resistance will be appropriately designated as CCs.

Other commenters encouraged CMS to examine the ICD–10–CM diagnosis codes that describe longstanding persistent and permanent atrial fibrillation to determine the hospital resource utilization related to addressing these diagnoses and to analyze whether these codes should be considered for severity designation changes. These commenters stated that from a resource perspective, patients with longstanding persistent atrial fibrillation or permanent atrial fibrillation require markedly more intensive management and typically face longer operative times, higher complication rates, prolonged hospital stays, and increased readmission risk.

Response: We appreciate the feedback.

In response to the request that CMS clarify that all future ICD–10–CM diagnosis codes describing antimicrobial resistance will be designated as CCs, as discussed in prior rulemaking and in section II.C.9 of this final rule, consistent with our established process for assigning new diagnosis or new procedure codes to MDCs, MS–DRGs, and the associated attributes (severity level and O.R. status), we examine the MDCs, MS–DRG assignment and severity level designation of the predecessor diagnosis codes to inform our assignments and designations. 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. As we have previously noted, this process does not automatically result in the new diagnosis or procedure code being assigned to the same MS–DRG or to have the same designation as the predecessor code.

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*.

We encourage individuals with comments about the severity level designations of ICD–10–CM diagnosis codes to submit these comments no later than October 20th of each year, via the Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*, so that they can be considered for possible inclusion in the annual proposed rule. When submitting requests to change the severity level designation of an ICD–10–CM diagnosis code when reported as a secondary diagnosis, we encourage the public to review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2024 MedPAR files as well as to provide a detailed explanation of how applying a suggested guiding principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code.

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

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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18065), we stated that the following tables identify the proposed additions and deletions to the diagnosis code MCC and 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.

We note that there was an inadvertent error in the listing of Table 6I.2 in the preamble of the proposed rule as there were no proposed deletions to the MCC list for FY 2026 and Table 6I.2 was not developed in association with the proposed rule.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC lists as shown in tables 6I.1, 6J.1, and 6J.2 associated with the proposed rule.

Response: We appreciate the commenters' support.

The following tables associated with this final rule reflect the finalized severity levels under Version 43 of the ICD–10 MS–DRGs for FY 2026 and are available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*; Table 6I.—Complete MCC List—FY 2026; Table 6I.1—Additions to the MCC List—FY 2026; Table 6J.—Complete CC List—FY 2026; Table 6J.1—Additions to the CC List—FY 2026; and Table 6J.2—Deletions to the CC List—FY 2026.

d. 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18065), we noted 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.

As discussed in the preamble of the FY 2026 IPPS/LTCH PPS proposed rule, the findings from our review indicated 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 noted 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 therefore proposed to remove the diagnosis codes listed in Table 6P.8a associated with the 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. In the proposed rule (90 FR 18065), we stated that 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 stated 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. As also discussed in the proposed rule, during our internal review we 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 proposed to add diagnosis code I12.9 to Principal Diagnosis Collection List number 1335 to exclude diagnosis code N18.5 from acting as a CC, proposed to remove the diagnosis codes listed in Table 6P.8a associated with the 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 proposed 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.

Comment: Several commenters agreed with our proposals to add diagnosis code I12.9 to Principal Diagnosis Collection List number 1335 to exclude diagnosis code N18.5 from acting as a CC, remove the diagnosis codes listed in Table 6P.8a associated with the 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 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. However, a commenter disagreed with the proposed addition of 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. According to the commenter, diagnosis codes I13.0 and I13.10 are combination codes and do not differentiate between a patient that is being admitted for congestive heart failure (CHF) or

chronic kidney disease (CKD). The commenter stated that the exclusion of codes N18.5 and N18.6 eliminates the complexity of these patients and the additional resources in management of their renal function when admitted for cardiogenic related conditions.

Response: We appreciate the commenters' support and feedback. In response to the commenter who disagreed with the proposal to exclude diagnosis codes N18.5 and N18.6 from acting as a CC/MCC when diagnosis code I13.0 or I13.10 is assigned as the principal diagnosis, we note that, as discussed in the FY 2026 IPPS/LTCH PPS proposed rule, the conditions described by diagnosis codes N18.5 and N18.6 describe chronic kidney disease, stage 5 and end stage renal disease (ESRD), respectively, 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. We also note that in the ICD–10–CM Tabular List of Diseases, there are instructional notes at diagnosis codes I13.0 and I13.10 that specifically direct the user to ''Use additional code to identify the stage of chronic kidney disease (N18.1–N18.4, N18.9)''. The instructional note does not list diagnosis codes N18.5 or N18.6 because they are not clinically applicable, as previously described. There is also another instructional note in the ICD–10–CM Tabular List of Diseases at diagnosis code I13.0 that specifically directs the user to ''Use additional code to identify the type of heart failure (I50.-)'' because diagnosis code I13.0 describes ''with heart failure'' (while diagnosis code I13.10 describes ''without heart failure''). With respect to the commenter's statement that the combination codes (I13.0 and I13.10) do not differentiate between a patient that is being admitted for CHF or CKD, we note that because these codes are classified as combination codes, they include both a CHF and CKD component. Therefore, the appropriate combination code (I13.0 or I13.10) is assigned on a claim to accurately reflect the conditions documented, and any additional codes would be assigned based on the Tabular instructions.

After consideration of the public comments we received, we are finalizing our proposals to add diagnosis code I12.9 to Principal Diagnosis Collection List number 1335 to exclude diagnosis code N18.5 from acting as a CC, remove the diagnosis codes listed in Table 6P.8a associated with this FY 2026 IPPS/LTCH PPS final 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 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, effective October 1, 2025 for FY 2026.

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*.

As discussed in the proposed rule (90 FR 18066 through 18067), 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. However, there were 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.

As discussed in the preamble of the FY 2026 IPPS/LTCH PPS proposed rule, 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	Average LOS	Average Cost	Number of Cases	Average 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. However, we noted in the proposed rule 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 noted 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 proposed to remove code R57.1 from the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive. We noted that 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.

Comment: Commenters expressed support for our proposal to remove code R57.1 from the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove code R57.1 (Hypovolemic shock) from the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive, without modification, effective October 1, 2025. Under this finalization, when reported as a secondary diagnosis, R57.1 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.

As discussed in the proposed rule, 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	Average LOS	Average Cost	Number of Cases	Average 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 proposed to add code T79.4XXA to the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive. We noted that 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.

Comment: Commenters expressed support for our proposal to add code T79.4XXA to the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add code T79.4XXA (Traumatic shock, initial encounter) to the list found in Appendix C—Part 2: Codes That are Major CC Only if Patient Discharged Alive, without modification, effective October 1, 2025. Under this finalization, when reported as a secondary diagnosis, T79.4XXA would be assigned as an MCC only when the patient is discharged alive.

In summary, the proposals and related findings discussed in connection with Appendix C and finalized in this section of the preamble of this final rule are reflected in the Version 43 ICD–10 MS–DRG Definitions Manual, which is available in association with this final rule at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18067), we proposed additional 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 the proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*.

We did not receive any public comments opposing the proposed CC Exclusions List.

The finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1, 6H.2, and 6K, associated with this final rule reflect the additions, deletions, and complete list of CC exclusions under Version 43 of the ICD–10 MS–DRGs. We have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026; and Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026; and Table 6K. Complete List of CC Exclusions—FY 2026. Tables 6G.1., 6G.2., 6H.1., 6H.2., and 6K associated with this FY 2026 IPPS/LTCH PPS final rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

For Table 6G.1, each secondary diagnosis code finalized for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses that 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 finalized 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 finalized for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the finalized deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Table 6K contains a list of all of the codes that are defined as either a CC or MCC when assigned as a secondary diagnosis. Each CC or MCC secondary diagnosis code is assigned to a principal diagnosis number that reflects a collection of diagnosis codes which, when reported as the principal diagnosis, will cause the CC or MCC secondary diagnosis to be considered as only a non-CC secondary diagnosis.

9. 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 final rule.

These tables are not published in the Addendum to the proposed rule or final 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 final rule. As discussed in section II.C.11. of the preamble of this FY 2026 IPPS/LTCH PPS final 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.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18067 through 18068), we proposed 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. We also stated that 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 reviewed 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 considered 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 noted 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.

In this FY 2026 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the proposed assignments, our responses to those comments, and our finalized policies.

Comment: Several commenters supported the proposed 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. A commenter expressed appreciation for the new diagnosis codes finalized that describe ''Fontan physiology'' (I27.840, Fontan-associated liver disease [FALD]; I27.841, Fontan-associated lymphatic dysfunction; I27.848, Other Fontan-associated condition; and I27.849, Fontan related circulation, unspecified) and stated they are needed. The commenter also stated they were thankful for the work the Committee and the submitters do to keep the code set current and accurate. Another commenter expressed strong support for the new diagnosis codes finalized related to pyrophosphate metabolism (E83.82, ENPP1 deficiency causing generalized arterial calcification of infancy; E83.822, ENPP1 deficiency causing autosomal recessive hypophosphatemic rickets type 2; E83.823, ABCC6 deficiency causing generalized arterial calcification of infancy; and E83.824, ABCC6 deficiency causing pseudoxanthoma elasticum) and stated providers and medical coders

will now be better equipped to more specifically document and report, which will be very useful for tracking patients diagnosed with these rare conditions and help to improve patient outcomes.

Response: We appreciate the commenters' support and feedback.

Comment: A commenter (the manufacturer) requested that CMS assign procedure code X2H13XB (Insertion of temporary phrenic nerve/diaphragm stimulation electrodes into superior vena cava, percutaneous approach, new technology group 11) that can be reported to describe use of the AeroPace® System, to MS–DRG 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures), MS–DRG 004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures), MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours), and MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours). The commenter stated that based on the predecessor code, CMS assigned this new procedure code to MS–DRG 264 (Other Circulatory System O.R. Procedures) under MDC 05 (Diseases and Disorders of the Circulatory System) and to MS–DRGs 981, 982, and 983 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) as reflected in Table 6B.—New Procedure Codes. The commenter also stated that it understands these are preliminary MS–DRG assignments and do not limit the MS–DRGs to which a case may group.

According to the commenter, because the Food and Drug Administration (FDA) indication for use of the technology is in patients ages 18 years or older on mechanical ventilation > 96 hours and who have not weaned, procedure code X2H13XB will be reported on claims that also report procedure code 5A1955Z (Respiratory ventilation, greater than 96 consecutive hours). The commenter stated that the data described in the new technology add-on payment application demonstrate that over 60 percent of beneficiaries who have received greater than 96 hours of mechanical ventilation are assigned to MS–DRGs 003, 004, 207, and 870.

Response: We thank the commenter for their feedback. We note that procedure code X2H13XB may be reported to describe the use of the AeroPace® System and was finalized following the September 10–11, 2024 ICD–10 Coordination and Maintenance Committee meeting. The materials for the discussion related to this topic are located on the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-materials*.

Under our established process, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new procedure code. We note that because the procedure code that identifies use of the AeroPace® System is describing temporary transvenous diaphragm activation via stimulation of the phrenic nerve(s), the predecessor code is 02HV3YZ (Insertion of other device into superior vena cava, percutaneous approach), which is designated as an O.R. procedure and assigned to MS–DRG 264 under MDC 05.

The logic for case assignment to Pre-MDC MS–DRG 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures) requires that either a procedure code describing extracorporeal membrane oxygenation (ECMO) or a procedure code describing a tracheostomy procedure with procedure code 5A1955Z is reported with any principal diagnosis that is not assigned to MS–DRGs 011, 012, or 013 (Tracheostomy for Face, Mouth and Neck Diagnoses or Laryngectomy with MCC, with CC, and without CC/MCC, respectively) and with a procedure code that is designated as a major operating room (O.R.) procedure. Accordingly, the appropriate MS–DRG assignment to Pre-MDC MS–DRG 003 or to Pre-MDC MS–DRG 004 would be determined when procedure code X2H13XB is reported on a claim with procedure codes that satisfy the logic for case assignment to the respective Pre-MDC MS–DRG.

We note that when procedure code X2H13XB is reported on a claim with procedure code 5A1955Z and a principal diagnosis from MDC 04 (Diseases and Disorders of the Respiratory System), the MS–DRG assignment will result in MS–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours). Specifically, the logic for case assignment to MS–DRG 207 requires any principal diagnosis from MDC 04 with procedure code 5A1955Z. When procedure code X2H13XB is reported on a claim with procedure code 5A1955Z and a principal diagnosis describing septicemia, the MS–DRG assignment will result in MS–DRG 870 (Septicemia or Severe Sepsis with MV >96 Hours). In those scenarios, it is the respiratory ventilation procedure code and the principal diagnosis that will determine the MS–DRG assignment. We refer the reader to the ICD–10 MS–DRG Definitions Manual, Version 43 available in association with this final rule 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.

Comment: Commenters expressed support for the seven new diagnosis codes describing various types of hyperoxaluria and the proposed CC severity level designation for three of the new codes as reflected in Table 6A.—New Diagnosis Codes that was made publicly available in association with the proposed rule. However, the commenters stated that the remaining four new codes were not proposed to be designated as CCs and recommended that CMS reconsider the proposed designations. A commenter stated that each hyperoxaluria type involves the excessive excretion of oxalate in urine that can lead to kidney stones and therefore, all seven codes should be considered for a CC designation.

Response: We appreciate the commenters' feedback. The seven new diagnosis codes describing various types of hyperoxaluria and their proposed severity level designation are shown in the following table:

ICD-10-CM Diagnosis Code	Description	Proposed Severity Level
E72.530	Primary hyperoxaluria, type 1	CC
E72.538	Other specified primary hyperoxaluria	CC
E72.539	Primary hyperoxaluria, unspecified	CC
E72.540	Dietary hyperoxaluria	NonCC
E72.541	Enteric hyperoxaluria	NonCC
E72.548	Other secondary hyperoxaluria	NonCC
E72.549	Secondary hyperoxaluria, unspecified	NonCC

Consistent with our established process, we identified diagnosis code E72.53 (Primary hyperoxaluria) which is designated as a CC, as the predecessor code for the three diagnosis codes describing a specified type of primary hyperoxaluria (E72.530, E72.538, and E72.539). We identified diagnosis code R82.992 (Hyperoxaluria) which is designated as a NonCC, as the predecessor code for the four diagnosis codes proposed to be designated as NonCC (E72.540, E72.541, E72.548, and E72.549). We also reviewed the FY 2024 Impact on Resource Use file available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software* for the predecessor codes and the C1, C2, and C3 counts reflected in the following table. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and a more detailed explanation of the columns in the table.

ICD-10-CM Code[a]	Description[b]	Total Count[c]	Cnt 1[d]	C1[e]	Cnt 2[f]	C2[g]	Cnt 3[h]	C3[i]
E72.53	Primary hyperoxaluria	92	2	1.19	31	2.90	59	3.30
R82.992	Hyperoxaluria	57	2	1.06	30	2.10	25	1.85

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is an MCC
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

The table shows that for diagnosis code E72.53 the C1 finding is 1.19 and the C2 finding is 2.90, and for diagnosis code R82.992, the C1 finding is 1.06 and the C2 finding is 2.10. A higher value in the C1 (or C2 and C3) field suggests more resource usage is associated with the diagnosis and an increased likelihood that it is more like a CC or MCC than a NonCC. Thus, a value close to 2.0 suggests the condition is more like a CC than a NonCC but not as significant in resource usage as an MCC. A value close to 3.0 suggests the condition is expected to consume resources more similar to an MCC than a CC or NonCC. The data suggest that when diagnosis code E72.53 is reported as a secondary diagnosis the resources involved in caring for a patient diagnosed with primary hyperoxaluria are aligned with a CC and may also consume resources more similar to an MCC. The data suggest that when diagnosis code R82.992 is reported as a secondary diagnosis that the resources involved in caring for a patient diagnosed with hyperoxaluria are more aligned with a NonCC.

Comment: Several commenters indicated their support for the initiative to refine ICD–10 coding for immune complex membranoproliferative glomerulonephritis (IC–MPGN), though they also expressed concerns regarding the finalized new diagnosis codes. Specifically, a commenter stated that historically, IC–MPGN and C3 glomerulonephritis (C3G) (code N00.A, acute nephritic syndrome with C3 glomerulonephritis) were two distinct but related conditions, and based on that understanding, the proposed codes make sense. However, the commenter reported that new evidence has emerged suggesting that IC–MPGN and C3G may actually be a spectrum of the same condition and some patients can present with IC–MPGN initially and a repeat kidney biopsy might show C3G or the opposite (that is, some patients can present with C3G initially and a repeat kidney biopsy might show IC–MPGN). According to the commenter, the true distinction between these two diagnoses is currently uncertain. The commenter suggested that new codes be developed to address circumstances where the distinction between IC–MPGN and C3G cannot be determined. Other commenters stated similar concerns and suggested that reconsideration be given to the implementation of these new codes, including postponement, until treatment pathways for these conditions become more distinctly defined.

Response: We appreciate the commenters' feedback. We note that the Centers for Disease Control and Prevention's National Center for Health Statistics (CDC/NCHS) has lead responsibility for updates and maintenance to the ICD–10–CM diagnosis code set and the code proposal for Immune Complex-mediated Membranoproliferative Glomerulonephritis (IC–MPGN) was discussed at the September 10–11, 2024 ICD–10 Coordination and Maintenance Committee meeting. The materials for the discussion relating to this topic are located on the CDC website at: *https://www.cdc.gov/nchs/icd/icd-10-maintenance/meetings.html.*

The finalized diagnosis codes describing IC–MPGN are:

ICD-10-CM Code	Description
N00.B1	Acute nephritic syndrome with idiopathic immune membranoproliferative glomerulonephritis(IC-MPGN)
N00.B2	Acute nephritic syndrome with secondary immune complex membranoproliferative glomerulonephritis (IC-MPGN)
N04.B1	Nephrotic syndrome with idiopathic immune complex membranoproliferative glomerulonephritis(IC-MPGN)
N04.B2	Nephrotic syndrome with secondary immune complex membranoproliferative glomerulonephritis(IC-MPGN)

We communicated with the CDC/NCHS staff regarding the feedback and concerns expressed by the commenters with respect to the new codes and they indicated that the public comments received in response to the code proposal were all in support.

Comment: A commenter stated that CMS proposed to assign ICD–10–PCS code D228DZZ (Stereotactic other photon radiosurgery of conduction mechanism) to MS–DRG 317 (Concomitant Left Atrial Appendage Closure and Cardiac Ablation). The commenter indicated that the ICD–10 meeting materials describe the code proposal as enabling the capture of procedures such as cardiac stereotactic body radiotherapy (SBRT). Additionally, the commenter stated the meeting materials reflect that cardiac SBRT, also called cardiac radioablation, is a non-invasive procedure to treat ventricular tachycardia (VT) that allows for the precise delivery of high-dose radiation to target tissue to any desired area within the body, including areas that may be inaccessible in traditional catheter ablation while also minimizing radiation exposure to adjacent anatomic structures. Alternatively, the commenter reported that intracardiac catheter ablation procedures are either percutaneous or surgical procedures, often involving femoral access and transeptal puncture to access the left atrium and ablate electrical irregularities causing atrial fibrillation. According to the commenter, because of the non-invasive nature of the cardiac SBRT procedure, its application to the treatment of VT, and the lack of identifiable current clinical concomitant performance with left atrial appendage closure (LAAC) during the same operative session, they stated their belief that the new procedure code (D228DZZ) is inappropriately proposed for assignment to MS–DRG 317. The commenter requested that CMS reconsider the appropriateness of this proposed assignment as well as the potential need for a different assignment when cardiac SBRT is performed without percutaneous LAAC.

Response: We appreciate the commenter's feedback. The proposal for a new procedure code to describe SBRT was discussed at the September 10, 2024 ICD–10 Coordination and Maintenance Committee meeting. 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 code request, including a recording of the discussion and the related meeting materials.

Procedure code D228DZZ was approved and finalized following the review and consideration of public comments effective with discharges on and after April 1, 2025, as reflected in Table 6B associated with the proposed rule (and available via the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*).

Under our established process, we reviewed the predecessor code. The predecessor code for SBRT is 02583ZZ (Destruction of conduction mechanism, percutaneous approach) which is designated as an O.R. procedure and is assigned to MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with MCC and without MCC, respectively) in addition to MS–DRG 317. Because SBRT is not considered an intracardiac catheter ablation procedure we did not propose assignment to MS–DRGs 273 and 274.

We acknowledge that SBRT and LAAC procedures may be performed for separate and distinct cardiac conditions (that is, ventricular tachycardia and atrial fibrillation, respectively) as reflected in the September 10, 2024 ICD–10 Coordination and Maintenance Committee meeting materials, however, recent studies also suggest that SBRT or stereotactic arrhythmia radioablation (STAR) may be indicated as a non-invasive treatment option for atrial fibrillation. Although studies are ongoing, we believe the assignment of SBRT to MS–DRG 317 is appropriate at this time. We note that if there is a lack of concomitant LAAC and SBRT procedures performed, there is no significant impact since, as previously stated, the designation of the procedure code that describes SBRT is designated as non-O.R. Specifically, in response to the commenter's request that CMS consider the potential need for a different assignment when cardiac SBRT is performed without percutaneous LAAC, we note that because the designation of procedure code D228DZZ is non-O.R., the reporting of procedure code D228DZZ only impacts the MS–DRG assignment when reported with a LAAC procedure as listed in the logic for case assignment to MS–DRG 317. Accordingly, when procedure code D228DZZ is reported in the absence of an LAAC procedure, the MS–DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a CC or MCC, other procedures or services performed, age, sex, and discharge status.

Comment: A commenter stated that the proposed MS–DRG assignment for new diagnosis code E11.A (Type 2 diabetes mellitus without complications in remission) to MDC 10 (Endocrine, Nutritional and Metabolic Diseases and Disorders) in MS–DRGs 637, 638, and 639 (Diabetes with MCC, with CC, and without CC/MCC, respectively) as listed in Table 6A in association with the FY 2026 IPPS/LTCH PPS proposed rule is not entirely consistent with the MS–DRG assignments of the predecessor code, E11.9 (Type 2 diabetes mellitus without complications). According to the commenter, in addition to MDC 10, diagnosis code E11.9 is also currently mapped to Pre-MDC MS–DRG 008 (Simultaneous Pancreas and Kidney Transplant), Pre-MDC MS–DRG 010 (Pancreas Transplant), and Pre-MDC MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis), as are diagnosis codes E08.9 (Diabetes mellitus due to underlying condition without complications), E09.9 (Drug or chemical induced diabetes mellitus without complications), E10.9 (Type 1 diabetes mellitus without complications), and E13.9 (Other specified diabetes mellitus without complications. The commenter stated that each of these five diagnoses describes a specific type of diabetes ''without complications''. However, the commenter also indicated that the five diagnosis codes do not appear to be clinically appropriate to be listed in the logic for Pre-MDC MS–DRGs 008, 010, and 019 because these MS–DRGs are defined by transplant procedures that are indicated for the treatment of diabetes ''with complications''. According to the commenter, a transplant procedure that is assigned to any one of the previously listed Pre-

MDC MS–DRGs would not be indicated for a patient diagnosed with diabetes that does not have any associated complications of the diabetes. The commenter suggested that CMS review the clinical appropriateness for assignment of these five diagnosis codes and consider removing them from the logic for Pre-MDC MS–DRGs 008, 010, and 019 and only maintaining assignment to MS–DRGs 637, 638, and 639 under MDC 10 for FY 2026.

Response: We thank the commenter for the feedback. The commenter is correct that the predecessor code E11.9 (as reflected in the FY 2026 ICD–10–CM Conversion Table available via the CMS website at: *https://www.cms.gov/medicare/coding-billing/icd-10-codes*) for new diagnosis code E11.A currently maps to Pre-MDC MS–DRGs 008, 010, and 019, in addition to MDC 10 MS–DRGs 637, 638, and 639. The commenter is also correct that diagnosis codes E08.9, E09.9, E10.9, and E13.9 describe specific types of diabetes ''without complications''. We agree with the commenter that these codes are not clinically appropriate to be listed in the logic for case assignment to Pre-MDC MS–DRGs 008, 010, and 019 because as the commenter noted, these MS–DRGs are defined by transplant procedures that are indicated for the treatment of diabetes ''with complications''. In light of these findings, we examined claims data from the September 2024 update of the FY 2024 MedPAR file for Pre-MDC MS–DRGs 008, 010, and 019 and for cases reporting any one of the five listed diagnoses. Our analysis yielded zero cases reporting any one of the five diagnoses describing a type of diabetes ''without complications''. For clinical appropriateness and because the diagnoses are not indicated for a pancreatic or kidney transplant procedure, we are removing diagnosis codes E08.9, E09.9, E10.9, E11.9, and E13.9 from the logic lists in Pre-MDC MS–DRGs 008, 010, and 019. We are maintaining the assignment of the diagnosis codes to MDC 10 in MS–DRGs 637, 638, and 639 effective October 1, 2025, for FY 2026.

After consideration of the public comments received, we are finalizing 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 associated with this final rule. In addition, the finalized severity level designations for the new diagnosis codes are set forth in Table 6A. and the finalized O.R. status for the new procedure codes are set forth in Table 6B associated with this final rule.

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

- 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.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026;
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026;
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026;
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026;
- Table 6I.—Complete MCC List—FY 2026;
- Table 6I.1.—Additions to the MCC List—FY 2026;
- Table 6J.—Complete CC List—FY 2026;
- Table 6J.1.—Additions to the CC List—FY 2026;
- Table 6J.2.—Deletions to the CC List—FY 2026; and
- Table 6K.—Complete List of CC Exclusions—FY 2026.

10. 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 final 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 MEARIS™ at *https://mearis.cms.gov/public/home* by October 20, 2025.

Based on the changes that we proposed to make for FY 2026, as discussed in section II.C. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, we proposed to modify the existing surgical hierarchy for FY 2026 as illustrated in the following tables. We noted in the proposed rule 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 noted 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.

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MDC 05 (Diseases and Disorders of the Circulatory System)			
		Current Version 42 Surgical Hierarchy	**Proposed Version 43 Surgical Hierarchy**
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)			
		Current Version 42 Surgical Hierarchy	Proposed Version 43 Surgical Hierarchy
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
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

Comment: Several commenters expressed support for the proposed changes to the surgical hierarchy for MDC 05 and MDC 08.

Response: We thank the commenters for their support.

Therefore, after consideration of the public comments we received, and based on the changes that we are finalizing for FY 2026, as discussed in section II.C. of the preamble of this final rule, we are finalizing our proposals to modify the existing surgical hierarchy under MDC 05 and MDC 08, effective with the ICD–10 MS–DRGs Version 43, with modification. As discussed in section II.C.4., we are creating MS–DRG 209, MS–DRG 213, MS–DRG 218, and MS–DRGs 359 and 360. As discussed in section II.C.5., we are not finalizing the creation of proposed new MS–DRGs 403 and 404 for FY 2026.

The finalized surgical hierarchy for MDC 05 and MDC 08 is shown in the following tables. These changes are also reflected in Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual, Version 43 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software*, effective October 1, 2025, for FY 2026.

MDC 05 (Diseases and Disorders of the Circulatory System)		
		Final Version 43 Surgical Hierarchy
MS-DRG 209	Complex Aortic Arch Procedures	1
MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures	2
MS-DRG 215	Other Heart Assist System Implant	3
MS-DRGs 216 - 218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization	4
MS-DRGs 231 - 232	Coronary Bypass with PTCA	5
MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization	6
MS-DRG 317	Concomitant Left Atrial Appendage Closure and Cardiac Ablation	7
MS-DRGs 219 - 221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization	8
MS-DRGs 233 - 234	Coronary Bypass with Cardiac Catheterization or Open Ablation	9
MS-DRG 213	Endovascular Abdominal Aorta with Iliac Branch Procedures	10
MS-DRGs 266 - 267	Endovascular Cardiac Valve Replacement and Supplement Procedures	11
MS-DRGs 276 - 277	Cardiac Defibrillator Implant	12
MS-DRGs 268 - 269	Aortic and Heart Assist Procedures Except Pulsation Balloon	13
MS-DRGs 235 - 236	Coronary Bypass without Cardiac Catheterization	14
MS-DRG 245	AICD Generator Procedures	15
MS-DRGs 270 - 272	Other Major Cardiovascular Procedures	16
MS-DRGs 228 - 229	Other Cardiothoracic Procedures	17
MS-DRGs 319 - 320	Other Endovascular Cardiac Valve Procedures	18
MS-DRGs 278 - 279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures	19
MS-DRGs 323 - 324	Coronary Intravascular Lithotripsy with Intraluminal Device	20
MS-DRGs 239 - 241	Amputation for Circulatory System Disorders Except Upper Limb and Toe	21
MS-DRG 265	AICD Lead Procedures	22
MS-DRGs 273 - 274	Percutaneous and Other Intracardiac Procedures	23
MS-DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device	24
MS-DRG 263	Vein Ligation and Stripping	25
MS-DRGs 252 - 254	Other Vascular Procedures	26
MS-DRGs 359 - 360	Percutaneous Coronary Atherectomy with Intraluminal Device	27
MS-DRGs 242 - 244	Permanent Cardiac Pacemaker Implant	28
MS-DRGs 260 - 262	Cardiac Pacemaker Revision Except Device Replacement	29
MS-DRG 318	Percutaneous Coronary Atherectomy without Intraluminal Device	30
MS-DRGs 321 - 322	Percutaneous Cardiovascular Procedures with Intraluminal Device	31
MS-DRGs 258 - 259	Cardiac Pacemaker Device Replacement	32
MS-DRGs 255 - 257	Upper Limb and Toe Amputation for Circulatory System Disorders	33
MS-DRGs 250 - 251	Percutaneous Cardiovascular Procedures without Intraluminal Device	34
MS-DRG 264	Other Circulatory System O.R. Procedures	35

MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue)		
		Final Version 43 Surgical Hierarchy
MS-DRGs 426 - 428	Multiple Level Combined Anterior and Posterior Spinal Fusion Except Cervical	1
MS-DRGs 429 - 430	Combined Anterior and Posterior Cervical Spinal Fusion	2
MS-DRGs 456 - 458	Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions	3
MS-DRGs 447 - 448	Multiple Level Spinal Fusion Except Cervical	4
MS-DRG 402	Single Level Combined Anterior and Posterior Spinal Fusion Except Cervical	5
MS-DRGs 463 - 465	Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders	6
MS-DRGs 450 - 451	Single Level Spinal Fusion Except Cervical	7
MS-DRGs 466 - 468	Revision of Hip or Knee Replacement	8
MS-DRGs 461 - 462	Bilateral or Multiple Major Joint Procedures of Lower Extremity	9
MS-DRGs 471 - 473	Cervical Spinal Fusion	10
MS-DRGs 474 - 476	Amputation for Musculoskeletal System and Connective Tissue Disorders	11
MS-DRG 483	Major Joint or Limb Reattachment Procedures of Upper Extremities	12
MS-DRGs 477 - 479	Biopsies of Musculoskeletal System and Connective Tissue	13
MS-DRGs 492 - 494	Lower Extremity and Humerus Procedures Except Hip, Foot and Femur	14
MS-DRGs 498 - 499	Local Excision and Removal of Internal Fixation Devices of Hip and Femur	15
MS-DRGs 485 - 487	Knee Procedures with Principal Diagnosis of Infection	16
MS-DRGs 521 - 522	Hip Replacement with Principal Diagnosis of Hip Fracture	17
MS-DRGs 480 -482	Hip and Femur Procedures Except Major Joint	18
MS-DRGs 518 - 520	Back and Neck Procedures Except Spinal Fusion or Disc Device or Neurostimulator	19
MS-DRGs 469 - 470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity or Total Ankle Replacement	20
MS-DRGs 510 - 512	Shoulder, Elbow or Forearm Procedures, Except Major Joint Procedures	21
MS-DRGs 503 - 505	Foot Procedures	22
MS-DRGs 500 - 502	Soft Tissue Procedures	23
MS-DRGs 495 - 497	Local Excision and Removal of Internal Fixation Devices Except Hip and Femur	24
MS-DRGs 507 - 508	Major Shoulder or Elbow Joint Procedures	25
MS-DRGs 488 - 489	Knee Procedures without Principal Diagnosis of Infection	26
MS-DRGs 513 -514	Hand or Wrist Procedures, Except Major Thumb or Joint Procedures	27
MS-DRG 506	Major Thumb or Joint Procedures	28
MS-DRGs 515 - 517	Other Musculoskeletal System and Connective Tissue O.R. Procedures	29

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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. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

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: *http://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 was April 18, 2025. Any new diagnosis and procedure codes for which there was consensus of public support, and for which complete tabular and indexing changes would be made by June 2025 are 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 final 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 final 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 and final rules, they are not subject to comment in the proposed or final rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available on the CMS website as discussed in section VI. of the Addendum to the proposed rule and this final 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.

Comment: A commenter stated that in March 2025, CMS decided to not present the Spring 2025 ICD–10–PCS procedure code topics during a public meeting. Instead, CMS posted the meeting materials on the CMS website and solicited public comments with a 30-day comment period. The commenter requested clarification from CMS regarding its plans for future ICD–10–PCS procedure code topics. Specifically, whether CMS intends to resume its previous practice of hosting a public meeting twice annually, in March and September, or if CMS plans to permanently discontinue these meetings. The commenter stated they do not oppose the current approach; however, appreciate any insight into CMS' intention for future code proposals.

Response: CMS will share any updates to our approach for upcoming ICD–10 Coordination and Maintenance Committee meetings through the CMS website and our Subscriber List. To sign up for ICD–10 Coordination and Maintenance Committee meeting and related updates, members of the public may join the ICD–10 Coordination and Maintenance Committee Meetings Subscriber List. Instructions are located in the Downloads section on the following CMS website: *https://www.cms.gov/medicare/coding-billing/icd-10-codes/icd-10-coordination-maintenance-committee-meetings*.

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*.

As discussed in the proposed rule (90 FR 18071), 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:

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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 04 21 24	143-145 166-168 907-909 957-959
0CYS0Z1	Transplantation of larynx, syngeneic, open approach	Y	03 04 21 24	143-145 166-168 907-909 957-959
0DX80Z7	Transfer small intestine to vagina, open approach	Y	13 21 24	748 907-909 957-959
0DX84Z7	Transfer small intestine to vagina, percutaneous endoscopic approach	Y	13 21 24	748 907-909 957-959
0TT00Z0	Resection of right kidney, open approach, allogeneic	Y	11 21 24	656-661 907-909 957-959
0TT00Z1	Resection of right kidney, open approach, syngeneic	Y	11 21 24	656-661 907-909 957-959
0TT00Z2	Resection of right kidney, open approach, zooplastic	Y	11 21 24	656-661 907-909 957-959
0TT10Z0	Resection of left kidney, open approach, allogeneic	Y	11 21 24	656-661 907-909 957-959
0TT10Z1	Resection of left kidney, open approach, syngeneic	Y	11 21 24	656-661 907-909 957-959
0TT10Z2	Resection of left kidney, open approach, zooplastic	Y	11 21 24	656-661 907-909 957-959

Procedure Code	Description	O.R.	MDC	MS-DRG
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 21	270-272 907-909
X2U93YA	Supplement right atrium with intraluminal device, heterotopic bioprosthetic valve(s), percutaneous approach, new technology group 10	Y	05	266-267
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

Procedure Code	Description	O.R.	MDC	MS-DRG
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
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.

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The 50 procedure codes are also reflected in Table 6B.—New Procedure Codes, in association with the proposed rule and 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 the FY 2026 IPPS/LTCH PPS proposed rule, we solicited 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 discuss the comments we received on these assignments in section II.C.9. of this final rule as well as our finalized assignments, as reflected in Table 6B.—New Procedure Codes in association with this final rule.

In the proposed rule, we also noted 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 final 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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule, 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.

In the proposed rule (90 FR 18074), we noted that for FY 2025, there are currently 74,044 diagnosis codes and 78,986 procedure codes. We also noted as displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with the 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 had been finalized for FY 2026 at the time of the development of the 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.

As discussed in section II.C.13 of the preamble of this final rule, we are making 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 available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* in association with this final rule. As shown in Table 6B.—New Procedure

Codes, there were procedure codes proposed for the Spring 2025 ICD–10 Coordination and Maintenance Committee Update that were not finalized in time to include in the proposed rule and are identified with an asterisk. We refer the reader to Table 6B.—New Procedure Codes associated with this final rule and available on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps* for the detailed list of these 142 new procedure codes finalized for FY 2026.

We also note, as reflected in Table 6C.—Invalid Diagnosis Codes and in Table 6D.—Invalid Procedure Codes, there are a total of 28 diagnosis codes and 27 procedure codes that will become invalid effective October 1, 2025. Based on these code updates, effective October 1, 2025, there are a total of 74,719 ICD–10–CM diagnosis codes and 79,115 ICD–10–PCS procedure codes for FY 2026 as shown in the following table.

FY 2025 ICD-10-CM	74,260 total codes	FY 2025 ICD-10-PCS	78,986 total codes
FY 2026 ICD-10-CM	487 additions	FY 2026 ICD-10-PCS	156 additions
FY 2026 ICD-10-CM	28 deletions	FY 2026 ICD-10-PCS	27 deletions
FY 2026 ICD-10-CM	**74,719 total codes**	**FY 2026 ICD-10-PCS**	**79,115 total codes**

As stated previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed during the ICD–10 Coordination and Maintenance Committee meeting. 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 will 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. Changes for FY 2026

As discussed in section II.C.3a. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, for FY 2026, under MDC 01, we proposed 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 were proposed for reassignment to MS–DRGs 020, 021, and 022. We also proposed 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 the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, for FY 2026, under MDC 05, we proposed 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 were 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 were 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 proposed 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 also proposed to continue to include the existing MS–DRGs currently subject to the policy.

As discussed in section II.C.3a of the preamble of this FY 2026 IPPS/LTCH PPS final rule, we are not finalizing our proposal 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. Consequently, a subset of the procedures currently assigned to MS–DRGs 023 and 024 will not be reassigned to MS–DRGs 020, 021, and 022. Therefore, we are not finalizing our proposal to add MS–DRGs 020, 021, and 022 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 for FY 2026. We are finalizing our proposal to make conforming changes to the titles of MS–DRGs 023 and 024 in the list of MS–DRGs subject to the policy, with modification. As discussed in section II.C.3a, we are finalizing the change of the description of the logic list in MS–DRG 023 from ''Chemotherapy Implant'' to ''Antineoplastic Implant''. Therefore, for consistency, we are finalizing a change to 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 Major Device Implant or Acute Complex Central Nervous System Principal Diagnosis with MCC or Antineoplastic Implant or Epilepsy with Neurostimulator'' in the list of MS–DRGs subject to the policy. We are not finalizing a change to the title of MS–DRG 024 in the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit for FY 2026.

As discussed in section II.C.4 of the preamble of this FY 2026 IPPS/LTCH PPS final rule, we are finalizing our proposals to create new MS–DRGs 209 and 213. We did not receive any public comments opposing our proposal to add proposed new MS–DRGs 209 and 213 to the list of MS–DRGs that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2025. Therefore, we are finalizing our proposal to add 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 for FY 2026.

We also note that under the current MS–DRGs version 42.1, MS–DRGs 466, 467, and 468 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 table that was made available in association with the proposed rule (90 FR 18075 through 18076). As previously discussed in this section of this final rule, 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. As discussed in section II.C.5. of the preamble of the FY 2026 IPPS/LTCH PPS proposed rule and this final rule, for FY 2026, under MDC 08, we proposed 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). A subset of the procedures currently assigned to MS–DRGs 466, 467, and 468 were proposed for assignment to proposed new MS–DRGs 403 and 404, however, we inadvertently omitted listing MS–DRGs 403 and 404 in the proposed list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit in the proposed rule. As discussed in section II.C.5. of the preamble of this final rule, we are not finalizing our proposal to create new MS–DRGs 403 and 404 for FY 2026. Therefore, MS–DRGs 403 and 404 are not reflected in the table of MS–DRGs that will be subject to the policy for FY 2026.

We did not receive any public comments opposing our proposal to continue to include the existing MS–DRGs currently subject to the policy. Therefore, for the reasons summarized, we are finalizing the list of MS–DRGs in the following table that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2025.

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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	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis With MCC or Antineoplastic Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or 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
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

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The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

13. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2026 IPPS/LTCH PPS proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in section II.C.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these 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. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

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 proposed 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 final rule includes discharges occurring on October 1, 2023, through September 30, 2024, based on bills received by CMS through March 31, 2025, 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 6,899,914 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 March 2025 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 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 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 final rule, we used the March 2025 update of the FY 2023 HCRIS for calculating the FY 2026 cost-based relative weights. Consistent with our historical practice, for this FY 2026 final 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 Final Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the FY 2026 relative weights based on 19 CCRs. The methodology we proposed 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 FY 2026 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this final 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 92.7 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 2025, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2026, 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 also proposed 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 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 national cost center CCRs. In the proposed rule, we stated that if we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy. We did not receive any comments on the groupings in this table and are finalizing the groupings as proposed.

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. In the FY 2026 proposed rule, we stated that 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 invited public comments on our proposals related to recalibration of the proposed FY 2026 relative weights and the changes in relative weights from FY 2025.

Comment: A commenter requested that CMS clarify whether MS–DRGs 016 and 017 were non-monotonic.

Response: The proposed rule inadvertently included an incorrect list of MS–DRGs where a calculation was applied to address non-monotonicity. This list should have been *MS–DRG 095 and MS–DRG 096, MS–DRG 217 and MS–DRG 218.*

After consideration of the comments received, we are finalizing our proposals without modifications related to the recalibration of the FY 2026 relative weights. We summarize and respond to comments relating to the methodology for calculating the relative weight for MS–DRG 018 in the next section of this final rule.

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 [11] 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 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 [12] 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

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

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

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'' 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 the proposed rule, for FY 2026 we proposed 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 final 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 proposed to also exclude claims with standardized drug charges below the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 when we calculate the average cost for MS–DRG 018. For the proposed rule, based on the December 2024 update of the FY 2024 MedPAR file, we estimated that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 is $29,819. We proposed 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 also proposed, 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 proposed 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 noted in the proposed rule 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 stated that 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 also proposed 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 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 the 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 proposed 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 the 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 applied the same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We also proposed to update the value of the adjustor based on more recent data for the final rule.

Comment: Commenters supported our proposal to exclude claims in MS–DRG 018 with standardized drug charges below the median standardized drug charges of cases identified as clinical trials in MS–DRG 018. Commenters stated that this proposal ensures that clinical trial and no-cost cases do not distort payment rates across the IPPS. We note a commenter mistakenly referred to our existing policy as still excluding cases that have a standardized drug charge of less than $373,000.

Commenters requested clarification about whether the median standardized drug charges includes all drug revenue lines and all clinical trial claims, including expanded access claims. Some commenters expressed support for the identification of cases involving patient assistance programs, where no cost is incurred, but expressed confusion regarding the language ''product not purchased in the usual manner'', stating that is subjective, which can lead to confusion and undue administrative burden for providers and varying interpretations by the MACs. A commenter requested that CMS modify the language to reflect the request in the comment summarized in the FY 2025 IPPS/LTCH PPS final rule, which referred to cases where the immunotherapy is ''obtained at no cost''.

Response: We appreciate commenters support for our proposal. While we indicated in the proposed rule that we calculate the median standardized drug charges for cases identified as clinical trial claims including cases that contain ICD–10–CM diagnosis code Z00.6 and do not include payer only code ZC, we note that in calculating the median standardized drug charges for cases identified as clinical trial claims, we included claims that (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'' or (b) contain condition code ''90''. Just as we treat cases identified as clinical trial cases and expanded access use cases in the same manner for payment purposes and in the calculation of the relative weights, we are also including both claims identified as clinical trial cases and claims identified as expanded access use cases in calculating the median drug charges. Since the provider does not incur the cost of the drug in cases identified as clinical trial cases or expanded access use cases, but still incurs costs for other drugs during the inpatient stay, we believe that using the median standardized drug charge for clinical trial and expanded access use cases would appropriately identify other cases involving products not purchased in the usual manner. The drug revenue lines are the same as those used in the relative weight calculations, which are shown in the Cost Center HCRIS Lines Supplemental Data File referenced earlier in this section.

With respect to the commenters who expressed concerns about the language ''product not purchased in the usual manner'', we note that this phrasing is not new; we have used the language ''product is purchased in the usual manner'' in prior rules with respect to MS–DRG 018. Furthermore, we believe that this language is appropriately phrased to include the broad range of scenarios that may fall under it. For example, as described later in this section, commenters raised the possibility of immunotherapy products administered over multiple encounters. Given that we cannot predict all possible scenarios where the product is not purchased in the usual manner, use of a condition code that reflects a broad array of circumstances will facilitate more accurate payment and ratesetting. We further note that the ''usual manner'' in which a product is purchased may differ for products administered in one dose versus split doses.

Comment: Commenters noted that some immunotherapy products may be administered over multiple encounters (including in an outpatient setting). A commenter requested that CMS confirm that a reduced payment for MS–DRG 018 does not apply when a hospital purchases an immunotherapy product (that is, incurs a cost), irrespective of whether it is administered in multiple encounters. This commenter requested that if CMS has specific requirements for how providers should handle these situations, it should clarify them or state that it is up to the individual provider to determine how to develop charges for multiple administrations of a single product obtained from a manufacturer. A commenter stated that unless manufacturers change their processes for products administered over multiple encounters, hospitals will continue to receive a single invoice and require guidance about how to report the charges.

Response: CMS does not dictate a provider's charge structure or how they itemize their charges. As stated in Chapter 22, Section 2203 of the Provider Reimbursement Manual (*https://www.cms.gov/regulations-and-guidance/guidance/manuals/paper-based-manuals-items/cms021929*), providers ''should have an established charge structure which is applied uniformly to each patient as services are furnished to the patient and which is reasonably and consistently related to the cost of providing the services''. Providers should bill in the manner that they customarily bill for split-dose administration and the charges should be reasonably and consistently related to the cost of providing the service in a split-dose administration circumstance. A split-dose administration should not result in twice the amount of payment just by virtue of the fact it is a split-dose administration. For example, we remind hospitals that Chapter 3, Inpatient Hospital Billing, section 40.2.5 of the Medicare Claims Processing Manual (*https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c03.pdf*) states that hospitals may place a patient on a leave of absence when readmission is expected and the patient does not require a hospital level of care during the interim period. Placing a patient on a leave of absence will not generate two payments. Only one bill and one DRG payment are made.

Comment: A commenter stated that a potential reason 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, is that the case involves a clinical trial of another product. The commenter stated that given the two-step and manual process in flagging these claims, (that is, the provider includes ''Diff Prod Clin Trial'' in the Remarks field and the MAC adds a payer-only condition code of ''ZC''), there is likely a percentage of cases where the condition code was not applied as it should be. The commenter noted that CMS' recent billing instructions that automate the application of ''ZC'' should reduce the number of claims with this profile.

Response: We appreciate the feedback on our comment solicitation and will continue to monitor CAR T-cell therapy claims for such potential anomalies.

Comment: Some commenters expressed concern that CMS no longer uses the $373,000 threshold to identify clinical trial cases and requested that CMS continue to refine its methodology to also consider standardized drug charges to correctly identify clinical trial cases. Commenters expressed concern that due to incorrect coding or incorrect application of condition codes, cases below the $373,000 threshold may be identified as clinical trials when the provider incurs the cost of the drug. The commenter stated that as a result, these cases would be included in ratesetting for MS–DRG 018 and these cases could be underpaid, particularly as more hospitals administer cell and gene therapies. The commenter requested that CMS publish information on future cases that are below the $373,000 threshold given the likely impact on the payment rate for MS–DRG 018.

Response: As we stated in the FY 2024 (88 FR 58791) and FY 2025 IPPS/LTCH PPS (89 FR 69112) final rules, while there continues to be a small percentage of claims that report standardized drug charges of less than $373,000 and do not report ICD–10–CM code Z00.6, we do not believe it is necessary to continue the use of the proxy until the number of cases reaches zero. In addition, our proposal to 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 (a) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (b) contain condition code ''90'') is expected to reduce the number of cases with low standardized drug charges that group to MS–DRG 018. We note that information on obtaining the MedPAR Limited Data Set is available on the CMS website, at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MEDPARLDSHospitalNational.*

Comment: A few commenters expressed confusion about CMS' differentiation between clinical trial and expanded access use cases. A commenter stated that it does not believe this differentiation is CMS' intent because expanded access use of CAR T-cell or other therapies that are grouped to MS–DRG 018 must occur as part of an Investigational New Device (IND) study, which would have a National Clinical Trial number and would meet criteria for routine costs of the clinical trial NCD 310.1. This commenter cited the FDA website [13] in support of these statements. Another commenter requested that CMS clarify that expanded access cases are a type of clinical trial.

A commenter requested that CMS clarify that expanded access use would also be excluded from ratesetting because facilities do not incur the cost of these products. A few commenters requested that CMS clarify that the agency would expect to see clinical trial billing indicators on expanded access claims (that is, diagnosis code Z00.6, condition code 30, value code D4, and the NCT number), in addition to condition code 90, which would help identify which clinical trial claims are expanded access claims.

Response. The FDA states, at the link provided by the commenter, ''Expanded access, sometimes called ''compassionate use,'' is the use of investigational new drug products *outside of clinical trials* to treat patients with serious or immediately life-threatening diseases or conditions when there are no comparable or satisfactory alternative treatment options''. While we utilize separate condition codes to identify clinical trial claims and expanded access use cases, we note that they are treated the same for payment purposes and in the calculation of the relative weights for MS–DRG 018.

Comment: A commenter stated that the MS–DRG payment for CAR T-cell therapy services has never been sufficient and provided various reasons for this, including problems with hospital chargemasters, CCRs, and charge compression. Commenters provided various suggestions to mitigate these concerns and increase the payment rate for MS–DRG 018. Commenters stated that the percentage of cases in MS–DRG 018 that are eligible for outlier payments has increased since FY 2021, which, the commenter stated, if left unaddressed, places a constraint on the outlier pool, which negatively impacts all hospitals.

A commenter stated that hospitals should not be targeted for having high outlier payments given that it is the ''new norm'' for cell and gene therapies, and that hospitals should not be questioned if they set their charges consistent with their CCRs. This commenter stated that CMS needs to provide more clarity so that stakeholders understand that hospitals have no choice but to mark up product charges, and that patients do not bear the cost of those charges. This commenter also requested that CMS consider other methodologies to pay for immunotherapies and expand CMMI's cell and gene therapy model.

Commenters requested that CMS explore the integration of Medicare Advantage claims into the ratesetting process for MS–DRG 018 to improve the sample size available for low volume products, which could improve the robustness and reliability of cost estimates. A commenter noted that as the percentage of enrollees in Medicare fee-for-service decreases, the number of claims used in the ratesetting process will decrease and become less representative for predicting resource utilization.

Response: Regarding the comments that the MS–DRG relative weight for MS–DRG 018 is inadequate and does not result in payment that fully covers the hospital resource costs, as well as comments regarding hospital charging practices, we refer readers to the FY 2022 IPPS/LTCH final rule (86 FR 44965) where we responded to similar comments. With respect to the commenter's statement about hospitals being ''targeted'' for having high outlier payments, we are unaware of the issue the commenter is raising. We note our proposal, as discussed in the CY 2026 OPPS proposed rule (90 FR 33476), to collect payer-specific negotiated charge data from MA organizations by MS–DRG for use in the MS–DRG relative weight setting, would, if finalized, obviate many of the concerns that commenters raised, including challenges with hospital charging practices and the potential role of MA claims in the ratesetting process.

Comment: Commenters requested that CMS revise its cost reporting instructions for cell and gene therapy products (revenue codes 0891 and 0892) to instruct providers to use cost center 78. A commenter requested that CMS also instruct providers to leave the services associated with these therapies in their original cost centers. This commenter stated that there is a precedent for CMS to define a cost center based on a revenue code, like it did for the implantable devices cost center. The commenter also requested that CMS clarify whether hospitals are allowed to use product charges and expenses as valid statistics to allocate administrative and general expenses to cost report line 78.

Response: We do not believe changes to billing guidance are needed at this time but will take these comments into consideration when developing policies and program requirements for future years for CAR T-cell therapy policy. We further note that under the proposal in

[13] *https://www.fda.gov/drugs/investigational-new-drug-ind-application/ind-applications-clinical-treatment-expanded-access-overview.*

the CY 2026 OPPS proposed rule to collect payer-specific negotiated charge data from MA organizations by MS–DRG for use in the MS–DRG relative weight setting, an additional cost center would not impact the relative weight for MS–DRG 018.

After consideration of the public comments we received, we are finalizing our proposals without modifications regarding the calculation of the relative weight for MS–DRG 018. We note that for this final rule, based on the March 2025 update of the FY 2024 MedPAR file, we estimated that the median standardized drug charge of claims identified as clinical trials in MS–DRG 018 (that is, claims that (a) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (b) contain condition code ''90'') is $27,466. Applying this finalized methodology, based on the March 2025 update of the FY 2024 MedPAR file used for this final rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($61,643.46) were 16 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as nonclinical trial cases ($384,471.59).

Accordingly, as we did for FY 2025, we are finalizing our proposal to adjust the transfer-adjusted case count for MS–DRG 018 by applying the adjustor of 0.16 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 final rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case, and other cases where immunotherapy product is not purchased in the usual manner, such as obtained at no cost, was adjusted by 0.16. As we did for FY 2025, we are applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations.

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 final rule, we present the 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 final budget neutrality adjustment for FY 2026, we refer readers to the Addendum of this final rule.

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

We developed the 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 final FY 2026 cost-based relative weights were then normalized by an adjustment factor of 1.922881 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 FY 2026 relative weight equal to 90 percent of the FY 2025 relative weight. The final relative weights for FY 2026 as set forth in Table 5 associated with this final 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 19 national average CCRs for FY 2026 are as follows:

NATIONAL AVERAGE CCRS	
Group	CCR
Routine Days	0.394
Intensive Days	0.335
Drugs and Cellular Therapies	0.177
Supplies & Equipment	0.297
Implantable Devices	0.255
Inhalation Therapy	0.148
Therapy Services	0.256
Anesthesia	0.071
Labor & Delivery	0.373
Operating Room	0.153
Cardiology	0.086
Cardiac Catheterization	0.098
Laboratory	0.098
Radiology	0.123
MRIs	0.065
CT Scans	0.032
Emergency Room	0.139
Blood and Blood Products	0.23
Other Services	0.327

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 proposed to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2026. In this final rule, using data from the FY 2024 MedPAR file, there are 9 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 proposed 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
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)

We did not receive any public comments on this proposal and therefore are finalizing it for FY 2026 without modification.

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 the proposed rule, we highlighted 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 final 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 final rule, by clicking on the FY 2026 IPPS Final 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 of 1996 (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[14] 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

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

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 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 [15] [16] (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 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. [17] [18] 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 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

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

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

[17] 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.*

[18] 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.*

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.[19] [20] 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 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.

Comment: A commenter expressed support for this clarification and, as FDA's review processes evolve or other challenges arise, encouraged CMS to be flexible and to consider additional opportunities to clarify documentation requirements to ensure technologies remain eligible for new technology add-on payment and reach patients who need them, without creating further delays in the availability of new technology add-on payment.

Response: We appreciate the commenter's support and note that an applicant may submit to us specific questions regarding their new technology add-on payment application using the resources described on the CMS website for the electronic application intake system: *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/new-medical-services-and-new-technologies.*

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 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

[19] 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.*

[20] 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.*

rule (87 FR 48986 through 48990) for further information regarding this policy. In the proposed rule, we stated that 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 stated that 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.

Comment: Multiple commenters asked CMS to reconsider finalizing or request additional input from interested parties through rulemaking before finalizing the inclusion of certain cost criterion information in the public posting beginning with FY 2027. Commenters stated that because CMS already summarizes the relevant cost analyses in the proposed rules to allow interested parties to comment on the analyses, there is no extra benefit to additional disclosures. Some commenters stated that disclosing applicants' cost analyses raises confidentiality concerns because information about expected inpatient volume and other data incorporated within cost analyses are based on confidential commercial and financial information, including proprietary market analyses. A commenter further explained that for therapies that target small patient populations, even high-level methodological detail may be commercially sensitive or permit back-calculation of pricing strategy. Commenters explained that such information should be kept confidential, consistent with long-standing statutes recognizing the need to protect confidential commercial and financial information against public disclosure. Multiple commenters also noted that because of the single annual application period, applicants generally submit their applications before their products are approved by FDA, creating special sensitivities in disclosing pricing information. Commenters stated that public release of this information could create disincentives for small or emerging companies that may be more risk-averse with respect to transparency of confidential methods.

Multiple commenters requested that CMS provide additional details on the guardrails and specific steps the Agency would employ to ensure proprietary and market sensitive cost and pricing data provided by new technology add-on payment applicants are not inadvertently publicized, either directly or indirectly, through this proposal. For example, a commenter noted that the application asks the applicant to provide the charges related to the new technology, as well as the cost-to-charge ratio used to convert the product's cost to charges, and if CMS were to publish these two data points, the public would be able to calculate the cost of the product. Another commenter further asked CMS to articulate the policy gaps this proposal would address and what stakeholder needs it would serve.

A commenter recommended that CMS modify the proposal to allow applicants to redact, generalize, or submit alternate public summaries of methodology where disclosure could reasonably reveal proprietary strategy. It also asked that CMS provide clear written guidance on what components of the cost methodology are considered ''public'' versus protected from disclosure.

Another commenter also stated its appreciation and support for CMS's commitment to only publishing an explanation of the applicant's cost analysis methodology without including cost or pricing data, and CMS's effort to bring additional information about new technology add-on payment applications to the public. The commenter further asked that CMS create a sub-section text box dedicated to capturing proprietary information in the cost analysis methodology section that would not be included in any publication. Finally, the commenter asked that CMS avoid use of artificial intelligence in drafting summaries of applications for public display, including in the proposed rule, or ensure human review of the summary before publication.

Response: We thank the commenters for their feedback and appreciate the commenters' raising their concerns regarding balancing the need to maintain the confidentiality of commercial and financial information with our intent to further improve and streamline our evaluation process and support transparency and engagement with interested parties.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized to publicly post online new technology add-on payment applications, including the completed application forms, certain related materials (for example, attachments, uploaded supportive 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). We also provided a mechanism for applicants to submit confidential information that would not be posted online, such as in a separate section of the application, or by identifying particular questions for which the information submitted would not be publicly posted. We also stated we would not publicly post cost and volume information; however, consistent with our current practice, we would continue to summarize and discuss certain cost and volume information for the proposed rule and will indicate as such in the application. 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 and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly.

While we did not initially include the cost criterion analysis and related materials in the public posting as we gained experience with the public posting process, as noted by the commenters, in the meantime, we have continued to summarize the information under the cost criterion, including the applicant's assertions and supporting data on how the technology meets the criteria under § 412.87, in the annual rules. This includes information such as: the inclusion/exclusion criteria used for the cost analysis, including the data source and list of ICD–10–CM/PCS codes and MS–DRGs used by the applicant, the number of claims and

MS–DRGs identified by the applicant for the cost analysis, the indirect and direct charges removed for prior technology (including the methodology used to estimate these charges), how the applicant standardized charges, the inflation factor applied to the standardized charges, the indirect and direct charges added for the new technology (including the methodology used to convert the cost of the new technology to charges), the average case-weighted threshold amount, and the final inflated average case-weighted standardized charge per case.

Under this current proposal, the processes described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) remain unchanged. The information described by commenters, including high-level methodological detail or information about data incorporated within cost analyses, is already included or subject to inclusion in the proposed and final rulemaking. Under our existing practice, we generally do not consider information that is marked as confidential, proprietary, or trade secret when determining whether a technology meets the criteria for new technology add-on payments. We would continue to indicate in the application where certain information will not be posted publicly (for example, contact information, cost and volume), otherwise, applicants should expect that everything else may be posted publicly. We would continue to provide a mechanism for applicants to submit confidential information that would not be posted online in a separate section of the application. Certain cost and volume information would continue to be included in the proposed or final rulemaking. For example, for an alternative pathway application, we continue to include, as applicable, the maximum add-on payment amount, where cost information is available. In the final rule, we would continue to provide, for approved technologies, the final add-on payment amounts and volume estimates.

When reviewing the public postings prior to publication, we would continue to use human review rather than review by artificial intelligence. Under this proposal, the case weighted threshold and final inflated case weighted standardized charge per case would be included in the public posting because they are currently subject to discussion in the cost criterion analysis for each eligible application in the proposed rule. The cost criterion analysis spreadsheet attachment would continue to be excluded from the public posting. Other cost or charge values, such as for charges related to the new technology, provided in the applicant's responses would not be included in the public posting. Human review would be used to identify and manually redact cost or charge values that may have been provided in the applicant's responses in the cost criterion section.

We continue to believe that providing additional information to the public by publicly posting the applications and certain related materials online helps further public engagement and fosters greater public input on the various new medical services and technologies presented annually for consideration for new technology add-on payments. We also continue to believe that posting the applications online reduces the risk that we may inadvertently omit or misrepresent relevant information submitted by applicants, or are perceived as misrepresenting such information, in our summaries in the rules. We do not believe that it would be appropriate for applicants to further redact, generalize, or provide alternate public summaries that would differ from the information provided in their new technology add-on payment applications for public review. As noted, we will continue to provide a mechanism for applicants to submit confidential information that would not be posted online in a separate section of the application.

Therefore, we are finalizing that, beginning with the new technology add-on payment applications submitted for FY 2027, 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 cost or charge values that may have been provided in the applicant's responses in the cost criterion section would not be included in the public posting. 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.

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 did not summarize any written comments in the proposed rule that were unrelated to the substantial clinical improvement criterion. In section II.E.5. of the preamble of the proposed rule, we summarized comments regarding individual applications, or, if applicable, indicated 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 CommitteIn 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. FY 2026 Status of Technologies Receiving New Technology Add-On Payments for FY 2025

In this section of the final rule, we discuss the 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. In the proposed rule, we presented 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 would still be considered ''new'' for purposes of new technology add-on payments for FY 2026. We also presented 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 would no longer be 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.

In the proposed rule, we provided Table II.E–01.A listing the technologies that were first approved for new technology add-on payments prior to FY 2025, for which we proposed to continue making new technology add-on payments for FY 2026 because they were 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 presented 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 referred readers to the cited final rules in the 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.

In the proposed rule, we also provided Table II.E–01.B listing the technologies that were first approved for new technology add-on payments in FY 2025, for which we proposed to continue making new technology add-on payments for FY 2026 because they were 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 presented 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 referred readers to the cited final rules in the 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 invited 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 of the proposed rule.

Comment: Multiple commenters supported CMS's proposed continuation of 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 would still be considered ''new'' for purposes of new technology add-on payments for FY 2026.

Response: We appreciate the commenters' support.

Comment: Commenters, including the applicant for CYTALUX® for use in lung cancer, stated that they found that providers often do not bill for the full cost of the single-use vials when only a portion of the vial is administered during the surgical procedure. Commenters noted that this appears to be due confusion about whether Medicare Part B's discarded drug billing rules apply to inpatient billing under Medicare Part A, or uncertainty about whether the full vial cost should be reported in cases where only partial use occurs due to patient-specific dosing considerations.

The applicant noted that although the non-reporting of the full vial cost does not affect the triggering of the new technology add-on payment because payment is driven by the unique ICD–10–PCS code for CYTALUX®, this practice can decrease the likelihood that a hospital's reported cost for a case will exceed the payment threshold. Furthermore, commenters noted that underreporting of the full cost of CYTALUX® can distort the hospital's cost report data, which CMS relies upon for rate-setting purposes and for future MS–DRG assignments.

Commenters requested that CMS clarify that because hospitals are not required to report drug wastage, they should bill for the full package size used in administration, and that hospitals should report the full acquisition cost of inpatient-administered drugs in their cost reports, regardless of the quantity administered. A commenter further suggested that CMS could instead support the reporting of waste for products within the billing process for Medicare Part A inpatient billing, similar to what is required on Medicare Part B.

Response: We thank the applicant and other commenters for their comment. We note that they are correct that the drug wastage policy applies to Medicare Part B. We encourage commenters to consult the CMS Medicare discarded drug policy website at *https://www.cms.gov/medicare/payment/part-b-drugs/discarded-drugs* for further information.

Comment: The applicant for ZEVTERA® (ceftobiprole medocaril sodium for injection) submitted a comment providing updated information on its commercial availability and to update its Wholesale Acquisition Cost (WAC). The applicant noted that ZEVTERA® received marketing approval from FDA on April 3, 2024, for the treatment of adult patients with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis, and adult patients with acute bacterial skin and skin structure infections (ABSSSI) and for adult and pediatric patients (3 months to less than 18 years old) with community-acquired bacterial pneumonia (CABP). The applicant also noted that ZEVTERA® received new technology add-on payment approval for FY 2025, with its newness period beginning on April 3, 2024.

Per the applicant, on December 14, 2024, it entered into a license and distribution agreement with Innoviva Specialty Therapeutics, LLC (ISTx) for the commercialization of ZEVTERA® in the United States. The applicant stated that transfer of ownership for the ceftobiprole Investigational New Drug (IND) Application (064407) and the ZEVTERA (ceftobiprole medocaril sodium for injection) NDA (218275) from Basilea to ISTx, LLC was submitted to FDA and was effective on March 18, 2025. ISTx, LLC announced on May 20th the commercial availability of ZEVTERA® for the US market. The applicant asserted that prior to this date, ZEVTERA® was not available to Medicare beneficiaries in the United States, and requested that CMS assign a newness date of May 20, 2025. The applicant asserted that CMS had delayed the newness dates for other products when market availability was significantly later than the FDA approval date, and provided examples from FY 2025: HEPZATO™ KIT, Annalise Enterprise CTB Triage—OH, and the LimFlow™ System.

The applicant also stated that ISTx, LLC made ZEVTERA® available for use on May 20, 2025, with a WAC of $235.00 per vial. The applicant explained that, with this updated pricing information, the average inpatient cost per case is $21,620 for the indication of SAB and $7,050 for the indication of ABSSSI and CABP. Therefore, because ZEVTERA® is a Qualified Infectious Disease Product (QIDP), the applicant requested that the maximum new technology add-on payment for a case involving the use of ZEVTERA® be updated to $16,215 for the indication of SAB and $5,288 for the indications of ABSSSI and CABP for FY 2026 (that is, 75 percent of the average cost of the technology).

Response: We thank the applicant for its comment and the updated cost information. We have updated the new technology add-on payment amount for ZEVTERA® accordingly.

ZEVTERA®'s current new technology add-on payment amount is $8,625.00 for the indication of SAB and $2,812.50 for the indications of ABSSSI and CABP, based on a WAC of $125 per vial. As we noted in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69237), for ABSSSI and CABP, the suggested daily dose is 3 vials per day for a duration of 5–14 days, resulting in an estimated average cost of $3,750 for a 10-day therapy. For SAB, the recommended dose is every 6 hours for the first 8 days, followed by every 8 hours for up to 42 days, and the applicant had made the assumption that patients would be inpatient for 28 days and then continue the therapy as an outpatient for up to 42 days. For FY 2026, the maximum new technology add-on payment amount is $16,215.00 for the indication of SAB and $5,287.50 for the indications of ABSSSI and CABP, as reflected in Table II.E.–01.B in this final rule.

With respect to the applicant's request that CMS should consider the beginning of the newness period to commence on May 20, 2025, which it states is the date on which ZEVTERA® became commercially available on the U.S. market, we note that that date occurred after new technology add-on payments for ZEVTERA® began, as it was approved for new technology add-on payment for FY 2025 (starting October 1, 2024). While we agree that per our policy, we may consider a documented delay in a technology's market availability in our determination of newness, we note that the new technology add-on payment for claims reporting ICD–10–PCS procedure codes for ZEVTERA® (XW0335A (Introduction of ceftobiprole medocaril anti-infective into peripheral vein, percutaneous approach) and XW0435A (Introduction of ceftobiprole medocaril anti-infective into central vein, percutaneous approach)) was available beginning October 1, 2024.

Furthermore, 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 would 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. If we were to consider the beginning of the newness period to commence on May 20, 2025, the date on which the applicant states ZEVTERA® became commercially available on the U.S. market, under our policy, the technology would potentially be eligible for new technology add-on payment for up to four years. Although the applicant stated that CMS had delayed the newness start dates for other technologies when market availability was significantly later than the FDA approval date, and that like these other products, ZEVTERA®'s newness period should commence on the date on which the technology became commercially available, we note that, unlike these other technologies, the applicant for ZEVTERA® is asserting a date of commercial availability that occurred after its new technology add-on payment began.

We also note that applicants may assert a delay in commercial availability due to business decisions made by the applicant. We are concerned that a delay in commercial availability extending beyond the implementation date for the new technology add-on payment would potentially allow applicants to postpone commercial availability for an indefinite period of time while the technology (and other technologies reported using the same codes) remain eligible for new technology add-on payment.

Therefore, we question whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology's new technology add-on payment. We note that regardless of whether we consider the beginning of the newness period to commence for ZEVTERA® on May 20, 2025, April 3, 2024, or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology would be considered new for FY 2026.

After consideration of the public comments we received, we are finalizing our proposals to continue new technology add-on payments for FY 2026 for the technologies that were approved for new technology add-on payment for FY 2025 and would still be considered ''new'' for purposes of new technology add-on payments for FY 2026, as listed in the proposed rule and in the following Tables II.E.–01.A and II–E.–01.B in this section of this final rule.

We note that the following Tables II.E.–01.A and II.E.–01.B are the same as Tables II.E.–01.A and II.E.–01.B that were presented in the proposed rule, but Table II.E.–01.A in this final rule includes the SAINT Neuromodulation System, as discussed later in this section, and Table II.E.–01.B in this final rule includes the updated cost information for ZEVTERA®, as discussed previously. Tables II.E.–01.A and II.E.–01.B in this final rule also present 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, maximum add-on payment amount, and coding assignments for each technology. We refer readers to the final rules cited in the following tables 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.

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TABLE II.E.-01.A: 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	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
12	*SAINT Neuromodulation System*	*	*10/01/2023*	*	88 FR 58937 through 58939	$12,675.00	X0Z0X18

*We note that as discussed later in this section, we are continuing to consider the applicable newness start date for this technology, but that it would continue to be eligible for new technology add-on payment in FY 2026.

TABLE II.E.-01.B: 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	Maximum NTAP Amount for FY 2026	Coding Used to Identify Cases Eligible for NTAP
1	*Amnalise Enterprise CTB Triage—OH*	*10/10/2023*	*10/01/2024*	*10/10/2026*	89 FR 69205 through 69208	$241.39	XXE0X1A
2	*ASTar® System*	*04/26/2024*	*10/01/2024*	*04/26/2027*	89 FR 69208 through 69210	$97.50	XXE5X2A
3	*Edwards EVOQUE™ Tricuspid Valve Replacement System ("EVOQUE™ System")*	*02/01/2024*	*10/01/2024*	*02/01/2027*	89 FR 69210 through 69213	$31,850.00	X2RJ3RA
4	*GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)*	*01/12/2024*	*10/01/2024*	*01/12/2027*	89 FR 69213 through 69215	$47,238.75	X2VE3SA
5	*LimFlow™ System*	*11/01/2023*	*10/01/2024*	*11/01/2026*	89 FR 69215 through 69218	$16,250.00	041M3JS, 041N3JS, 041P3JS, 041Q3JS, 041R3JS, 041S3JS, 041T3JS, or 041U3JS
6	*Paradise™ Ultrasound Renal Denervation System*	*11/7/2023*	*10/01/2024*	*11/07/2026*	89 FR 69218 through 69221	$14,950.00	X051329
7	*PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter*	*12/13/2023*	*10/01/2024*	*12/13/2026*	89 FR 69221 through 69225	$6,337.50	02583ZF
8	*Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter*	*11/17/2023*	*10/01/2024*	*11/17/2026*	89 FR 69225 through 69228	$10,400.00	X05133A
9	*TriClip™ G4*	*04/01/2024*	*10/01/2024*	*04/01/2027*	89 FR 69228 through 69230	$26,000.00	02UJ3JZ
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*	*	*10/01/2024*	*	89 FR 69236 through 69238	$5,287.50	XW0335A or XW0435A
12	*ZEVTERA™ (ceftobiprole medocaril); SAB indication*	*	*10/01/2024*	*	89 FR 69236 through 69238	$16,215.00	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	XW0533T9 **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

*We note that as discussed previously in this section, we are continuing to consider the applicable newness start date for this technology, but that it would continue to be eligible for new technology add-on payment in FY 2026.

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In the proposed rule, we provided a Table II.E.–02 listing 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 proposed to discontinue making new technology add-on payments for FY 2026 because they were 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 presented 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 referred readers to the cited final rules in the 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 we discussed in section II.E.6. of the preamble of the 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. Additionally, 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 the proposed rule, we proposed 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 believed 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 invited public comments on the use of these codes to exclude the indication for use of CERAMENT® G related to bone infections, which we stated would not be eligible for the new technology add-on payment for FY 2026, if approved.

Comment: Commenters expressed general support of the proposed ICD–10–CM codes for which CMS specifically sought input.

Response: We thank the commenters for their comments. As discussed in section II.E.6. of the preamble of this final rule, we are approving 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. Therefore, cases involving the use of CERAMENT® G related to bone infections, which will no longer be eligible for new technology add-on payment in FY 2026, will 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 invited 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 proposed rule.

Comment: Multiple commenters, including the applicant for SAINT Neuromodulation System, requested that CMS recognize a delay in commercial availability of the technology to April 5, 2024, and subsequently extend new technology add-on payment for the SAINT Neuromodulation System for FY 2026.

Commenters presented the timelines for use of the device at their hospitals. A commenter stated that equipment was installed at the hospital on May 9 through 10, 2024; physicians and staff were trained by the manufacturer on May 15 through 17, 2024; and the first patient was treated on May 23, 2024. Another commenter stated that equipment was installed at its hospital on April 23, 2024; physicians and staff were trained between April 29 and May 1, 2024; and the first patients were treated on May 30, 2024. Commenters stated their hope that innovation for inpatient mental health patients would continue to be available to hospitals in 2026.

The applicant also asserted that the SAINT Neuromodulation System was commercially available in the United States on April 5, 2024, and provided a timeline of the device's availability. The applicant stated that although the device received FDA clearance on September 1, 2022, there were significant product development, manufacturing design, and compliance steps that it needed to complete before the device became commercially available. Per the applicant, initially, it had planned to develop and manufacture its own hardware; however, it was determined in the second half of 2023 that the best course was to work with third-party manufacturers for the stimulator and neuronavigation hardware. The applicant stated that for compliance purposes, it followed a development plan consistent with its quality system and the commercial product could not be sold until the manufacturing processes were designed, developed, and validated according to FDA quality guidelines. Per the applicant, this process was finished on April 5, 2024, which was the earliest possible date the device could be sold in compliance with FDA regulations.

The applicant further stated that in the FY2025 IPPS/LTCH PPS final rule, it was surprised to learn that there had been claims submitted with the ICD–10–PCS section X code that was created to administer the new technology add-on payment for the SAINT Neuromodulation System, before it was commercially available. The applicant stated it analyzed the claims using the Medicare Inpatient Standard Analytic Files (IPSAF) from October 2022 through March 2024 and confirmed that none of the billed cases were submitted by providers with access to the device or had discussed the device with the applicant.

The applicant further looked at the primary diagnoses, all diagnoses, and MS–DRG mapping for these claims. The applicant explained that the device is intended to treat patients with major depressive disorder with claims including ICD–10–CM diagnosis codes F33.2 or F32.2 and whose cases map to MS–DRG 885 (Psychoses), yet none of the claims contained either a psychiatric diagnosis or were assigned to MS–DRG 885. The applicant asserted that these claims used the ICD–10–PCS code inappropriately, and provided additional details in a summary table. Per the applicant, in the FY 2026 final rule, CMS stated that the applicant stated the specific ICD–10–PCS code X0Z0X18 is ''used to uniquely describe procedures involving the use of SAINT Neuromodulation System,'' which the applicant stated supports its contention that the procedure code was intended to be used specifically for the device or a procedure that is virtually the same when the technology was introduced into the clinical setting. Therefore, the applicant asserted that the 5 claims should not have been accepted as qualifying claims and should not be

included in the evaluation of continued eligibility.

The applicant asked that CMS establish the newness start date for the SAINT Neuromodulation System to be April 5, 2024, and noted that this would allow for the new technology add-on payment to continue in FY 2026. The applicant further asserted that this accurate newness date and continued new technology add-on payment would no longer result in premature termination of payment. The applicant stated that to fulfill the requirement for an adequate period of data collection of no less than 2 and no more than 3 years, terminating the new technology add-on payment at the end of FY 2025 would fall short of two years of active new technology add-on payment.

Response: We thank the applicant and the commenters for their comments and further details regarding the claims reporting the ICD–10–PCS code X0Z0X18 (Computer-assisted transcranial magnetic stimulation of prefrontal cortex, new technology group 8). As discussed in greater detail previously in this section, we question whether, where the applicant asserts a date of commercial availability that occurred after the new technology add-on payment for the technology began, it would be appropriate to instead consider the beginning of the newness period to commence with the start of the technology's new technology add-on payment. We note that regardless of whether we consider the beginning of the newness period to commence for SAINT Neuromodulation System on April 5, 2024; a date that reflects the start of the technology's new technology add-on payment in FY 2024; or a date in between, the three-year anniversary date would occur after April 1, 2026, and, therefore, the technology would be considered new for FY 2026.

Comment: Multiple commenters, including the applicant for EchoGo® Heart Failure 1.0 (referred to as EchoGo® Heart Failure), requested that CMS extend new technology add-on payment for EchoGo® Heart Failure for a third year. The commenters noted that EchoGo® Heart Failure, developed by Ultromics, is an FDA-cleared, AI-powered decision support platform designed to assist clinicians in detecting heart failure with preserved ejection fraction (HFpEF) using a single, routine echocardiogram view, and described the clinical need and clinical value of the device in identifying HFpEF from a standard echocardiogram.

The applicant stated that the request to extend new technology add-on payment is consistent with CMS's longstanding policy that the newness period begins with availability of the product on the market, which is when data become available. The applicant explained that the device was not available on the market until November 2023, when it entered its first contract with a customer and invoiced a customer for the service. As such, the applicant asserted that the three-year anniversary of entry into the U.S. market would be in November of 2026. The applicant noted that CMS has recognized a later date where an applicant could prove a delay in actual availability of a product after FDA approval or clearance. Therefore, the applicant stated that consistent with this policy, CMS should not use the identified date of November 23, 2022 (date of FDA marketing authorization) as the newness start date for EchoGo® Heart Failure because that does not reflect when the product was first available.

The applicant explained that the reason for the gap in time from FDA clearance to sales of EchoGo® Heart Failure was that upon FDA clearance, it had to perform considerable architectural and workflow changes to integrate the software into the product platform. Additionally, the applicant stated that it took considerable time to implement its product platform into a hospital's Picture Archiving and Communication System (PACS) and electronic health record (EHR) systems, all of which delayed it being able to have a viable and available product for which it could sign a commercial contract until 12 months after clearance. The applicant explained that it was not until late in 2023 that it could pursue contracts with customers, the first of which was signed in November of 2023, leading to a first invoice dated November 30, 2023. The applicant further stated that in light of this information, supplemented by its understanding that there are no claims for the ICD–10–PCS procedure code tied to the technology (XXE2X19) in the MedPAR database of FY 2023 claims, it asked CMS to apply its current policy and consider the starting point for the newness period for EchoGo® Heart Failure to begin in November of 2023, not November of 2022, such that EchoGo® Heart Failure would continue to receive new technology add-on payment for FY 2026.

Commenters stated that that while EchoGo® Heart Failure had been available with new technology add-on payment since October 2023, the technology is still in the early stages of adoption across U.S. hospitals. Commenters explained that new technology add-on payment has been instrumental in facilitating access to the device by offsetting the additional costs associated with its use. However, commenters asserted that broader clinical integration and real-world evidence generation of novel technologies require more than two years, particularly in the context of hospital operational cycles, education, and ongoing validation in diverse patient populations. Commenters explained that extending new technology add-on payment for a third year would: ensure continued access to EchoGo® Heart Failure for Medicare beneficiaries, particularly as hospitals complete the necessary training and workflow adjustments; support ongoing data collection and outcomes research, further establishing the clinical and economic value of the technology; and encourage adoption in a wider range of hospital settings, including those serving high-risk and underserved populations disproportionately affected by HFpEF.

The applicant stated that if CMS did not believe this extension is warranted under current policy, it should make changes to the new technology add-on payment policy to provide new technology add-on payment for three years for all technologies, similar to what was done under the hospital outpatient prospective payment system pass-through policy. The applicant explained that it can take a considerable period of time for a new technology to enter into the market, and that having a later year's data should provide more fulsome data set for rate setting. The applicant stated that CMS should not settle for data that would not be insufficient, but instead should strive to use as fulsome a data set as possible when making the important determination as to how to work a new technology into the MS–DRGs.

Response: We thank the applicant and commenters for their comments. We note that while CMS may consider a documented delay in the technology's market availability in our determination of newness, our policy for determining whether to extend new technology add-on payments for an additional year generally applies regardless of the volume of claims for the technology after the beginning of the newness period (83 FR 41280). We do not consider the date of first sale of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale. Similarly, our policy for determining whether to extend new technology add-on payments for a third year generally

applies regardless of the claims volume for the technology after the start of the newness period (88 FR 58801 through 58802).

The applicant stated the device was not available on the market until November 2023, which is when the applicant was able to enter its first contract with a customer and invoice a customer for the service; however, it is not clear to us when the technology first became *available* for sale. The applicant noted that it was not until late in 2023 that it had taken such steps that it could pursue contracts with customers, the first of which was signed in November of 2023, leading to a first invoice dated November 30, 2023. However, it seems that a viable product would have needed to be available for sale before the applicant would be able to pursue and enter its first contract. Furthermore, we note that according to the applicant's website, the device was available in the United States as of the press release on July 5, 2023,[21] if not earlier. This further conflicts with the applicant's assertion that the device was not available for sale until November 2023.

Therefore, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. Accordingly, we are finalizing that we consider November 23, 2022, the date on which the technology received FDA 510(k) clearance for the indication covered by its Breakthrough Device designation, to be the date the technology became available on the market and the beginning of its newness period.

We also disagree with the applicant's request that if CMS does not believe this extension is warranted under current policy, we should make changes to the new technology add-on payment policy to provide new technology add-on payment for three years for all technologies, similar to the hospital outpatient prospective payment system pass-through policy, to allow for as fulsome a data set as possible. When we had stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69241) that we did not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting, we also noted that, as described in the FY 2005 IPPS final rule (69 FR 49003), even if a technology does not receive new technology add-on payments, CMS continues to pay for new technologies through the regular payment mechanism established by the DRG payment methodology. In addition, 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 (88 FR 58648). We further noted that whether a technology receives new technology add-on payments or not does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate.

After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the technologies as listed in the proposed rule and in the following Table II.E.-02 of this final rule for FY 2025 because they are no longer ''new'' for purposes of new technology add-on payments. We note that Table II.E.-02 is the same as Table II.E.-02 that was presented in the proposed rule, but Table II.E.-02 in this final rule no longer lists the SAINT Neuromodulation System, as discussed previously. This Table II.E.-02 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 final rules cited 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.

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[21] CMS Establishes HCPCS code for Ultromics EchoGo® Heart Failure, Accelerating Access to Precision HFpEF Detection: *https://www.ultromics.com/press-releases/cms-establishes-hcpcs-code-for-echogo-heart-failure-accelerating-access-to-precision-hfpef-detection.*

TABLE II.E.-02: 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)* *ELREXFIO™ (elranatamab-bcmm) and TALVEY™ (talquetamab-tgvs)*	*11/09/2022*	*10/01/2023* *10/01/2024*[22]	*11/09/2025*	88 FR 58885 through 58891 89 FR 69120 through 69126 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

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5. 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 final 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 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 the proposed rule. Subsequently, prior to the issuance of this final rule, one additional application was withdrawn for DuraGraft® (Vascular Conduit Solution). We are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2026. We are addressing the remaining 13 applications. We are not approving new technology add-on payments for 8 technologies: AUCATZYL® (obecabtagene autoleucel), COBENFY™ (xanomeline and trospium chloride), FIBRYGA® (fibrinogen (human)), IntelliSep® Test, Neuroguard IEP® 3-in-1 Carotid Stent and Post-Dilation Balloon System with Integrated Embolic Protection, RYSTIGGO® (rozanolixizumab-noli), SYMVESS™ (acellular tissue engineered vessel-tyod), and ZIIHERA® (zanidatamab-hrii) for the reasons discussed in the following sections. We are approving new technology add-on payments for FY 2026 for the remaining 5 technologies: AURLUMYN™ (iloprost injection), BREYANZI® (lisocabtagene maraleucel), GRAFAPEX™ (treosulfan), IMDELLTRA® (tarlatamab-dlle), and TECELRA® (afamitresgene autoleucel). A discussion of these applications is presented in the following sections.

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.[23]

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

[22] 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.

[23] 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®.

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.

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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).

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As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18092), we had the following concerns with regard to the newness criterion. We noted 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 noted 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 questioned 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 noted 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 stated our belief 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 stated we were unclear how a technology's dosing schedule is relevant to its mechanism of action. Accordingly, as it appeared 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 stated our belief that these technologies may be substantially similar to each other. We noted 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 stated our belief that the newness period for this technology would begin on November 22, 2017, the date KYMRIAH® became commercially available.[24] 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 stated we were interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and newness criterion.

We invited public comments 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.

Comment: Several commenters submitted comments in support of new technology add-on payments for AUCATZYL®. Some of the commenters disagreed with CMS's proposal to treat AUCATZYL® as substantially similar to other CD19-directed CAR T-cell therapies. A commenter argued that CMS's proposed approach does not take into consideration the specifics of the technological advancements that differentiate how mechanisms of action are achieved. Some commenters stated that when determining whether a CAR T-cell therapy sufficiently demonstrates substantial similarity compared to an existing technology, CMS should recognize innovations in the newer generation of therapies and how they differentiate these from previous CAR T-cell therapies. According to these commenters, those advancements should form the basis for differentiation as a distinct mechanism of action and without recognition of such advancements, continued innovation in the CAR T-cell therapy field may be discouraged and Medicare beneficiaries may be denied equitable access to such treatment advances. Some commenters argued that CMS should consider each CAR T-cell therapy application for new technology add-on payments on its own merits and not overly anchor to previous decisions to inform evaluation of the current fiscal year's applications. Per a commenter, it is especially important that CMS consider technological advancements when evaluating similarity of mechanisms of actions because they can translate directly into improved clinical outcomes.

Response: We thank the commenters for their comments. We note that we have stated in prior rulemaking (73 FR 48561 through 48563) that we first determine whether a new technology meets the newness criterion, and only if so, do we make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. Further, as we have discussed in prior final rules (69 FR 49018 through 49019, and 70 FR 47344), it is our past and present practice to analyze the new medical service or technology add-on payment criteria in the following sequence: Newness, cost threshold, and finally substantial clinical improvement.

Comment: The applicant and several commenters submitted public comments regarding the newness criterion for AUCATZYL®. The applicant reiterated that AUCATZYL® is a B-lymphocyte antigen CD19 CAR T-cell therapy designed to overcome the immune-related limitations in clinical activity and safety compared to current CD19 CAR T-cell therapies, with a fast target binding off-rate to minimize excessive activation of the programmed T cells, which reduces immune-mediated toxicity and is less prone to T-cell exhaustion, and that decreased T-cell exhaustion has been shown to enhance persistence. The applicant reiterated that based on the overall results from the pivotal phase 1b/2 FELIX study (N=127), the largest and most diverse patient population CAR T-cell study for adults with R/R B–ALL, a single treatment of AUCATZYL® reduces immune-mediated toxicity and results in reduced T cell exhaustion and improved persistence, leading to high levels of durable remissions.

The applicant stated that AUCATZYL® is not the same or substantially similar to TECARTUS®, the only other currently available CD19 CAR T-cell therapy approved for adult R/R B–ALL. The applicant reiterated that AUCATZYL® has a significantly distinct immune-modulating mechanism of action designed to model physiologic T-cell activation, and that it is constructed using the differentiated 4–1BB co-stimulatory domain with a novel, proprietary low affinity, fast off-rate anti-CD 19 (CAT) hybridoma-derived anti-CD19 scFv (CAT19 binding domain) designed to improve potency and persistence and to reduce immune-mediated toxicity, including CRS and ICANS. The applicant provided an illustration of various components of AUCATZYL®, which facilitate its immune-modulating mechanism of

[24] 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.*

action. These components included the CAT19 fast off-rate binder, the CD8-derived hinge region/transmembrane domain, the 4–1BB co-stimulatory domain, shown to enhance CAR T-cell expansion and reduce exhaustion compared with CD28 CARs in preclinical studies, and the CD3-zeta activation domain. The applicant reiterated that shorter cell-cell contact resulting from the greater than 40-fold lower affinity of CAT19 (off-rate of 3.7 minutes) compared with the FMC63 antigen-binding domain used in other currently available CAR T-cell therapy, including TECARTUS®, reduces cytokine release and toxicity and CAR T-cell exhaustion, and enhances CAR T-cell persistence. The applicant also reiterated that 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 mitochrondrial biogenesis, greater oxidative metabolism, and sustained CAR T-Cell persistence.

The applicant stated although it agreed that both AUCATZYL® and TECARTUS® target and kill CD19-expressing cancer cells, AUCATZYL® has a differentiated mechanism of action in how it binds CD19, with the key difference residing in the components of the respective CAR constructs. The applicant described differences in the CAR single chain variable fragments (scFv) for each technology and how they were derived, as well as the differing co-stimulatory domains, reiterating that the resulting shorter target interaction with targeT-Cells for AUCATZYL® due to its lower affinity for CD19 mimics physiologic T-cell activation, and the 4–1BB co-stimulatory domain is generally associated with longer persistence. The applicant stated that the use of these different features in AUCATZYL® leads to a unique mechanism of action characterized by differentiated binding kinetics, engraftment, persistence and immune-elicited responses. Regarding differentiated binding kinetics, the applicant stated that the CD19 (CAT) CAR binds CD19 with an above 40-fold lower affinity, resulting in faster disengagement, and >40 shorter half-life compared to the CD19 (FMC63) CAR used in currently marketed CAR–Ts, including TECARTUS® (CAT 3.73 min vs FMC63 2.8 hours). Per the applicant, both antibodies bind to an overlapping epitope of CD19 consisting of residues within loops 1 and 2 of the CD19 ectodomain and provided a chart that shows the results of the Ghorashian (2019) study. The applicant stated that, in particular, in *in vitro* studies, AUCATZYL® showed a higher equilibrium dissociation constant with CAT scFv (14 nM) as a result of a much faster off-rate (CAT: 3.1×10^{-3} s^{-1} vs FMC63: 6.8×10^{-5} s^{-1}), whereas the on-rate was equivalent compared to FMC63 scFv (CAT: 2.2×10^{5} $M^{-1}s^{-1}$ vs FMC63: 2.1×10^{5} $M^{-1}s^{-1}$). According to the applicant, the fast off-rate and subsequent shorter cell-cell contact is advantageous by reducing cytokine release and thereby reducing toxicity, as well as reducing T-cell exhaustion, which enhances CAR T-cell persistence. The applicant stated that these features are designed to address major limitations of CAR T-cell therapy in B–ALL, namely, toxicity and lack of durable responses.

Regarding engraftment and persistence, the applicant stated that owing to the differentiated binding kinetics of AUCATZYL®, differenT-Cell kinetics at initial expansion and persistence compared to TECARTUS® are observed. According to the applicant, the pharmacokinetics for each patient in the Infused Set of Cohort IIA (N=94) of the FELIX study were assessed between Day 1 and Day 28, and AUCATZYL® demonstrated a rapid and high level of expansion of the cells following infusion. The overall geometric mean of C_{max} was 114,982 copies/µg/deoxyribonucleic acid (DNA) (range 129–600,000 copies/µg DNA) with a median time to maximum (or peak) concentration (T_{max}) of 14 days (range 2–55 days) and a geometric mean AUC0–28d of 1,138,188 copies/µg DNA (range 179,000–7,230,000 copies/µg DNA * day). The applicant stated that expansion, measured by droplet digital PCR (ddPCR), was high regardless of whether patients achieved complete remission/complete remission with incomplete count recovery (CR/CRi) or not. Per the applicant, no biologically significant differences were seen in the geometric mean or median, interquartile range of C_{max}. Per the applicant, in CR/CRi patients, approximately 68.4 percent (54.6 percent–78.7 percent 95 percent confidence interval [CI]) demonstrated persistence at 6 months with a maximum duration of 21 months. The applicant added that 75 percent (27/36) of the patients who had ongoing remission as of the data cut-off date had ongoing CAR T persistence at the last laboratory assessment as of the data cut-off date. According to the applicant, in comparison to other FMC63-based CARs approved for ALL, such as TECARTUS®, the median C_{max} was 38.35 cells/uL (range: 1.31–1533.4) and median $AUC_{0–28}$ was 424.03 cells/uL × day (range: 14.12–19390.42) in responding patients treated with TECARTUS® (ZUMA–3 trial) compared to 0.49 cells/uL (range 0.0–183.50) and 4.12 cells/uL × day (range 0.0–642.25) for C_{max} and AUC0–28d respectively for non-responders. The applicant added that no CAR persistence was seen for TECARTUS® in the ZUMA–3 trial beyond 3 months by flow cytometry and 6 months by ddPCR.

Per the applicant, not only was CAR–T expansion generally lower for TECARTUS® than that seen for AUCATZYL®, an even lower expansion was observed in patients who did not respond compared to patients who responded, and CAR–T expansion of AUCATZYL® demonstrated a less than 3-fold increase in patients in CR/CRi vs patients not in CR/CRi. According to the applicant, this is strikingly different from TECARTUS® where ~80-fold increase in CAR–T expansion is seen in CR/CRi vs patients not in CR/CRi and where there is minimal CAR–T expansion in patients not in CR/CRi (0.49 cell/uL). The applicant referred to the chart that shows the comparative results of the Ghorashian (2019) study.

The applicant further stated that the immune-elicited responses for AUCATZYL® are not similar to TECARTUS®. Per the applicant, at an early stage of AUCATZYL® development, it was hypothesized that the scFv of obe-cel's CAT CAR with a greatly reduced affinity for CD19 would improve the post-infusion immune-mediated cytokine release kinetics and toxicity profile common to currently marketed CAR Ts using the FMC63 CAR construct. The applicant stated that the novel 2-step fractionated tumor burden-guided dosing regimen further enhances the ability to reduce immunotoxicity, which has been linked to both disease burden and expansion of CAR T-cells. The applicant stated that supportive data from a number of different CD19 CAR T-cell trials in acute lymphoblastic leukemia indicated that higher disease burden is predictive of more severe CRS. The applicant further stated this led some groups to mitigate this toxicity by either administering a lower dose of CAR T-cells to patients with higher disease burden or splitting the total dose. Furthermore, the applicant stated that tumor burden-guided dosing provides an opportunity to tailor AUCATZYL® doses based on the patient-specific tumor burden, which may reduce the extent and rate of expansion, and thereby affect the severity of CRS. The applicant stated that spacing between the dose fractions takes into consideration the duration of IL–15 surge following lymphodepletion

(LD), which is important for CAR T-cell expansion and function as well as timing of early signals of subsequent severe toxicity. The applicant also stated that tumor burden-guided dose is also unlikely to increase the risk of immune-mediated reactions to the murine sequence present in the CD19 antigen-binding domain of AUCATZYL®. The applicant stated thaT-Cellular immune response at the time of the second dose, on Day 10, will be significantly reduced by the LD chemotherapy administered before AUCATZYL® infusion. The applicant added that the humoral immune response, which takes approximately 14 days to be generated, will be impaired by the B cell aplasia and subsequent hypogammaglobulinaemia induced by the CD19 CAR T-cells administered on Day 1. The applicant also stated that a range of serum biomarkers were evaluated in the FELIX study, and per the applicant, in accordance with AUCATZYL®'s distinct immune-modulating mechanism of action, the profiles observed for induced inflammatory soluble serum biomarkers were overall consistently and considerably lower than those reported for TECARTUS® in the ZUMA–3 trial. The applicant illustrated this finding with a table that compares selected peak inflammatory soluble serum biomarkers between the FELIX and ZUMA–3 trials.

Per the applicant, the efficacy of CAR–T-cell therapy with impressive response rates in hematologic malignancies must be weighed with immune-mediated toxicities, notably CRS, a toxicity requiring urgent diagnostic and therapeutic interventions, and targeted modulation of key cytokine pathways represents the mainstay of CRS management. The applicant stated that the expected risk of developing CRS grade 3 after AUCATZYL® treatment was reduced relative to TECARTUS® (2.4 percent vs 25 percent). Per the applicant, the observed magnitude of difference in grade 3 CRS substantiates the distinct functional and biological properties of AUCATZYL®. The applicant acknowledged the limitations of unadjusted comparisons between single-arm trials and conducted a prospectively designed matching-adjusted indirect comparison (MAIC) of AUCATZYL® and TECARTUS® which, per the applicant, demonstrated that patients treated with TECARTUS® are significantly more likely to experience a grade 3 CRS event or immune-mediated neurotoxicity relative to patients treated with AUCATZYL®.

The applicant concluded that AUCATZYL®'s immune-modulating mechanism of action is not the same or substantially similar to TECARTUS® because the novel CD19 (CAT) CAR in AUCATZYL® exhibits distinct functional and biological characteristics, notably lower affinity binding kinetics, prolonged persistence, and a differentiated immune-modulating mechanism of action that leads to a marked decrease in the release of inflammatory cytokines and a decrease in the incidence of grade 3 CRS and immune-mediated neurotoxicity.

According to the applicant and several commenters, KYMRIAH® is not a relevant comparator for treatment of the Medicare population, as it is only approved for treatment of patients aged 25 or younger with R/R B–ALL. The applicant stated that in the pivotal AUCATZYL® Phase 2 Cohort IIA FELIX study population (n=94, infused), the median age was 50 years (range 20–81), with 88.3 percent over the age of 25. The applicant, as well as several commenters, also stated that while KYMRIAH® also uses the 4–1BB co-stimulatory domain, its scFv is FMC63-derived and therefore differences in binding kinetics described previously for TECARTUS® apply to KYMRIAH® as well. The applicant stated that therefore, AUCATZYL® is non-similar to KYMRIAH® in its mechanism of action and its intended population. In addition, the applicant stated that AUCATZYL® has a fundamentally different mechanism of action as a CAR T-cell therapy compared to immunotherapy, BLINCYTO® and BESPONSA®. The applicant stated that BLINCYTO® is a bispecific T-cell engager molecule derived from two distinct monoclonal antibodies that bind CD19 and CD3, while BESPONSA® is an antibody-drug conjugate (ADC) composed of a CD22-directed monoclonal IgG4 antibody linked to a cytotoxic agent. The applicant also explained that while immunotherapy is recommended as first-line treatment and considered superior to standard chemotherapy, CAR T-cell therapy is recommended following immunotherapy. The applicant stated that therefore, the focus of the substantial similarity test for AUCATZYL® should be TECARTUS®.

Response: We appreciate the additional information from the applicant and commenters with respect to whether AUCATZYL® is substantially similar to existing technologies. We agree that AUCATZYL® has a different mechanism of action as a CD19-directed CAR T-cell therapy compared to BLINCYTO® and BESPONSA®, which are bispecific T-cell engager molecule and antibody-drug conjugates. We also agree with the applicant that because KYMRIAH® is only approved for treatment of patients aged 25 or younger, representing a very small fraction of adults compared to AUCATZYL®, it therefore treats a different population and is not substantially similar. However, we disagree with the applicant and commenters that AUCATZYL® has a unique mechanism of action because we do not believe there is a clear differentiation between the mechanism of action of AUCATZYL® and that of TECARTUS®. While the applicant highlights differences such as the binding domain, costimulatory/activation domains, binding kinetics, and dosing regimen, we do not believe these meaningfully differentiate the mechanism of action of AUCATZYL® from other CD19-directed CAR T-cell therapies, which are all genetically modified autologous T-cell immunotherapies that bind to CD–19 expressing cancer cells. We refer the reader to the FY 2019 and FY 2022 IPPS/LTCH PPS final rules (83 FR 41287 through 41291, and 86 FR 44999 through 45000) for further discussion of this issue, where we determined that the mechanisms of action for CAR T-cell therapies were not new based on similar factors. While the applicant stated that AUCATZYL® uses a fast-on-fast-off mechanism, we disagree that a shorter length of binding time for AUCATZYL® represents a different mechanism of action than the other CAR T-cell therapies. We also disagree that any association between AUCATZYL®'s binding and the rates of CRS and ICANS would represent the technology's mechanism of action, nor would CAR T-cell persistence and how it affects durability of response, as any differences between AUCATZYL® and existing technologies in observed outcomes would relate to an assessment of substantial clinical improvement rather than the newness criterion.

Therefore, after consideration of the comments we received on AUCATZYL®'s newness, we believe that AUCATZYL® and TECARTUS® use the same mechanism of action to achieve a therapeutic outcome: 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, and are assigned to the same MS–DRG. We also agree with the applicant that AUCATZYL® treats the same or similar patient population and disease as TECARTUS®, which is used in treatment for adult patients with R/R B–ALL.

Because AUCATZYL® meets all three of the substantial similarity criteria, we

believe AUCATZYL® is substantially similar to TECARTUS®. In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period for AUCATZYL®. Therefore, we consider the newness period for AUCATZYL® to begin on October 1, 2021, the date TECARTUS® became commercially available. Since the 3-year anniversary date of TECARTUS®'s entry onto the market occurred prior to FY 2026, AUCATZYL® does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2026. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2026, we are not summarizing comments received or making a determination on those criteria in this final rule.

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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18096), we stated we were 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 expected that AURLUMYN™ will be dosed in the inpatient setting for 8 consecutive days using a total of eight single-use vials (one per day).

The applicant submitted a request for unique ICD–10–PCS procedure codes for AURLUMYN™ beginning in FY 2026 and was granted approval for the following procedure codes effective October 1, 2025: XW033QB (Introduction of iloprost into peripheral vein, percutaneous approach, new technology group 11) and XW043QB (Introduction of iloprost into central vein, percutaneous approach, new technology group 11). 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.

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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 prostaglandin I2 (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. AURLUMYMN™ 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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18097), we noted 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 stated our belief that the use of AURLUMYN™ will not change the MS–DRG assignment and will, therefore, map to the same MS–DRGs as other treatments for severe frostbite. 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 noted that there are other severe frostbite treatments that are commonly used including rapid rewarming, fasciotomy, thrombolysis, and sympathectomy.

We invited public comments on whether AURLUMYN™ is substantially similar to existing technologies and whether AURLUMYN™ meets the newness criterion.

Comment: A few commenters, including the applicant, stated that AURLUMYN™ meets the newness criterion because it is the only FDA-approved treatment for severe frostbite and the only available intravenous formulation of iloprost, which enhances blood flow and accelerates the healing

process through preserving tissue integrity and minimizing complications.

Response: We thank the applicant and other commenters for their input and have taken it into consideration in determining whether AURLUMYN™ meets the newness criterion, as discussed later in this section.

Comment: The applicant reiterated that AURLUMYN™ does not use the same or substantially similar mechanisms of action as any technology or drug therapy assigned to any MS–DRG in the 2023 MedPAR data, nor of any drug currently marketed in the U.S. The applicant further stated that AURLUMYN™ is a stable synthetic analog of PGI2 and is a potent prostacyclin receptor agonist as well as the only intravenous form of iloprost available in the U.S. In response to CMS's note that use of AURLUMYN™ will not change the MS–DRG assignment and will map to the same MS–DRGs as other treatments for severe frostbite, the applicant agreed that patient cases with severe frostbite where AURLUMYN™ is administered will map to the same MS–DRGs as other frostbite cases where AURLUMYN™ is not part of the frostbite treatment regimen, but noted that there are no claims for medical therapies or procedures in the 2023 MedPAR data with the same or similar mechanism of action as AURLUMYN™. Lastly, the applicant reiterated that patient cases where AURLUMYN™ is administered will be uniquely identified by two ICD–10–PCS codes specific to AURLUMYN™.

In response to CMS's note that there are other commonly used severe frostbite treatments, the applicant stated that prior to AURLUMYN™'s availability, frostbite treatment in the U.S. was limited to off-label use of tissue plasminogen activator (tPA) within 24 hours of injury. The applicant further stated that AURLUMYN™ extends the treatment window beyond the <24 hours recommended for off-label use of tPA, and AURLUMYN will be available to more patients with severe frostbite who, without access to AURLUMYN, would be contraindicated for the use of tPA with its associated significant bleeding risks and contraindications in trauma, recent surgery, recent stroke, and many other conditions that might pose a bleeding risk. Furthermore, the applicant stated that other non-pharmacologic post-thaw medical therapy options, such as hydrotherapy, hyperbaric oxygen therapy, sympathectomy, and fasciotomy, are part of multimodal frostbite treatment regimens; however, none of these non-pharmacologic treatments replace AURLUMYN™ or are used at the exclusion of AURLUMYN™.

In addition, a few commenters stated that AURLUMYN™ meets an unmet need for targeted, early intervention for patients with severe frostbite and represents a major advancement by uniquely promoting vasodilation and improving microcirculatory flow, thereby addressing the underlying pathophysiology of frostbite in a way that no other medication currently does.

In response to CMS's request for additional information about the delay in AURLUMYN™'s commercial availability, the applicant commented that, while AURLUMYN™ received FDA approval on February 13, 2024, the BLA sponsor, EICOS, delayed market availability because it lacked the necessary commercial infrastructure and needed to search for a capable commercial partner, and that the newness period should begin on November 1, 2024. The applicant stated that it acquired AURLUMYN™ on October 18, 2024, and immediately initiated production, resulting in AURLUMYN™ becoming available for order and shipment on November 1, 2024. The applicant stated that CMS should use November 1, 2024, as the market availability date for the newness period, and therefore, allow AURLUMYN™ to receive new technology add-on payments for a full 3 years instead of a 2-year period if the FDA approval date of February 13, 2024 is used.

Response: We thank the applicant and other commenters for their comments. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for AURLUMYN™, we agree with the applicant that AURLUMYN™ is the first synthetic analog of PGI2 that binds to prostacyclin receptors leading to vasodilation and inhibition of platelet activation approved by FDA to treat severe frostbite, and therefore uses a unique mechanism of action. Therefore, we agree with the applicant that AURLUMYN™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on November 1, 2024, the date on which AURLUMYN™ became commercially available.

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.
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 invited public comments on whether AURLUMYN™ meets the cost criterion.

Comment: Multiple commenters, inclusive of the applicant, stated that AURLUMYN™ meets the cost criterion. A few commenters also asserted that the current DRG payments for an inpatient hospitalization for severe frostbite are inadequate to account for the total cost of care and suggested that, without approval of new technology add-on payments, hospitals may not be able to use AURLUMYN™ for the treatment of frostbite in Medicare patients.

Response: We thank the applicant and other commenters for their comments. Based on the information submitted by the applicant as part of its FY 2026 new technology add-on payment application, as previously summarized, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both scenarios. Therefore, we agree that 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.[25] 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.

[25] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.*

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18098 through 18099), after review of the information provided by the applicant, we stated we had 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 noted 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.

We stated that 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 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™. We noted that 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 noted 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,[26] 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, we stated it appeared that there are other treatment options for frostbite other than AURLUMYN™. We stated that 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

[26] 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.*

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 questioned whether the composition of the AURLUMYN™ and standard of care treatment groups in these two published studies were sufficiently comparable and, consequently, whether the outcomes demonstrated were clinically significant. Specifically, we questioned 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 noted 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 raised 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 questioned 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 noted 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 stated concerns about the generalizability of the Cauchy et al. (2011) and Crooks et al. (2022) studies to the Medicare population. We noted 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 questioned 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 noted 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.[27]

We invited public comments on whether AURLUMYN™ meets the substantial clinical improvement criterion.

Comment: We received several comments in support of AURLUMYN™'s new technology add-on payment application. These commenters stated that denying AURLUMYN™'s application would leave a large gap in frostbite treatment and would be a grave disservice to the most vulnerable patients, as AURLUMYN™ offers a critical opportunity to change the trajectory of their lives. A few commenters specifically stated that AURLUMYN™ meets the substantial clinical improvement criterion because it has demonstrated a reduced risk of amputation, a clear improvement in patient quality of life, and a reduction in long-term costs associated with disability, rehabilitation, prosthetic use, and readmission. A commenter also stated that the inclusion of AURLUMYN™ into a multimodal treatment regimen has the potential to improve patient flow within healthcare systems, streamline the care of frostbite patients, decrease the burden on Q1 providers, facilitate more effective use of resources, and enhance continuity of care during critical treatment windows.

Several commenters, including the applicant, expressed general support for approval of AURLUMYN™'s new technology add-on payment application.

Response: We thank the commenters for their input and have taken it into consideration in determining whether AURLUMYN™ meets the substantial clinical improvement criterion as discussed later in this section.

Comment: The applicant submitted a comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. In response to our concern that the applicant did not identify a patient population that is unresponsive to, or ineligible for, the standard-of-care treatment where AURLUMYN™ does offer a treatment option, the applicant reiterated that AURLUMYN™ reduces significant risk of amputation and grade 3 and grade 4 frostbite's associated long-term complications, which impact a patient's ability to cope with normal everyday routines as well as health-related and functional quality of life. The applicant also reemphasized the 2024 Wilderness Medical Society Practice Guidelines for the Prevention and Treatment of Frostbite (WMS Guidelines) strong recommendation that AURLUMYN™ be used as a first-line therapy for grade 3 and 4 frostbite up to 48 hours after thawing, and possibly up to 72 hours. The applicant stated that the WMS Guidelines underline the need to consider the risk and benefits of using a thrombolytic, such as tPA, that is contraindicated in trauma, recent surgery, recent stroke, and many other conditions that might pose a bleeding risk; that has potential risks of systemic and catheter site bleeding, compartment syndrome, and failure to salvage tissue; and in which the long-term, functional consequences of digit salvage has not been evaluated. The applicant concluded that AURLUMYN extends the treatment window for patients beyond the <24 hours recommended for off-label use of tPA, and it provides an

[27] 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.*

important treatment option for patients with severe frostbite who are contraindicated for the off-label use of tPA.

In addition, a few commenters, including the applicant, asserted that AURLUMYN™ is an important component of a multimodal treatment regimen that includes pharmacologic and non-pharmacologic treatment for frostbite, such as rewarming, pain management, systemic hydration, and pharmacologic treatment. These commenters further stated that although non-pharmacologic post-thaw medical therapy, such as hydrotherapy, hyperbaric oxygen therapy (HBOT), sympathectomy, and fasciotomy, should be considered in a multimodal frostbite treatment regimen, these therapies do not replace AURLUMYN™ and instead are complementary. To demonstrate this, the applicant stated that they attached or enclosed two examples of clinical practice protocols for frostbite, which vary from institution to institution, but we note that there were no enclosures/attachments of that nature.

In response to CMS's concern as to whether the Cauchy et al. (2011) and Crooks et al. (2022) studies were sufficiently comparable and demonstrated clinically significant outcomes, the applicant reiterated the results from these two studies. The applicant also stated that Cauchy et al. (2011) reported results from the largest and only randomized, controlled, open-label study of severe frostbite treatment, which included 46 patients with grade 3 or grade 4 frostbite and 1 patient with grade 2 frostbite who were treated with buflomedil, AURLUMYN™, or recombinant tPA plus AURLUMYN™. The applicant also stated that the results from this study played a role in the WMS Guidelines recommending AURLUMYN™.

With regard to rapid rewarming, a commenter stated that a substantial proportion of the patients in Crooks et al. (2022) presented after the frostbitten tissue was already thawed and did not undergo rapid rewarming, which may have contributed to less favorable outcomes compared to the patients in Cauchy et al. (2011) who all underwent rapid rewarming. The commenter also stated that sympathectomy has not been shown to improve outcomes in frostbite and can be performed regardless of treatment with thrombolytics or AURLUMYN™, and fasciotomy is rarely necessary to treat frostbite but should be performed regardless of other treatments when required.

In addition, the applicant cited a retrospective chart review of 22 patients and a multicenter prospective single-arm study of 28 patients. The applicant stated that the retrospective chart review of 22 patients in Whitehorse, Yukon Territory, Canada, who presented to the hospital with grade 2, 3, or 4 frostbite, found that patients treated with AURLUMYN™, or AURLUMYN™ in addition to alteplase and heparin in the case of grade 4 frostbite, exhibited lower than expected amputation rates. Specifically, the applicant stated that no digits with grade 2 or 3 frostbite were amputated in patients treated with AURLUMYN™, and 50 percent of the digits with grade 4 frostbite treated with AURLUMYN™, alteplase, and heparin, required amputation. The applicant stated that overall, 29 of 142 (20.4 percent) digits were amputated, and the majority of digits amputated (N = 19) were from 1 patient who, according to direct correspondence with the author, was a very extreme case with frostbite extending beyond the carpal/tarsal region of the patient's limbs.[28] The applicant referenced expected rates of amputation of 1 percent for grade 2 digits, 31 to 67 percent for the grade 3 digits, and 98 to 100 percent for grade 4 digits, based on the Cauchy 2001 study.[29] The applicant also stated that a multicenter prospective single-arm study of 28 patients with grade 3 or 4 frostbite conducted in Switzerland and France compared early HBOT and AURLUMYN™ to treatment with AURLUMYN™ alone. The applicant stated that after 1 year of follow-up, 92 percent of injured digits/limbs treated with AURLUMYN™ did not require amputation, (85 percent in the AURLUMYN™ only control group and 98 percent in the AURLUMYN™ + HBOT group).[30] The applicant stated that this study's interpretability is limited, as the study does not report the amputation outcome rate in comparable patients who did not receive AURLUMYN™.

In response to CMS's concerns related to the Crooks et al. (2022) study's potentially inaccurate severity grading and the adequacy of the comparator in the absence of tPA in the control group, a commenter stated that the study authors listed both factors as limitations and that some or all of the 41 patients that presented within 24 hours had other contraindications to the use of tPA, including only grade 2 frostbite. The commenter further stated that Crooks et al. (2022) did not report which patients in the standard care group presented within 24 hours with grade 2 frostbite and noted that clinicians can sometimes have difficulty distinguishing between grade 2 and grade 3 frostbite initially, leading most clinicians to err on the side of caution and classifying the frostbite as grade 3.

In response to CMS's concern that the applicant did not present evidence that directly compared AURLUMYN™ with other therapies that are also strongly recommended by the WMS, the applicant stated that it is unaware of any published literature examining frostbite injury cases following treatment with AURLUMYN™ that are described specifically referencing results of other adjunctive post-thaw treatment options described in the WMS Guidelines (hydrotherapy, sympathectomy, and fasciotomy). The applicant reiterated that iloprost is a part of the multimodal treatment protocol hospitals follow and does not replace any of these non-pharmacologic treatment approaches; nor are these options employed at the exclusion of iloprost.

In response to CMS's concern about the Cauchy et al. (2011) and Crooks et al. (2022) studies' generalizability to the Medicare population, the applicant stated that, in its analysis of 2023 MedPAR data, Medicare paid 62 patient claims for severe frostbite, the majority of which (about 63 percent) were for Medicare beneficiaries under 65 years of age. The applicant stated that these findings mirror the age demographics in the cited AURLUMYN™ studies. The applicant also stated that evidence-based guidance for the prevention and treatment of frostbite does not vary by age groups nor by geographic region, which according to the applicant, aligns with the Cauchy et al. (2011) and Crooks et al. (2022) studies' results which demonstrate that regardless of age or geographic region, patients treated with AURLUMYN™ showed substantial clinical improvement. Another commenter stated that whether studies were conducted outside the U.S. is irrelevant as there is no evidence to suggest that the physiology of frostbite varies by location. The commenter also stated that it is prudent to treat older patients and patients with comorbidities using AURLUMYN™ when there are no contraindications because there is no evidence to suggest the effects of frostbite vary with age or that the response to treatment with

[28] Poole A, et al. Management of severe frostbite with iloprost, alteplase and heparin. A Yu-kon case series. CMAJ open 9 (2021), E585–E591.

[29] Cauchy E, et al. Retrospective study of 70 cases of severe frostbite lesions. A proposed new classification scheme. Wilderness & Environmental Medicine 2001;12, 248–255.

[30] Magnan MA, et al. Hyperbaric oxygen therapy with iloprost improves digit salvage in severe frostbite compared to iloprost alone. Medicina (Kaunas, Lathuania) 57 (2021).

AURLUMYN™ differs between older and younger patients but frostbite outcomes are likely to be worse in older patients or patients with comorbidities, such as diabetes. The commenter further stated that the proposed rule incorrectly reports the age range in the Crooks et al. (2022) study to be between 29 to 54 years and that these were instead interquartile ranges (90 FR 18099).

The applicant summarized adverse events reported in Cauchy et al. (2011) and Crooks et al. (2022), as well as a multicenter retrospective cohort study and the AURLUMYN™ prescribing information. The applicant also referenced the NDA sponsors clinical trial program for patients with systemic sclerosis who received either placebo or AURLUMYN™ to support the clinical safety of AURLUMYN™ in patients with severe frostbite. The applicant stated this clinical trial reported no deaths, study drug-related serious adverse events, or adverse events of special interest leading to study drug discontinuation, and all adverse events related to the study drug were expected and consistent with the established safety profile of AURLUMYN™.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree with the applicant and other commenters that AURLUMYN™ represents a substantial clinical improvement over existing technologies for the treatment of severe frostbite in adults because it reduces the risk of digit amputation compared to the standard of care, especially for patients who are contraindicated for tPA or are beyond the <24 hours treatment window recommended for off-label use of tPA.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that AURLUMYN™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2026. Cases involving the use of AURLUMYN™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW033QB (Introduction of iloprost into peripheral vein, percutaneous approach, new technology group 11) or XW043QB (Introduction of iloprost into central vein, percutaneous approach, new technology group 11).

In its application, the applicant estimated that the cost of AURLUMYN™ is $44,000 per patient, based on eight single-use 100 mcg per mL vials (one per day over 8 days) at a cost of $5,500 per vial. 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, the maximum new technology add-on payment for a case involving the use of AURLUMYN™ is $28,600 for FY 2026.

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 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 noted 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/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.[31] 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 110×10^6 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, percutaneous approach, new technology group 7) or XW043N7 (Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7). 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:

[31] 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).

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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18100), we invited 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.

Comment: We received comments expressing general support of the use of the listed ICD–10–CM codes for which CMS specifically sought input. A few commenters, including the applicant, agreed that these ICD–10–CM codes properly identify the R/R SLL/CLL indication for BREYANZI®. One of the commenters also suggested that CMS consider four additional diagnosis codes that also identify the indication of R/R SLL/CLL, including C91.Z0 (Other lymphoid leukemia not having achieved remission), C91.Z2 (Other lymphoid leukemia, in relapse), C91.90 (Lymphoid leukemia, unspecified not having achieved remission), and C91.92 (Lymphoid leukemia, unspecified, in relapse).

Response: We thank the applicant and commenters for their input. We note that the four additional ICD–10–CM codes describing ''other lymphoid leukemia'' and ''lymphoid leukemia, unspecified'' are not specific to SLL or CLL. Therefore, we do not believe those diagnosis codes are appropriate to identify the indication of R/R SLL/CLL. We agree with the applicant that the codes listed by the applicant accurately identify the indication for BREYANZI®.

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.

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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 of 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 later in this section. 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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18101), we noted 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, we noted that 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 questioned whether BREYANZI® treats

a different type of disease or patient population than existing technologies.

We invited public comments on whether BREYANZI® is substantially similar to existing technologies and whether BREYANZI® meets the newness criterion.

Comment: The applicant submitted a public comment that asserted BREYANZI® meets the newness criterion because it does not use a mechanism of action that is the same or similar to other therapies currently approved for the treatment of R/R CLL/SLL, and is not assigned to the same MS–DRG as those therapies. With respect to BREYANZI®'s mechanism of action, the applicant stated that BREYANZI® remains the only cell-based immunotherapy to be successfully manufactured for patients with CLL/SLL, which is characterized by profound T-cell dysfunction, and reiterated that BREYANZI® differs from other treatments as a CAR T-cell therapy that does not require repeated dosing until progression nor incur cumulative toxicity and drug resistance. With respect to BREYANZI®'s MS–DRG assignment, the applicant stated that no other therapies indicated for the treatment of patients with R/R CLL/SLL are assigned to MS–DRG 018.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for BREYANZI®, we agree with the applicant that BREYANZI® uses a unique mechanism of action because it is a CD19-directed, autologous CAR T-cell immunotherapy that initiates proliferation of CAR T cells that result in the cytotoxic killing of target cells for the treatment of adult patients with R/R CLL/SLL who have received two or more prior LOTs, including a BTKi and a BCL2i. We also agree with the applicant that BREYANZI® is not assigned to the same MS–DRG as other therapies currently approved for the treatment of these patients. Therefore, we agree with the applicant that BREYANZI® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on March 14, 2024, the date on which BREYANZI® was granted accelerated approval of its sBLA from FDA.

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).
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 invited public comments on whether BREYANZI® meets the cost criterion.

Comment: The applicant reiterated that the cost criterion analysis submitted with its application demonstrates that BREYANZI® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in the applicant's cost analysis. Therefore, 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.[32] 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

[32] Background articles are not included in the following table but can be accessed via the online posting for the technology.

improvement criterion and the supporting evidence provided.

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Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.

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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 summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18103).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18103) that we had the following concerns regarding whether BREYANZI® meets the substantial clinical improvement criterion. First, we questioned 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®.[33] We noted 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.

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 stated we had questions regarding the evidence provided in support of this claim. The applicant provided several

[33] 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.*

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 noted 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 noted 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, 3.6–10.1].[34] 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.[35] We stated our concern 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. We stated that these differences may have an impact on clinical outcomes that was independently of BREYANZI® or the comparator treatments. Moreover, we noted 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.[36] 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 noted that in the trial in which patients with R/R CLL/SLL received Jaypirca®, the PFS was 16.8 months.[37] We questioned 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 questioned whether these claims support that BREYANZI® improves clinical outcomes for this patient population.

We invited public comments on whether BREYANZI® meets the substantial clinical improvement criterion.

Comment: Several commenters expressed support for approval of BREYANZI® for new technology add-on payments. A few commenters stated that approval of BREYANZI®'s new technology add-on payment application will remove a potential barrier to accessing innovative treatments and tools advancing this approach to care for unmet medical needs. Another commenter stated that the new technology add-on payment program was created to eliminate the limitations on access to new therapies due to lack of reimbursement in the inpatient setting, and the use of BREYANZI® for the FDA-labeled indications would require hospitals to incur costs that, without a new technology add-on payment, would have to be fully absorbed by the treating hospital.

A few commenters also emphasized that CAR T-cell therapies are a critical and important advancement in the treatment of certain cancers and for patient populations with few existing treatment options. A commenter stated that BREYANZI® is a new CAR T-cell therapy for patients with CLL and a new option for patients who have exhausted all other treatment options. The commenter further urged CMS to consider adding BREYANZI® to the set of tools available to address the significant unmet need for additional lines of therapy for CLL, regardless of whether a patient receives BREYANZI® as their first treatment after progressing on two or more lines of therapy or after a noncovalent BTKi and/or a PI3Ki.

Response: We thank the commenters for their input and have taken it into consideration in determining whether BREYANZI® meets the substantial clinical improvement criterion as discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant asserted that BREYANZI® provides a substantial clinical improvement relative to services or technologies previously available for the treatment of Medicare beneficiaries with R/R CLL/SLL who have limited therapy options, according to National Comprehensive Cancer Network (NCCN) Guidelines. The applicant further stated that BREYANZI® is the only NCCN Guidelines-preferred regimen that offers patients a treatment-free disease remission interval with improved quality of life and the potential to achieve a deep and durable response (20 percent CR) while other regimens, such as PI3Ki, have concerning benefit-risk profiles and are associated with poor outcomes characterized by high risks of fatal adverse events and the absence of complete disease remission.

In response to CMS's question about the applicant's assertion that BREYANZI® offers a treatment option for patients unresponsive to or ineligible for other existing therapies, the applicant stated that BREYANZI® is a novel, promising treatment option not only for patients with R/R CLL/SLL who have received at least two prior lines of therapy, including a BTKi and a BCL–2i (double class exposed), but is also the only treatment intentionally studied and proven efficacious in patients with highly refractory and aggressive CCL/SLL who experienced disease progression while on BTKi and failed to respond to Venclexta®. Per the applicant, these highly refractory patients represent a particularly difficult-to-treat population with no existing effective treatments. The applicant also stated that BREYANZI® substantially improves treatment of the double class exposed population, that is, patients with R/R CLL/SLL who had received at least 2 prior lines of therapy, achieving a 20 percent CR rate and improvements in health-related quality of life, whereas existing therapies, including Jaypirca® (pirtobrutinib), the recently approved non-covalent BTKi, rarely achieve CR in this population. The applicant asserted that BREYANZI® addresses the critical unmet need in this patient population by offering the possibility of a durable CR following a one-time treatment. The applicant stated that in this subpopulation, BREYANZI® demonstrated a consistent rate of 20 percent CR that was durable, with median PFS and DOR not reached at

[34] Siddiqi (2023b), *op.cit.*

[35] Siddiqi (2024), *op.cit.*

[36] Mato (2023b), *op.cit.*

[37] Mato (2023b), *op.cit.*

31.4 and 31.7 months of follow up respectively. The applicant further stated that PI3Kis, such as Copiktra® and Zydelig®, are not preferred treatment options for double class exposed patients due to their benefit-risk profile. The applicant noted that 31 percent of Copiktra®-treated patients and 48 percent of Zydelig®-treated patients experienced fatal/serious infections, while 18 percent and 20 percent of patients experienced fatal/serious diarrhea or colitis respectively. The applicant added that 15 percent of Copiktra®-treated patients demonstrated treatment-related mortality, and accordingly, an FDA expert panel voted on April 21, 2022 to recommend that future FDA approvals of PI3Kis be supported by randomized data, rather than single-arm data only, and further discontinuing the use of almost all PI3Kis in hematologic treatment. Another commenter stated that CMS's inquiry into whether there is a particular subpopulation that is unresponsive to or ineligible for alternatives to BREYANZI® did not recognize that a new treatment line in a chronic cancer can offer an incremental, additive survival benefit.

In response to CMS's concern about the lack of historical controls in the single-arm TRANSCEND CLL 004 trial to compare the effects of BREYANZI® on clinical outcomes, the applicant stated that it conducted an external control arm analysis to compare BREYANZI® to the standard of care treatments for double case exposed patients with R/R CLL/SLL using patients from the TRANSCEND CLL 004 monotherapy cohort matched to real-world patients from U.S. oncology practice and cancer centers. Per the applicant, to ensure fair and robust comparisons, it employed an advanced causal inference methodology, Inverse Probability of Treatment Weighting combined with regression modeling, to adjust for the differences in patient and disease characteristics between the clinical trial and the real-world cohorts. The applicant stated that this analysis demonstrated that BREYANZI® significantly improved response, including higher CR rates ([95% CI] of 17.9% [9–34] for BREYANZI® vs 2.2% [1–5]) for standard of care treatments, P<0.0001) and ORR rates ([95% CI] of 52.5% [35–79] for BREYANZI® vs 19.2% [14–26] for standard of care treatments, P=0.0007), and also delayed disease progression and prolonged OS compared with standard of care treatments. According to the applicant, the median PFS [95 percent CI] was 12.0 months (10.8–13.2) with BREYANZI® vs 4.4 months (3.2–5.5) for standard of care treatments (hazard ratio, 0.40; 95% CI, 0.24–0.68, P=0.0007). The probabilities of PFS at 24 and 36 months were 46.3 percent and 30.3 percent with BREYANZI®, compared to 11.5 percent and 5.1 percent for standard of care treatments, respectively. The applicant also stated that mOS [95 percent CI] was 33.6 months (31.7–35.5) for BREYANZI® vs 14.8 months (9.4–20.1) for standard of care treatments (hazard ratio, 0.47; 95% CI 0.28–0.79, P=0.0043). The probability of OS at 24 and 36 months were 73.4 percent and 42.6 percent with BREYANZI®, compared to 35.1 percent and 29.7 percent with standard of care treatments respectively. The applicant asserted that these statistically significant and clinically meaningful results confirm that treatment with BREYANZI® results in improved outcomes compared with historical controls for double class exposed patients with R/R CLL/SLL.

A commenter, in response to CMS's concern about the single-arm design of the BREYANZI® pivotal trial, cited a study [38] that asserted single-arm trials can provide substantial evidence of effectiveness and safety when randomized controlled trials are infeasible. The commenter also cited an article [39] that assessed the use of single-arm studies and found that almost all the single-arm studies (174 out of 176) identified were for locally, advanced, or metastatic disease and that most were for second-line or later treatment (49 percent), third-line or later treatment (20 percent), fourth-line or later treatment (4 percent), or fifth-line or later treatment (1 percent). This commenter asserted that FDA's acceptance of single-arm studies reflects both the challenges research sponsors face in designing randomized controlled trials in these patient populations and FDA's interest in getting promising treatments to patients who need them. Another commenter urged CMS to recognize the inherent ethical challenges to designing randomized studies in disease states, such as R/R CLL, in which patients have few treatment options and are unlikely to survive through a study duration if the investigational treatment is withheld. The commenter stated that for many rare diseases, the underlying biology and disease progression have not reached a level of broad scientific understanding. The commenter asserted that limited natural history data makes it difficult to choose appropriate endpoints, assess whether a drug is effective, or even determine the optimal timing or duration for the intervention and the trials. The commenter agreed with the applicant that the R/R patient population has limited treatment options. Per the commenter, while a poor prognosis does not establish a case for significant improvement, it explains the applicant's decision not to incorporate historic controls.

In response to CMS's concern about the mixed clinical outcomes of BREYANZI® compared to Jaypirca®, the applicant stated it is critical to note the key differences in the two studies' patient populations. The applicant stated that the TRANSCEND CLL 004 study's patients were more heavily pretreated (a median of 5 prior lines of therapy compared to 3 in the Jaypirca® BRUIN phase ½ pivotal trial cohort [40]), had significantly higher prior exposure to both BTKi and BCL–2i (80 percent versus 40.5 percent in the BRUIN trial), and experienced disease progression while on a BTKi and failed to respond to Venclexta®, making it a study population with highly refractory and aggressive disease that is not represented in the Jaypirca® BRUIN study. The applicant stated that BREYANZI® resulted in a 20 percent CR rate in this double-class exposed (DCE) population, while Jaypirca® failed to induce CR. The applicant also asserted that sustained durability of response in CLL has been shown to closely correlate with achieving a complete response, underscoring the risk of disease progression over time for patients treated with Jaypirca®. Per the applicant, this was reflected in the outcomes—although Jaypirca® demonstrated an overall response rate at 70 percent, the CR rate was 0 percent, and the durability of response (DoR) was inferior compared to BREYANZI®. In the DCE population, the median DoR with BREYANZI® was 35.3 months (95% CI, 12.4-not reached [NR])32 versus 12.2 months (95% CI, 9.3–14.7) among patients treated with Jaypirca®.

In addition, the applicant stated that the median PFS of 11.9 months associated with BREYANZI® that CMS referenced in the proposed rule pertains specifically to the primary efficacy analysis set in the TRANSCEND CLL

[38] Sundeep Agrawal, MD, Agrawal S, Arora S, Amiri-Kordestani L, et al. Use of single-arm trials for US Food and Drug Administration drug approval in oncology, 2002–2021. *JAMA Oncol.* 2023; 9(2): 266–272. doi:10.1001/jamaoncol.2022.5985.

[39] Nierengarten, M.B. (2023), Single-arm trials for US Food and Drug Administration cancer drug approvals. Cancer, 129: 1626–1626. *https://doi.org/10.1002/cncr.34830.*

[40] Mato AR, Woyach JA, Brown JR, et al (2023). Pirtobrutinib after a Covalent BTK Inhibitor in Chronic Lymphocytic Leukemia. *N Engl J Med* 2023;389:33–44. DOI: 10.1056/NEJMoa2300696.

004 study, which was the cohort of patients who experienced disease progression while on BTKi and failed to respond to Venclexta®. The applicant asserted that BREYANZI® uniquely demonstrates efficacy in an especially high-risk, refractory, and disease-aggressive population, which was not represented in the Jaypirca® study. The applicant further stated that it is inappropriate to compare the outcomes of BREYANZI®'s primary efficacy analysis set to those of the Jaypirca® study, who showed a median PFS of 16.8 months, because the patient population of the Jaypirca® study was previously treated with a BTKi and Venclexta® but not required to exhibit refractoriness to these treatments. The applicant further commented that the Jaypirca® study showed that the median PFS of double class exposed patients treated with Jaypirca® decreased to 15.9 months at a median follow-up of 27.5 months. The applicant contrasted these results to those of the TRANSCEND trial, in which 80 percent of the treated patients were double class exposed, and the median PFS for these patients remained at 18 months and among the patients who responded to BREYANZI®, the median PFS was 26.2 months at a median follow-up of 31.7 months. The applicant further stated that BREYANZI® results in treatment-free disease remission, which is manifested as health-related quality of life improvements in the R/R CLL/SLL population. Per the applicant, in the TRANSCEND–CLL–004 trial, clinically meaningful improvements were achieved in the key domains of global health status/quality of life, physical function, role functioning, symptom burdens, and fatigue after BREYANZI® infusion, and exceeded the pre-defined minimum important difference thresholds. The applicant also stated that BREYANZI®'s one-time infusion eliminates the compliance and adherence challenges commonly associated with existing continuous treatment technologies.

Another commenter stated that part of the clinical improvement BREYANZI® offers by virtue of being the only approved CAR T-cell therapy indicated for R/R CLL/SLL is the additional survival benefit from a new line of treatment for patients with few available options. The commenter further stated that BREYANZI® and its incremental benefit are best viewed as additions to that accrued by both prior and subsequent treatments, unlike second generation covalent BTKis, which are unlikely to be effective after progression on another treatment in its class. The commenter also stated that, during CMS's Medicare Drug Price Negotiation Program Town Hall for Initial Price Applicability Year 2027, CLL researchers and clinician experts emphasized that the treatment goal for CLL is to prolong survival without compromising quality of life. The commenter further stated that patients may remain in a ''wait and see'' period after diagnosis and may delay second and subsequent lines of treatment to delay or avoid progression through available treatments, and therefore, the ''time to next treatment'' endpoint is highly relevant to CLL. The commenter stated that median time to next therapy following treatment with BREYANZI® 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, 3.6–10.1] [41]). The commenter stated that this improvement in time to next therapy is an important clinical improvement for patients with R/R CLL/SLL from both a patient and clinician perspective. In addition, the commenter stated that, according to clinicians and researchers, patients prefer treatment regimens of fixed duration and those that offer remission with shorter times on treatment. The commenter therefore stated it believes the option of receiving a course of therapy through a single infusion is an important benefit of BREYANZI®. In addition, the commenter stated that patients treated with BREYANZI® or Jaypirca® are not choosing between the median PFS of each therapy, but instead the decision is one of sequencing, and the incremental benefit in terms of PFS and/or overall survival is additive and significant. Moreover, the commenter argued that use of BREYANZI® for the FDA-labeled indications would require hospitals to incur costs that, without new technology add-on payments, would have to be fully absorbed by the treating hospital. The commenter asserted that the mechanism of new technology add-on payments was created to eliminate the limitations on access to new therapies due to lack of reimbursement in the inpatient setting.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree with the applicant and other commenters that BREYANZI® represents a substantial clinical improvement over existing technologies because BREYANZI® is a one-time treatment that significantly improves CR with lower risk of adverse events in R/R CLL/SLL patients who have received prior BTKi and BCL2i therapy.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that BREYANZI® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2026. Cases involving the use of BREYANZI® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW033N7 (Transfusion of lisocabtagene maraleucel immunotherapy into peripheral vein, percutaneous approach, new technology group 7) or XW043N7 (Transfusion of lisocabtagene maraleucel immunotherapy into central vein, percutaneous approach, new technology group 7) in combination with one of the following ICD–10–CM codes:

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

[41] Siddiqi et al. (2023), *op. cit.*

ICD-10-CM Code	Description
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

In its application, the applicant estimated that the cost of a one-time intravenous infusion of BREYANZI® is $487,477 per patient. 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, the maximum new technology add-on payment for a case involving the use of BREYANZI® is $316,860.05 for FY 2026.

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 stated we were 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.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for COBENFY™ and was granted approval to use the following procedure code effective October 1, 2025: XW0DXVB (Introduction of xanomeline and trospium chloride into mouth and pharynx, external approach, new technology group 11). 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 substantially similar to other currently available technologies.

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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.

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We invited public comments on whether COBENFY™ is substantially similar to existing technologies and whether COBENFY™ meets the newness criterion.

Comment: The applicant stated that COBENFY™ meets the newness criterion because it received FDA approval on September 26, 2024, which is within the eligibility window for FY 2026 new technology add-on payment consideration. Additionally, the applicant noted that as the first antipsychotic medication for schizophrenia that specifically targets muscarinic receptors instead of dopamine receptors, COBENFY™ represents the first novel pharmacological approach to schizophrenia treatment in decades. The applicant further explained that COBENFY™ selectively targets M1 and M4 receptors in the brain without blocking D2 receptors, making it fundamentally different from all existing antipsychotics that have relied on dopamine receptor modulation for over 70 years. The applicant also stated that FDA recognized this distinction, noting that COBENFY™ ''takes the first new approach to schizophrenia treatment in decades'' and ''offers a new alternative to the antipsychotic medications people with schizophrenia have previously been prescribed.'' The applicant concluded that COBENFY™ is not substantially similar to any other product currently available to treat schizophrenia because the therapy has a unique mechanism of action, distinctive safety profile, and a recent FDA-approval date. Additional commenters also noted the unique mechanism of action for COBENFY™ since it targets

cholinergic receptors and the muscarinic pathway rather than blocking dopamine receptors, which is the target for existing treatments.

The applicant asserted that the newness period for COBENFY™ should begin on October 9, 2024, to reflect the date that COBENFY™ was first commercially available for purchase. In response to CMS's request for additional information regarding the cause of any delay in commercial availability, the applicant explained that the delay between FDA approval on September 26, 2024, and market availability on October 9, 2024, was for multiple reasons. The applicant stated it allowed for complete standard launch preparation activities that typically follow regulatory approval, including finalizing the distribution network and ensuring support teams were fully prepared. The applicant stated that additional time was also needed to ensure sufficient inventory would be available across retail pharmacies nationwide to meet initial and anticipated patient demand without interruption. The applicant further stated that the delay was also needed following its acquisition of COBENFY™ from Karuna Therapeutics, since it needed additional time to properly scale up manufacturing and distribution capabilities to support a successful nationwide retail-pharmacy-based launch. The applicant urged CMS to use October 9, 2024 as the newness date, to align with new technology add-on payment statutes and to reflect the date of COBENFY™'s first commercial availability for inpatient hospital use.

Response: We thank the applicant for its comment. Based on our review of the comment received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for COBENFY™, we agree with the applicant that COBENFY™ uses a unique mechanism of action because it is the first schizophrenia treatment for adults to target muscarinic receptors in the brain by combining the muscarinic agonist, xanomeline, and the muscarinic antagonist, trospium chloride, unlike typical and atypical antipsychotics currently used to treat schizophrenia, which antagonize dopamine receptors. Therefore, we agree with the applicant that COBENFY™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on October 9, 2024, the date on which COBENFY™ became commercially available.

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.
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 invited public comments on whether COBENFY™ meets the cost criterion.

Comment: The applicant submitted a comment stating that its cost analysis was calculated to best represent the patients with schizophrenia who the applicant believes will be eligible for treatment with COBENFY™, specifically patients being treated for psychosis or other mental diseases or disorders in an inpatient or outpatient setting. The applicant also reiterated the methods it used in its cost criterion analysis and that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, 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 noted that two additional articles (Cornett et al., 2017 and Lieberman et al., 2005)[42] submitted as supporting evidence would more appropriately be characterized as background articles because they do not directly assess the use of COBENFY™.[43] [44] 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.

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[42] Background articles are not included in the following table but can be accessed via the online posting for the technology.

[43] Cornett EM, Novitch M, Kaye AD, Kata V, Kaye AM. Medication-Induced Tardive Dyskinesia: A Review and Update. Ochsner J. 2017 Summer;17(2):162–174. PMID: 28638290; PMCID: PMC5472076.

[44] 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.*

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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)
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.*

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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 summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18107).

After review of the information provided by the applicant and the

public comment received in response to the New Technology Town Hall meeting, we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18107 through 18108) that we had the following concerns regarding whether COBENFY™ meets the substantial clinical improvement criterion. We noted that the applicant did not identify a patient population for which 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 noted 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 noted that the other trials excluded patients with a history of treatment resistance to schizophrenia medications, and we therefore questioned how the trials demonstrated 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 noted 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 questioned 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 noted that, per the applicant, there are more than 20 FDA-approved therapies for schizophrenia, and we stated we were 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 noted 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, stated we were unclear if the applicant is stating that COBENFY™ may reduce the prevalence of TD only compared to typical antipsychotics. We also noted 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 stated that 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 noted 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 questioned whether these rates of adverse events may increase over time. For these reasons, we questioned 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 questioned long-term efficacy, given that the only data submitted for this claim was from two 5-week trials (EMERGENT–1 and EMERGENT–3).

We invited public comments on whether COBENFY™ meets the substantial clinical improvement criterion.

Comment: A few commenters urged CMS to approve new technology add-on payments for COBENFY™. These commenters highlighted that COBENFY™ offers a critical new option for a patient population that has seen limited innovation despite urgent unmet need, has been effective in reducing positive and negative symptoms of schizophrenia demonstrated over 1 year of use, and provides an alternative option for patients to avoid the significant side effects associated with antipsychotic medications, such as TD, significant weight gain, metabolic disturbances, sedation and fluid retention, among others. A commenter stated that by offering a temporary payment adjustment, the new technology add-on payment ensures that hospitals don't face financial penalties for making clinically-driven decisions that benefit the schizophrenic community because hospitals are reimbursed through MS–DRG rates that struggle to reflect the value of innovative therapies. In addition, the commenter stated that without the new technology add-on payment, institutions may default to outdated inpatient care models that overlook recent advances in science and patient experience, simply to remain financially viable. This commenter also stated that delays in access to novel therapeutics increase the likelihood of patient relapse, readmission, or discontinuation of medication. The commenter further highlighted that inadequate treatment of schizophrenia contributes to severe consequences, including neurological damage, worsening symptoms, and an average lifespan that is 15 years shorter than that of the general population.

Another commenter stated that CMS should ensure coverage of new therapies, such as COBENFY™, to allow clinicians the ability to choose medications based on their expertise and patient needs, while also allowing patients to benefit from the full range of schizophrenia treatment options and to determine which therapy is an appropriate, advantageous option for them.

Response: We thank the commenters for their input and have taken it into consideration in determining whether COBENFY™ meets the substantial clinical improvement criterion as discussed later in this section. We note that whether a technology receives new technology add-on payments or not does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate.

Comment: The applicant for COBENFY™ submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant asserted that COBENFY™ satisfies the substantial clinical improvement criterion by introducing the first novel pharmacological approach to schizophrenia treatment in decades. The applicant reiterated that COBENFY™ fundamentally differs from all existing antipsychotics as a first-in-class muscarinic agonist that selectively targets M1 and M4 receptors without blocking dopamine receptors. The applicant also stated that COBENFY™ has the potential to break the cycle of treatment resistance progression through its innovative mechanism and that the placebo-controlled trials submitted as part of its application were scientifically appropriate for evaluating this groundbreaking medication. The applicant also noted COBENFY™'s differentiated safety profile relative to existing antipsychotics across both 5-week and 52-week trials, as well as comprehensive long-term data that confirms sustained efficacy.

In response to CMS's concern that the applicant did not identify a patient population for which COBENFY™ could be used that is unresponsive to other available treatments, the applicant stated that by leveraging its novel mechanism of action, COBENFY™ offers a promising alternative that addresses multiple unmet needs in patients with schizophrenia by providing an effective and safe treatment option, particularly because all other approved antipsychotics work through varying degrees of dopamine receptor modulation.

In response to CMS's concern that the clinical trials excluded patients with a history of treatment resistance to schizophrenia medications, and questioned how the trials demonstrate that COBENFY™ treats patients unresponsive to other therapies, the applicant clarified that FDA recognizes treatment-resistant schizophrenia as a distinct indication from the general treatment of schizophrenia, as evidenced by FDA granting a separate indication to clozapine for treatment-resistant patients. The applicant also stated that treatment-resistant schizophrenia is estimated to affect only about 30 percent of individuals with the disease, meaning that roughly 70 percent of patients do not meet the criteria for treatment resistance and typically respond to standard therapies. The applicant asserted that while the COBENFY™ clinical trials focused on the primary indication of schizophrenia, the trials' exclusion of patients with documented treatment resistance does not preclude potential benefits across a broad segment of the schizophrenia population, namely the 70 percent of patients who do not meet the criteria for treatment resistance. The applicant further stated that because COBENFY™ does not rely on dopamine receptor antagonism, this therapy creates the potential for broader benefit. The applicant stated that medical literature suggests that the occurrence of treatment resistance in schizophrenia may develop through successive treatment failures, a cycle perpetuated by the limited mechanistic diversity of available therapies, such that patients experiencing insufficient response or intolerable side effects with one antipsychotic often encounter similar challenges when switching to another. The applicant explained that COBENFY™ presents an opportunity to interrupt patients' progression toward treatment resistance by offering a genuinely different pharmacological option. The applicant also stated that, although COBENFY™ does not carry a specific FDA-approved indication for treatment-resistant schizophrenia, it provides clinicians with an entirely different neurobiological approach that has the potential to benefit patients across the disease spectrum, including but not limited to, those who have experienced inadequate response or intolerable side effects with traditional antipsychotics that modulate dopamine receptors.

The applicant also stated that the side effects associated with conventional antipsychotics frequently lead to antipsychotic discontinuation and stem directly from dopamine receptor blockade and other associated receptor interactions, contributing to the cycle of treatment failures. The applicant asserted that COBENFY™'s fundamentally different mechanism of action significantly reduces the risk of these dopamine-related side effects, such as weight gain, diabetes, TD, extrapyramidal symptoms, sedation, and cognitive dulling, and may only result in manageable and transient effects, such as nausea and dyspepsia. The applicant also stated that there is a significant economic burden associated with managing antipsychotic-induced side effects due to the chronic nature of schizophrenia treatment and the potential need for long-term management of side effects, which can result in costs greater than $10,000 to $15,000 per patient annually. The applicant stated that COBENFY™ may reduce the need for such costly interventions, providing not only a clinically significant alternative but also a financially prudent option for healthcare systems and patients. The applicant asserted that this further highlights how COBENFY™ addresses the real unmet needs faced by patients with schizophrenia and underscores its importance in breaking the cycle of treatment failures that contribute to treatment resistance development.

In response to CMS's request for additional information comparing COBENFY™'s clinical outcomes to other FDA-approved therapies, the applicant stated that it made the scientifically sound and regulatory-compliant methodological decision to conduct placebo-controlled trials. The applicant explained that it believes placebo-controlled trials represent the most rigorous and appropriate methodology for establishing the safety, tolerability, and efficacy profile of COBENFY™. The applicant stated that placebo-controlled clinical trials are sufficient as well as the standard approach for obtaining initial FDA approval. The applicant further explained that placebo-controlled trials are particularly appropriate for psychiatric medications because FDA specifically prefers them to evaluate efficacy and safety due to the unique challenges inherent in psychiatric research and considers them essential to establish that a drug has an effect beyond nonspecific trial effects, such as expectation, rater bias, and regression to the mean—all of which are prominent in psychiatric trials. The applicant reiterated the findings from the three 5-week trials (EMERGENT–1, EMERGENT–2, and EMERGENT–3) and

2 52-week trials (EMERGENT–4 and EMERGENT–5) submitted in its new technology add-on payment application. Additionally, the applicant noted that despite being placebo-controlled, these trials demonstrate the comparative advantages of COBENFY™ with respect to its safety profile across both the 5-week trials and 52-week trials, indicating the sustained tolerability advantage of COBENFY™.

In response to CMS's concern whether COBENFY™ improves tolerability and side-effects relative to previously available therapies, the applicant stated that COBENFY™'s unique mechanism of action suggests potential benefits over both typical and atypical antipsychotics, although the Cornett et al. (2017) review it submitted only focused on typical antipsychotics. The applicant explained that, unlike any existing antipsychotics, COBENFY™ does not target dopamine receptors, which is the fundamental mechanism implicated in TD development. The applicant, therefore, asserted that this represents a categorical distinction rather than a marginal improvement, suggesting that COBENFY™ results in potential TD risk reduction compared to all current antipsychotics, both typical and atypical.

In response to CMS's concern that the clinical trials submitted in its application may be too brief in duration to observe some side effects, such as TD, the applicant summarized the safety data from the EMERGENT clinical trials. Specifically, the applicant stated there were no cases of TD reported in the three 5-week clinical trials, with the primary adverse effects being mild gastrointestinal symptoms. The applicant highlighted that the two 52-week EMERGENT trials did not show any new safety concerns compared with the 5-week trials. The applicant also stated that COBENFY™ demonstrated sustained symptom improvement through 52 weeks of treatment, and the trials only observed two cases of TD, which the primary investigator adjudicated as unrelated to treatment with COBENFY™, as the patients had pre-existing TD histories. The applicant asserted that the EMERGENT–4 and EMERGENT–5 52-week clinical trials directly address the potential emergence of delayed adverse effects and provide compelling evidence of COBENFY™'s long-term tolerability compared to the characteristic adverse effects associated with both typical and atypical antipsychotics that the applicant notes are commonly understood to be a result of prolonged dopamine receptor blockage, which COBENFY™ avoids. The applicant provided the side effect data from COBENFY™'s package insert: nausea (19 percent), dyspepsia (18 percent), vomiting (15 percent), hypertension (11 percent), abdominal pain (8 percent), diarrhea (6 percent), dizziness (5 percent), and tachycardia (5 percent). The applicant also indicated that motor disturbances, sedation, vision impairments, seizures, weight gain, hyperlipidemia, insulin resistance/diabetes, QTc prolongation, extrapyramidal symptoms, tardive dyskinesia, and sexual dysfunction are common antipsychotic side effects.

In response to CMS's concern whether the EMERGENT–1 and EMERGENT–3 clinical trials demonstrate COBENFY™'s long-term efficacy in reducing illness severity, the applicant provided additional evidence from the 52-week EMERGENT–4 trial, which showed COBENFY™ improves disease severity, as measured by the CGI–S scale, throughout a full 52-week trial period. The applicant explained that 47.4 percent of participants who remained on COBENFY™ by week 52 achieved CGI–S scores 3, compared to the mean baseline scores of 4, which reflected clinically meaningful improvement to mild disease severity or better. The applicant also stated that the EMERGENT–4 study demonstrates COBENFY™'s sustained efficacy across core schizophrenia symptoms as measured by the PANSS total score. Specifically, the applicant stated that nearly 70 percent of participants in the overall modified intent-to-treat population achieved at least a 30 percent reduction in PANSS total score from baseline to week 52, with 37.1 percent of participants achieving a 50 percent or greater reduction. The applicant asserted that the trial observed these PANSS total score improvements consistently across both positive and negative symptom domains, supporting the robust and durable therapeutic benefit of COBENFY™ beyond short-term clinical trials. Lastly, the applicant reiterated the EMERGENT–4 and EMERGENT–5 trials' pooled safety and tolerability data that it submitted in its application. The applicant asserted that these pooled data demonstrate durable effectiveness beyond dopamine receptor-based therapies, with a tolerability profile that can support improved medication adherence and reduce the risk of cumulative side effects that often complicate long-term antipsychotic use.

Response: We thank the applicant and commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received and all data received to date, we continue to have concerns as to whether COBENFY™ meets the substantial clinical improvement criterion to be approved for new technology add-on payments. Specifically, it remains unclear that COBENFY™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments for schizophrenia in adults and that the use of COBENFY™ significantly improves clinical outcomes over existing technologies.

While the applicant noted that COBENFY™ may be able to help patients who do not respond to or are intolerant of other therapies, the basis for this assertion was COBENFY™'s different mechanism of action rather than data supporting it. There was also no data provided indicating that other antipsychotics cannot manage negative symptoms. Therefore, we do not believe the evidence provided indicates COBENFY™ is a treatment option for patients who are unresponsive to or ineligible for other therapies.

With regard to the assertion that COBENFY™ improves clinical outcomes relative to previously available therapies, we note that there was no data provided comparing COBENFY™ to other therapies for schizophrenia in adults with regard to efficacy and safety. While the potential risk of certain side effects was noted for treatments for schizophrenia, there was no data provided comparing the relative risk of these side effects for COBENFY™ versus typical and atypical antipsychotics. In addition, while the applicant stated that COBENFY™'s different mechanism of action reduces the risk of the side effects that frequently lead to antipsychotic discontinuation, there was no comparative data provided indicating a lower risk of discontinuation for COBENFY™ compared to typical and atypical antipsychotics.

After consideration of all the information received from the applicant as well as the public comments we received, we are unable to determine that COBENFY™ represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule, and therefore, we are not approving new technology add-on payments for COBENFY™ for FY 2026.

e. 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.[45] 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.

The applicant submitted a request for approval for unique ICD–10–PCS procedure codes for FIBRYGA® and was granted approval to use the following procedure codes effective October 1, 2025: XW133YB (Transfusion of nonautologous (human) fibrinogen concentrate, shelf-stable into peripheral vein, percutaneous approach, new technology group 11) and XW143YB (Transfusion of nonautologous (human) fibrinogen concentrate, shelf-stable into central vein, percutaneous approach, new technology group 11). 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 stated 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 invited 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.

Comment: Commenters expressinged general support for the use of the ICD–10–CM code for which CMS specifically sought input.

Response: We thank the commenters and agree that D68.4 (Acquired coagulation factor deficiency) accurately identifies the indication for FIBRYGA®.

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.

[45] 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.

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18114), we noted 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 noted 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 noted 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.[46] [47] Therefore, we questioned 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 noted that the applicant asserted that FIBRYGA® has the same mechanism of action as cryoprecipitate and works by providing a source of fibrinogen that the body can use to form blood clots to stop bleeding. We also noted that INTERCEPT® Fibrinogen Complex provides a source of fibrinogen, and therefore, we questioned whether FIBRYGA® and INTERCEPT® Fibrinogen Complex have the same mechanism of action. We also noted 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 stated that FIBRYGA® would map to the same MS–DRGs as INTERCEPT® Fibrinogen Complex.

Therefore, as it appeared 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 stated our belief that these technologies may be substantially similar to each other. We noted 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 stated that we believe the newness period for this technology would begin on May 5, 2021, the date INTERCEPT® Fibrinogen Complex became commercially available.[48] In addition, because the 3-year anniversary date of the INTERCEPT® Fibrinogen Complex's entry in 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 stated we were interested in information on how these technologies may differ from each other with respect to the substantial similarity criteria and the newness criterion.

We invited public comments 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.

Comment: The applicant and another commenter submitted public comments regarding the newness criterion. In response to CMS's question of whether FIBRYGA® and INTERCEPT®

[46] 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.*

[47] *https://intercept-usa.com/products/intercept-fibrinogen-complex/#:~:text=INTERCEPT%C2%AE%20Fibrinogen%20Complex%20is,day%20post%2Dthaw%20shelf%20life.*

[48] 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.

Fibrinogen Complex have the same mechanism of action, the applicant and another commenter stated that they have different mechanisms of action. The applicant agreed with CMS that FIBRYGA® and INTERCEPT® Fibrinogen Complex are both used in patients with hemorrhage and acquired hypofibrinogenemia, but asserted that the clinical behavior, regulatory oversight, and administration logistics differ substantially. The applicant stated that, despite sharing a general mechanism of restoration of fibrinogen to support clot formation, the way each product achieves this outcome is materially distinct. The applicant provided a table comparing regulatory status, pathogen inactivation, composition, dosing, administration time, and storage between FIBRYGA® and INTERCEPT® Fibrinogen Complex. Another commenter further detailed that the INTERCEPT® Fibrinogen Complex, a cryoprecipitate, is derived from pooled plasma through the INTERCEPT™ Blood System, which uses amotosalen and UVA light for pathogen reduction, but contains variable concentrations of fibrinogen and other plasma proteins, including factor VIII, vWF, factor XIII, and fibronectin.

The applicant and another commenter stated that FIBRYGA®'s active component is fibrinogen. The other commenter further stated that FIBRYGA® is manufactured through a multi-step purification process including solvent/detergent treatment, ion exchange chromatography, and nanofiltration to remove viral contaminants, resulting in purity levels consistently above 96 percent and a defined fibrinogen concentration of 20 mg/mL, allowing for precise dosing based on patient weight and clinical needs. The applicant stated that the precise biochemical composition of FIBRYGA® ensures that it only works by interacting with thrombin in the last step of secondary hemostasis to promote clot formation via fibrin production from fibrinogen. The applicant and another commenter stated that, in addition to fibrinogen, cryoprecipitate and INTERCEPT® Fibrinogen Complex contain plasma proteins such as von Willebrand factor (vWF), factor VIII, factor XIII, and fibronectin. The applicant stated that this means cryoprecipitate and INTERCEPT® Fibrinogen Complex promote clotting via primary hemostasis, where vWF interacts with platelets to form a plug at the site of bleeding. The applicant further asserted that the presence of factor VIII results in the activation of factor X in the final common pathway of coagulation, resulting in the production of thrombin to promote clot formation. The applicant asserted that FIBRYGA® has a different mechanism of action because it does not work via these pathways.

The applicant also stated that FIBRYGA® is FDA-approved as a biologic for the treatment of acquired and congenital fibrinogen deficiency and is manufactured under a BLA with full FDA batch release and monitoring. The applicant stated that, in contrast, INTERCEPT® Fibrinogen Complex is approved as a blood component for the treatment of acquired fibrinogen deficiency. The applicant stated that INTERCEPT® Fibrinogen Complex is pathogen-inactivated but contains other active coagulation proteins that can potentially affect coagulation and carry risk when treating a patient who is only hypofibrinogenemic. The applicant and another commenter further asserted that since it is regulated as a blood component, fibrinogen content is variable and not standardized. The commenter further stated that a study by Stanford et al. (2023) found significant variability in cryoprecipitate-based products compared to the consistent profile of fibrinogen concentrate whereas, in contrast, Schulz et al. (2018) demonstrated that FIBRYGA® contains negligible amounts of other clotting factors and plasma proteins, creating a different pharmacologic profile than cryoprecipitated plasma products. The commenter also stated that Wikkelsø et al. (2013) demonstrated significant compositional differences between fibrinogen concentrates and cryoprecipitate products, affecting their mechanism of action in clinical settings. The applicant stated that FIBRYGA® is shelf-stable and ready to use immediately without the thawing wait time of INTERCEPT® Fibrinogen Complex. A commenter also expressed concerns regarding the accurate classification of products, reimbursement alignment, and recognition of meaningful clinical and operational differences within fibrinogen replacement therapies. The commenter stated that FDA classified and labeled INTERCEPT® Fibrinogen Complex as a Pathogen-Reduced Cryoprecipitated Fibrinogen Complex to distinguish it as a blood component, rather than a pharmaceutical.

In response to CMS's concern that FIBRYGA [acirc;] would map to the same MS–DRGs as INTERCEPT® Fibrinogen Complex, the commenter stated that while cases utilizing either product may initially map to the same MS–DRGs, substantial evidence indicates FIBRYGA® can affect ultimate MS–DRG assignments through improved outcomes. The commenter further explained that multiple clinical studies demonstrate that FIBRYGA® reduces the need for allogeneic blood product transfusions compared to cryoprecipitate-based products such as INTERCEPT® Fibrinogen Complex. The commenter stated that the FIBRES trial post-hoc analysis revealed a statistically significant decrease in allogeneic blood product use in specific patient populations, particularly those with longer surgical procedures (Bartoszko et al., 2022). The commenter stated that studies demonstrated that patients receiving fibrinogen concentrate had shorter ICU stays (5.13 days) compared to those receiving cryoprecipitate (6.15 days) after cardiac surgery (Ayaganov et al., 2024), and significantly shorter in-hospital and intensive care unit LOS compared to those receiving cryoprecipitate (Joseph et al., 2022). This commenter stated that reduced LOS, combined with the established decreased need for allogeneic blood product transfusion shown in multiple studies, provides strong evidence that patients receiving FIBRYGA® may experience different clinical courses and resource utilization patterns, which could influence MS–DRG-related metrics compared to those receiving INTERCEPT® Fibrinogen Complex.

In response to CMS's question about whether FIBRYGA® and INTERCEPT® Fibrinogen Complex treat the same or similar patient population and disease, the applicant and a commenter agreed with CMS that both treat bleeding associated with acquired fibrinogen deficiency but stated that FIBRYGA® and INTERCEPT® Fibrinogen Complex treat different patients. Specifically, the applicant and commenter asserted that FIBRYGA® is shelf-stable and can be stored in patient care areas such as trauma bays, operating rooms (ORs), Labor and Delivery (L&D) suites, and rural emergency settings for immediate use, and therefore treats a broader patient population than INTERCEPT® Fibrinogen Complex, which must be stored in a temperature-controlled blood bank and requires thawing and has cross-matching requirements. The applicant stated that FIBRYGA® avoids the delivery of vWF and factor VIII proteins present in INTERCEPT® Fibrinogen Complex and cryoprecipitate, which may increase thrombotic risk, especially in cardiovascular, trauma, and obstetric patients. A commenter further stated that due to the varied amounts of coagulation factors and plasma proteins

in the INTERCEPT® Fibrinogen Complex, accurate dosing is challenging in patients with coagulopathic bleeding (Stanford et al., 2023), whereas FIBRYGA® supports a more precise and timely therapeutic approach for those lacking blood type-compatible cryoprecipitate, those requiring urgent fibrinogen replacement, patients who are allergic and/or respond poorly to plasma products, and at-risk immunocompromised patients. The applicant reiterated that FIBRYGA® has been associated with a reduced need for packed red blood cells (PRBCs) and fresh frozen plasma (FFP), lowering the incidence of infections and allergic reactions.

In response to CMS's statement that FIBRYGA® and INTERCEPT® Fibrinogen Complex can be stored at room temperature and are immediately available, the applicant commented that FIBRYGA® may be stored at room temperature with a 48-month shelf life, while INTERCEPT® Fibrinogen Complex may be frozen with a 1-year shelf-life but expires 5 days after thaw. A commenter noted that there are significant differences in practical availability and storage requirements. The commenter agreed with CMS that INTERCEPT® Fibrinogen Complex has a 5-day room temperature shelf life once thawed, while FIBRYGA® has a 30-month shelf life at room temperature (2–25° C) in its unreconstituted form and can be stored directly in emergency departments, operating rooms, and obstetric units. The commenter referenced several additional studies of fibrinogen concentrate as supporting evidence, including Franchini and Lippi (2012), which noted that fibrinogen concentrate is stored as a lyophilized powder at room temperature and can be reconstituted quickly with sterile water and infusion volumes are low, allowing for rapid administration without delays for thawing or cross-matching; Winearls et al. (2021), which found that fibrinogen concentrate administration in trauma patients with major hemorrhage and hypofibrinogenemia was achieved significantly faster than cryoprecipitate; and Sørensen and Bevan (2010), which emphasized the critical difference in storage and availability between fibrinogen concentrate and cryoprecipitate products, noting that the latter's requirement for blood bank processing creates significant barriers to rapid administration in emergent bleeding scenarios.

Response: We appreciate the additional information from the applicant and commenter with respect to whether FIBRYGA® is substantially similar to existing technologies. However, we disagree with the applicant and commenter that FIBRYGA® has a new mechanism of action compared to cryoprecipitate and INTERCEPT® Fibrinogen Complex. We note that the applicant had originally stated in its application that FIBRYGA® works by providing a source of fibrinogen that the body can use to form blood clots to stop bleeding, which is the same mechanism used by cryoprecipitate, and we agree with this statement. We also believe that this is also the same mechanism of action as INTERCEPT® Fibrinogen Complex, a pathogen-inactivated cryoprecipitate, since all three products provide a source of fibrinogen to promote clot formation. We note that the applicant stated in its comment that FIBRYGA® only contains fibrinogen and therefore only works by interacting with thrombin in the last step of secondary hemostasis to promote clot formation and that INTERCEPT® and cryoprecipitate contain additional factors that may affect primary hemostasis. However, these products also contain fibrinogen and therefore the interaction with thrombin in secondary hemostasis remains the same across all three products. In addition, while the applicant and commenter provided differences between FIBRYGA® and INTERCEPT® Fibrinogen Complex in FDA regulatory classifications, pathogen inactivation, composition, dosing, administration time, and storage, we do not believe that the differences described in these public comments constitute a difference in the mechanism of action because, as stated previously, both treatments work by providing a source of fibrinogen the body can use to form blood clots to stop bleeding. Additionally, while the applicant stated that FIBRYGA® and INTERCEPT® Fibrinogen Complex have better safety profiles (thrombotic risk) and exposure risks (due to the need for PRBCs and FFP), we note that these differences in clinical outcomes are not evaluated as part of the mechanism of action, but rather substantial clinical improvement. Therefore, we believe that all three products have the same mechanism of action of providing exogenous fibrinogen to promote clot formation in patients with acquired fibrinogen deficiency.

In regard to the second criterion, whether a technology is assigned to the same or a different MS–DRG, we agree with the applicant's assertion in its application that it is not expected that the use of FIBRYGA® will affect the MS–DRG assignment. We note that outcomes that change as a result of the technology's administration do not change the MS–DRG mapping. We further note that, as the applicant stated in its application, cases requiring this type of treatment include a broad range of clinical situations in which a diagnosis of acquired coagulation factor deficiency or postpartum afibrinogenemia is present. Therefore, we continue to agree with the applicant that the use of FIBRYGA® would not change the MS–DRG assignment.

In regard to the third criterion, whether a technology treats the same or similar type of disease and patient populations, we disagree that the use of FIBRYGA® and INTERCEPT® Fibrinogen Complex involves different patient populations or disease types. Both technologies treat patients with hemorrhage and acquired hypofibrinogenemia and address fibrinogen deficiency in bleeding patients. While the applicant and a commenter commented that FIBRYGA® treats a different patient population than INTERCEPT® Fibrinogen Complex because it is shelf-stable and ready to use immediately, as we stated previously and in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45149), the 5-day shelf life post-thaw of INTERCEPT® Fibrinogen Complex makes it immediately available in a ready-to-transfuse form as a fibrinogen source. While the commenter stated that FIBRYGA® treats a different patient population because certain subsets of patients may benefit from fibrinogen concentrates such as those with plasma allergies or who are immunocompromised and for whom the risk of pathogen-reduced cryoprecipitate remains too great, these represent clinical practice considerations rather than distinct patient populations requiring different therapeutic approaches. Specifically, we note that the FDA label for FIBRYGA® also includes warning regarding risks of allergic reactions and transmission of infectious agents, noting that FIBRYGA® is made from human plasma.[49] Therefore, it seems that the factors described by the commenter relate to treatment preferences and logistical considerations within the same patient population (those with fibrinogen deficiency) rather than identifying a different patient population. We also note that both FIBRYGA® and INTERCEPT® Fibrinogen Complex are indicated for the same disease and the same patient population for which the applicant is seeking new technology add-on payment status. We further disagree that FIBRYGA®'s standardized,

[49] FIBRYGA®. USPI (06–19–25). Section 5: Warnings and Precautions.

purified formulation and ease of administration results in the treatment of a different patient population compared to INTERCEPT® Fibrinogen Complex because while these differences may or may not lead to improved clinical outcomes, they do not differentiate the disease or patient population being treated by the two technologies.

Because FIBRYGA® meets all three of the substantial similarity criteria, we believe FIBRYGA® is substantially similar to the INTERCEPT® Fibrinogen Complex. Therefore, we consider the beginning of the newness period for FIBRYGA® to begin on the date the INTERCEPT® Fibrinogen Complex became commercially available for the treatment and control of bleeding, including massive hemorrhage, associated with fibrinogen deficiency. Since INTERCEPT® Fibrinogen Complex has been on the U.S. market since May 5, 2021, the 3-year anniversary date of its entry onto the market occurred prior to FY 2026, and therefore, FIBRYGA® does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2026. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2026, we are not summarizing comments received or making a determination on those criteria in this final rule.

f. 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 (alloHSCT) 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 alloHSCT 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 stated that we were 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,[50] 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 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.

[50] Oncotec Pharma Produktion GmbH. GRAFAPEX™ [package insert]. (Revised 2/2025). Available at: *https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/214759s001lbl.pdf.*

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) and 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 alloHSCT 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.

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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 alloHSCT 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 alloHSCT itself. It is Medexus's understanding that other conditioning treatments prior to alloHSCT also would typically be assigned to MS-DRG 014. Some cases also may be assigned to MS-DRG 004.
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 alloHSCT 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 alloHSCT conditioning agent for AML and MDS. A landmark multicenter RCT discusses how alloHSCT 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.

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With respect to the substantial similarity criteria, we noted in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18119) 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 a unique structure that allows it to bypass liver metabolism and subsequently reduce treatment related toxicity, we questioned 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 questioned 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 more comorbid patients, RIC and NMA may still be options for these patients.

We invited public comments on whether GRAFAPEX™ is substantially similar to existing technologies and whether GRAFAPEX™ meets the newness criterion.

Comment: The applicant submitted a public comment reiterating that GRAFAPEX™ is not substantially similar to any existing technology because GRAFAPEX™ does not use the same or similar mechanism of action when compared to existing technologies to achieve a therapeutic outcome and does not involve treatment of the same or similar type of disease and patient population when compared to any existing technology. The applicant explained that GRAFAPEX™ is the first and only FDA-approved alloHSCT conditioning agent for AML and MDS, and that prior to FDA's approval of GRAFAPEX™, patients with AML or MDS had no FDA-approved treatment option for an alloHSCT conditioning agent. In addition, the applicant cited the FY 2020 IPPS/LTCH PPS final rule (84 FR 42243) and asserted that CMS has repeatedly recognized that being the first FDA-approved therapy for a particular indication is relevant to the new technology add-on payment newness criterion and relates to mechanism of action. The applicant further stated that GRAFAPEX™ is the first drug with its mechanism of action approved by FDA to treat patients with AML or MDS and, therefore, GRAFAPEX™ is not substantially similar to existing technologies and meets the newness criterion.

The applicant also reiterated that GRAFAPEX™ is a new chemical entity and novel prodrug of a bifunctional alkylating agent with antileukemic properties used for alloHSCT conditioning. The applicant further specified that GRAFAPEX™ is a non-enzymatically activated prodrug that targets bone marrow cells for alkylation, and the pharmacologically inactive treosulfan is converted spontaneously under physiological conditions into the active monoepoxide intermediate (2S,3S)-1,2-epoxybutane-3,4-diol-4-methanesulfonate) and finally to active L-diepoxibutane (2S,3S)-1,2:3,4-diepoxybutane). The applicant also stated that GRAFAPEX™ has a unique chemical structure resulting from two hydroxide bonds that are not present in other alkylating agents and due to these unique hydroxide bonds, GRAFAPEX™'s mechanism of alkylation is entirely different than that of busulfan and other alkylating agents. The applicant stated that the distinct structure and unique mechanism of alkylation further distinguish GRAFAPEX™'s mechanism of action from all other alkylating agents.

The applicant provided additional explanation of GRAFAPEX™'s mechanism of action and chemical properties of the medication. The applicant stated that not all alkylating agents are prodrugs, and neither busulfan or melphalan are prodrugs. The applicant contrasted the mechanism of action of GRAFAPEX™ with cyclophosphamide, the only other alkylating agent used for alloHSCT conditioning that is also a prodrug, and stated that the mechanism of action for cyclophosphamide requires enzymatic breakdown by the liver to activate the drug. The applicant then stated that GRAFAPEX™'s mechanism of action is uniquely characterized by non-enzymatic bioactivation, which allows GRAFAPEX™ to bypass the liver when activating and producing its effect in the body, unlike other alkylating agents. The applicant asserted that GRAFAPEX™ being a prodrug and an agent that is non-enzymatically activated are especially important in the bone marrow transplant (BMT) space because the act of processing a drug in the liver increases the inflammatory milieu and predisposes patients to adverse events such as veno-occlusive disease and graft-versus-host disease. Additionally, the applicant stated these aspects result in spontaneous conversion under normal physiological conditions, such that it is activated in the blood, as opposed to requiring enzymatic activity in order to activate like other alkylating agents. The applicant added that cyclophosphamide specifically requires the enzyme P450 in order to activate, which is mostly located in the liver. The applicant further explained that other alkylating agents used in alloHSCT conditioning, such as busulfan and melphalan, also require enzymatic activation just as cyclophosphamide does. The applicant asserted that GRAFAPEX™'s uniquely non-enzymatic mechanism of activation is a distinct and critical aspect of its unique mechanism of action.

The applicant stated that the National Cancer Institute's definition of mechanism of action describes how a drug or other substance produces an effect in the body and, in certain cases, may help provide information about the safety of the drug and how it affects the body. The applicant stated that GRAFAPEX™'s unique mechanism of action also has the effect of reducing treatment-related toxicity compared to other alkylating agents used for alloHSCT conditioning. The applicant cited four publications to clarify GRAFAPEX's lower toxicity results from its distinct mechanism of action. The applicant stated that Romanski et al. (2018) noted the low organ toxicity of treosulfan-based conditioning compared with busulfan-based treatment and that the clinical exposure of the lungs and brain to the epoxide (the active form of GRAFAPEX™) was lower than to busulfan while the exposure to bone marrow was similar, indicating that the distinct non-enzymatic activation of GRAFAPEX™ is connected to the clinical observations that treosulfan-based conditioning regimens demonstrate lower hepato-, pulmo-, and neurotoxicity than busulfan-based conditioning regimens, but comparable myeloablation strength.[51] The applicant also stated Chichra et al. (2024) found that patients receiving a GRAFAPEX™-based regimen experienced fewer acute toxicities than the patients receiving a melphalan-based regimen and that severe mucositis and diarrhoea were significantly less frequent with GRAFAPEX™ than melphalan. The applicant cited Lorenzo et al. (2021) regarding the ability for successful pregnancy or fatherhood after alloHSCT with GRAFAPEX™ related to lower gonadal toxicity compared to other alkylating agents such as busulfan.[52] The applicant added that Scheulen et al. (2000) observed these types of differences between GRAFAPEX™ and other alkylating agents, noting that neither severe nephrotoxicity, bladder toxicity, cardiotoxicity, nor severe central nervous system toxicity that had been reported after high-dose treatments with other alkylators such as ifosfamide

[51] Michael Romanski et al., Treosulfan Pharmacokinetics and its Variability in Pediatric and Adult Patients Undergoing Conditioning Prior to Hematopoietic Stem Cell Transplantation: Current State of the Art, In-Depth Analysis, and Perspectives, 57 Clin. Pharmacokinet. 1255, 1255 (2018).

[52] Lorenzo Lazzari et al., Treosulfan-Based Conditioning Regimen Prior to Allogeneic Stem Cell Transplantation: Long-Term Results From a Phase 2 Clinical Trial, 11 Frontiers Oncology art. no. 731478, at 9 (2021); Rohtesh S. Mehta et al., Long-Term Outcomes and Quality of Life with Treosulfan-Based Conditioning in Hematological Malignancies, 9 Blood Advances 2691, 2693 (2025) (''Mehta et al. (2025)'') (''The 16 pregnancies observed in our cohort are encouraging, contrasting with the 4 reported pregnancies in a very large registry study following nonmyeloablative HCT.'').

or cyclophosphamide was evident after high-dose treosulfan.[53] The applicant also stated that Scheulen at al. (2000) discussed these differences in the context of GRAFAPEX™'s mechanism of action, stating that, in contrast to busulfan, high-dose treosulfan did not induce severe hepatotoxicity or veno-occlusive disease in the nine patients treated at or above MTD of 47 g/m2, and that this might be considered a consequence of the different mode of alkylation and the reliable i.v. infusion of high-dose treosulfan. The applicant asserted that these points confirm GRAFAPEX™'s unique mechanism of action and demonstrate that bypassing liver metabolism and allowing for delivery of the alkylating agent directly to the blood is a key aspect of GRAFAPEX™'s mechanism of action by reflecting and underscoring the distinct way that GRAFAPEX™ produces an effect in the body.

In response to CMS's note that MAC, NMA, and RIC are all options for patients with AML or MDS, the applicant stated that this does not reflect the clinical realities, individual patient circumstances, and complex balancing that physicians and patients must work through in treating these conditions. The applicant further stated that while some previously available regimens could be used in older and/or more comorbid patients, not all such patients could be treated with a previously available regimen, and GRAFAPEX™-based conditioning provides a new and critically important option for these patients. The applicant also stated that GRAFAPEX™ is the first and only FDA-approved allo-HSCT conditioning agent to treat patients with AML or MDS. The applicant further stated that, within the population of patients with AML or MDS, GRAFAPEX™ is specifically designed to be used in conditioning regimens for older and/or more comorbid patients who are ineligible for previously existing MAC regimens where RIC may be attempted, but results in compromised effectiveness. The applicant explained that, because of MAC regimens' high toxicity and RIC regimens' higher risk of relapse, and thus, lower effectiveness, many patients would be prevented from pursuing BMT. In addition, the applicant stated that in the absence of GRAFAPEX™ availability, there is a subset of patients who would be viewed as nonviable BMT candidates due to the lack of an appropriate conditioning regimen. The applicant added that many patients with MDS or AML who are older and/or have significant comorbidities are not referred to and do not undergo alloHSCT; but instead, only a highly select group of patients in this sub-population are viewed as viable candidates for this treatment. The applicant cited a review article in which the authors note that age alone was one of the most frequent barriers to BMT because of dated assumptions and bias against older patients, a lack of prospective studies in older adults, perceived higher risks versus benefits, current guidelines, higher levels of comorbidities, and a bias against HSCT as a modality in older adults among physicians.[54] The applicant asserted that GRAFAPEX™ provides an appropriate, and therefore, a critical new conditioning regimen for this subpopulation that can help address the previously observed resistance to providing BMT for these patients.

The applicant cited multiple studies that discuss the unmet need among older patients and/or those with significant comorbidities for alloHSCT. The applicant stated that GRAFAPEX™-based regimens are particularly well-suited and provide significant clinical benefits for this patient population. The applicant reiterated that Scott et al. (2017), submitted as part of its application, discusses how alloHSCT conditioning regimens available prior to FDA approval of GRAFAPEX™, are not suitable for all patients, especially older and/or more comorbid patients. The applicant also stated that published literature recognizes the limits of conventional MAC and RIC regimens. In addition, the applicant stated that multiple peer-reviewed studies submitted in its application confirm that GRAFAPEX™ is a critical novel regimen that addresses the unmet need for older and/or comorbid AML and MDS patients. The applicant also stated GRAFAPEX™-based conditioning uniquely provides a regimen with myeloablative-intensity combined with significantly lower toxicity, without an increase in mortality. The applicant asserted that GRAFAPEX™-based conditioning, thereby fuses RIC regimens' lower organ toxicities with MAC regimens' potent antileukemic properties, expanding the availability of myeloablative conditioning to a new patient population. The applicant reiterated results from Beelen et al. (2022), which per the applicant, demonstrates the superiority of GRAFAPEX™-based conditioning over busulfan-based conditioning in overall survival (OS), event-free survival (EFS), non-relapse mortality (NRM), and adverse events, such as GVHD in older and/or more comorbid patients who were ineligible for MAC. The applicant stated that the authors of the pivotal phase 3 clinical trial, Beelen et al. (2022), concluded that the treosulfan regimen appears particularly suitable for older AML and MDS patients.

In response to CMS's request for additional information regarding the cause of delay in commercial availability, the applicant reiterated that GRAFAPEX™ received FDA approval on January 21, 2025, and the first commercial sale of GRAFAPEX™ occurred on February 20, 2025. The applicant further explained that, in its new technology add-on payment application, it had estimated the amount of time (2 to 3 months) after FDA-approval required to bring GRAFAPEX™ to market, which included building inventory and stocking the third-party logistic wholesalers. The applicant stated that during the 1-month period prior to commercial availability, it undertook critical activities to ensure complete readiness across both product and services to support all stakeholders, which included: transfer of NDA ownership from Medac in Germany to the applicant in the U.S.; submission of required FDA filings; shipping the final drug product from its manufacturing site in Germany to the U.S., which required the product to be cleared by U.S. Customs and Border Protection; labeling and preparation of the product into approved packaging; conduction of batch record reviews; releasing the final product to the applicant's third-party logistics provider for distribution to the market; and ensuring that all wraparound services, such as pharmacovigilance program, medical affairs training and certification, and its patients services hub, were fully operational. The applicant asserted that the newness period for GRAFAPEX™ should begin on the date of commercial availability, February 20, 2025.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for GRAFAPEX™, we agree with the applicant that GRAFAPEX™ has a unique mechanism

[53] Max E. Scheulen et al., 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 Malignancy, 6 Clinical Cancer Research 4209, 4209 (2000).

[54] Colin Flannelly et al., Barriers to Hematopoietic Cell Transplantation for Adults in the United States: A Systematic Review with a Focus on Age, 26 Biol. Blood Marrow Transplant. 2335, 2341 (2020).

of action because it is the first and only FDA-approved allo-HSCT conditioning agent for patients with AML and MDS. Therefore, we agree with the applicant that GRAFAPEX™ is not substantially similar to existing treatment options and meets the newness criterion.

With regards to the commercial availability of GRAFAPEX™, as we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. Although the applicant stated in its public comment that GRAFAPEX™ became commercially available on February 20, 2025, the date of first sale, we note that we do not consider the date of first sale of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale (88 FR 58802). It is unclear from the information provided when the technology first became available for sale and, absent additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. Therefore, we consider the beginning of the newness period for GRAFAPEX™ to commence on January 21, 2025, when GRAFAPEX™ received FDA marketing authorization.

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 invited public comments on whether GRAFAPEX™ meets the cost criterion.

Comment: The applicant reiterated that the two cost criterion analyses submitted with its application demonstrate that GRAFAPEX™ meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both of the scenarios. Therefore, 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 alloHSCT 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-occulsive 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.[55] 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.

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Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available	

[55] Background articles are not included in the following table but can be accessed via the online posting for the technology.

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.*

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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 summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18121 through 18122).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18122 through 18123) that we had 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 noted 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 noted 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, we stated that 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 × 4 plus busulfan 3.2mg/kg × 2 plus total body irradiation 2Gy, and fludarabine plus melphalan 140mg/m2. We also noted that RIC and NMA are additional options for these patients. Therefore, we questioned 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 questioned 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 questioned whether differences in treatment guidelines and regimens between countries could affect generalizability to the Medicare population. Second, we noted 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 questioned 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 alloHSCT, 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 questioned whether these studies would be generalizable to the Medicare population due to the potential influence of confounding variables. We also noted 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 noted 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 noted 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, we stated that 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 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, we stated that 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 invited public comments on whether GRAFAPEX™ meets the substantial clinical improvement criterion.

Comment: A commenter stated its support for the approval of GRAFAPEX™'s new technology add-on payment application. The commenter stated their experience as a physician using GRAFAPEX™ with patients and added that GRAFAPEX™ is the first and only FDA-approved alloHSCT preparative regimen for AML and MDS. The commenter also stated that GRAFAPEX™ uniquely combines myeloablative-level intensity with lower toxicity, making GRAFAPEX™-based conditioning distinctly suitable for the AML or MDS patients who are older and/or have significant co-morbidities and would not be able to tolerate a higher-toxicity MAC regimen, but would have a significant risk of compromised outcomes with a lower-intensity RIC regimen. The commenter described their utilization of GRAFAPEX™ in their clinical practice and research, citing several studies [56] [57] where the commenter was a lead or co-author. In addition, the commenter cited the phase II clinical trial of GRAFAPEX™ conducted by Deeg et al. (2018) [58] and stated it found that GRAFAPEX™ results in minimal toxicity and very low NRM in a cohort of patients up to 70 years old, two-thirds with co-morbidity scores of 3 or higher, patients with a history of prior allo-HSCT, and patients previously treated with cytotoxic therapy for malignancies preceding AML or MDS/CMML. The commenter further stated that GRAFAPEX™ is distinct among alloHSCT conditioning agents due to its unique combination of myeloablative-level intensity with notably lower toxicity, providing an important new tool for patients who are older and/or have significant comorbidities.

Response: We thank the commenter for its input and have taken it into consideration in determining whether GRAFAPEX™ meets the substantial clinical improvement criterion as discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant stated that GRAFAPEX™ represents a substantial clinical improvement over previously existing therapy options because GRAFAPEX™ offers an alloHSCT conditioning treatment option for older and/or more comorbid patients who have AML or MDS, who are ineligible for previously available MAC regimens. In addition, the applicant asserted that GRAFAPEX™-based conditioning has shown superior outcomes for EFS, OS, NRM, and significant reductions in several adverse events. Further, the applicant stated that clinical tradeoffs in RIC regimens include compromised effectiveness, increased risk of relapse, and additional negative side effects. The applicant asserted that GRAFAPEX™ offers a conditioning regimen for older and/or more comorbid patients with MAC-level intensity without the increased relapse risk of RIC for those that cannot tolerate MAC-level conditioning from a toxicity perspective. The applicant also asserted that its application, Town Hall presentation, and Town Hall comment discuss in detail evidence demonstrating GRAFAPEX's unique clinical benefits and significant clinical improvement for older and/or more comorbid populations with AML or MDS compared to a wide range of many previously available regimens, including conventional MAC regimens, RIC or NMA regimens, and other regimens that potentially could be described as ''reduced toxicity conditioning'' or ''RTC'' regimens.

In response to CMS's note that RIC and NMA are options for older and/or more comorbid patients, the applicant

[56] Filippo Milano et al., Treosulfan-based conditioning is feasible and effective for cord blood recipients: a phase 2 multicenter study, 4 Blood Advances 3302, 3308 (2020).

[57] Mehta RS, Lee SJ, Gooley TA, Thur L, Dahlberg A, Delaney C, Gyurkocza B, Vo PT, Deeg HJ, Milano F. Long-Term Outcomes and Quality of Life with Treosulfan-Based Conditioning in Hematological.

[58] H. Joachim Deeg et al., Transplant Conditioning with Treosulfan/Fludarabine with or without Total Body Irradiation: A Randomized Phase II Trial in Patients with Myelodysplastic Syndrome and Acute Myeloid Leukemia, 24 Biology Blood & Marrow Transplantation 956, 962 (2018).

stated that is not necessarily true for all patients, and the clinical consequences of RIC regimens should be taken into account, namely that such regimens involve reduced treatment intensity leading to higher rates of relapse and other adverse effects. The applicant further stated that GRAFAPEX™ provides a critical treatment option for the set of older and/or more comorbid AML or MDS patients who otherwise would not be candidates for BMT due to the lack of a suitable conditioning regimen. The applicant stated that Scott et al. (2017) concluded that MAC is superior to RIC when patients can tolerate the regimen due to RIC's substantially higher relapse rate with only a modest decrease in transplant-related mortality (TRM). The applicant stated that prior to the availability of GRAFAPEX™, patients would have either no option at all or, in an effort to do something to treat their life-threatening conditions, would be faced with no choice other than RIC and its significantly increased risk of relapse and additional negative side effects. The applicant added that Beelen et al (2022) concluded that the GRAFAPEX™-based conditioning regimen led to superior outcomes after alloHSCT compared with the reference RIC busulfan regimen, thereby appearing particularly suitable for older AML and MDS transplantation candidates. In addition, the applicant stated that other studies, such as Wedge et al. (2020) and Pasic et al. (2024), that have similarly focused on patients ineligible for conventional MAC regimens, have also confirmed the Beelen et al. (2022) results. Specifically, the applicant highlighted that Wedge et al. (2020), which studied mostly MDS patients, found similar overall survival among GRAFAPEX™, standard myeloablative conditioning (SMA), and NMA regimens with GRAFAPEX™ having lower rates of chronic GVHD and similar rates of acute GVHD compared to both SMA and NMA. The applicant also stated that Pasic et al. (2024) found significantly higher overall and event-free survival with GRAFAPEX™ compared to RIC and Nagler et al. (2017) found a relative lack of adverse effects in patients treated with a GRAFAPEX™-based conditioning regimen.

In response to CMS's concern regarding the higher rate of relapse with GRAFAPEX™-based conditioning regimens compared to RIC in Fraccaroli et al. (2024) and Bug et al. (2023), the applicant asserted that the isolated results of overall relapse in these two studies do not reflect the totality of evidence submitted within its application or the overall weight of the data. The applicant stated that this type of isolated analysis fails to acknowledge the positive outcomes reflected in these two studies. The applicant further stated that, in terms of overall relapse, the Fraccaroli et al. (2024) and Bug et al. (2023) results are outliers compared to the multiple additional peer-reviewed, published studies that it provided in its new technology add-on payment application. The applicant asserted that the nature of clinical research is such that results are not always uniform across all studies for every single outcome measure and that they submitted multiple studies for this reason, and state that CMS has noted that it evaluates the new technology add-on payment ''substantial clinical improvement'' criterion based on a ''totality of circumstances'' analysis, and the body of literature presented in their application and their comments reflects a totality of circumstances based on more than ten peer-reviewed published studies showing strong evidence and trends of superiority in key clinical outcomes including EFS, OS, and NRM for GRAFAPEX™-based regimens compared to many other existing conditioning regimens. In addition, the applicant reiterated the Bug et al. (2023) and Fraccaroli et al. (2024) studies' results regarding NRM and stated that NRM is an especially significant outcome measure for older patients and/or those with significant comorbidities, an important subpopulation for Medicare, who may be considered for BMT because they face particularly significant risk of treatment-related mortality.

In response to CMS's questions regarding the submitted studies' generalizability to the Medicare population, the applicant stated the cited literature includes significant percentages and numbers of Medicare-eligible patients which demonstrates the extensive study of treatment with GRAFAPEX-based conditioning in patients who are older and/or have significant comorbidities or disabilities, as is typically reflective of the majority of Medicare beneficiaries. The applicant highlighted several examples of additional peer-reviewed literature which demonstrate that GRAFAPEX™ has been used and studied specifically in U.S. populations, in addition to the Canadian and European cohorts, and stated that these articles indicate positive results with GRAFAPEX-based conditioning that are consistent with the studies previously submitted.[59] [60] [61] [62] The applicant stated that the multiple studies it provided with Canadian and European patient populations are also generalizable to the Medicare population, as clinical guidelines in these countries do not vary in meaningful ways from U.S. clinical guidelines in this area, and there is no evidence indicating that patients' experiences of AML or MDS or responses to conditioning regimens vary depending on the country where they are located. Additionally, the applicant stated that clinical guidelines and treatment practices for older patients with AML or MDS are similar throughout the developed world, including Europe, Canada, and the United States, with data used across the globe to develop treatment recommendations. The applicant also stated that both European and U.S. BMT clinical guidelines include and describe GRAFAPEX™ as a myeloablative conditioning treatment option.

In response to CMS's question whether the age of patients in the studies submitted are generalizable to the Medicare population, the applicant stated that its application and this submitted comment included multiple peer-reviewed published studies that enrolled significant percentages and numbers of both older patients and patients with disabilities and significant comorbidities. The applicant asserted that the patients in its submitted studies are highly generalizable to the Medicare population, which includes not only individuals age 65 or older but also patients with significant comorbidities and disabilities. The applicant summarized the patient demographics of seven studies in its application that included those over 65 years of age and more comorbid participants.[62] [63] [64] [65] [66] [67] [68] [69] The applicant reiterated that there is a subpopulation of AML or MDS patients who are older and/or have significant comorbidities and who, prior to the availability of GRAFAPEX™, were not considered candidates for BMT because their treatment teams concluded there was no appropriate conditioning regimen available. In addition, the

[59] Eneida R. Nemecek et al., Conditioning with treosulfan and fludarabine followed by allogeneic hematopoietic cell transplantation for high-risk hematologic malignancies, 17 Biology Blood & Marrow Transplantation 341 (2011).

[60] Deeg, 2018, op. cit.

[61] Filipino, 2020, op. cit.

[62] Mehta, 2025, op. cit.

[63] Beelen, 2022, op. cit.

[64] Shimoni, 2021, op cit.

[65] Bug, 2023, op. cit.

[66] Pasic, 2024, op cit.

[67] Fraccaroli, 2024, op. cit.

[68] Wedge, 2020, op. cit.

[69] Gavriilaki, 2023, op. cit.

applicant stated that AML and MDS are diseases that primarily affect older patient populations, with a median age at diagnosis 69 and 70 years, respectively. The applicant concluded by noting that GRAFAPEX™'s pivotal clinical trial observed no significant differences in safety or effectiveness between subjects age 65 or older and younger subjects.

In response to CMS's question about small sample sizes in two submitted studies and generalizability to the Medicare population, the applicant stated that it is important to place these 2 studies in the broader context of all the studies it submitted in its application and comments, including more than 10 published peer-reviewed studies in which GRAFAPEX™ was used to treat patients, representing hundreds of patients with consistent trends in key results. The applicant added that totaling the participants of all its submitted studies accounts for more than 3,000 patients, of which over 1,200 received treatment with GRAFAPEX™. The applicant emphasized that these studies also included significant numbers of patients 65 years or older and/or patients with significant comorbidities and disabilities, who are highly generalizable to the Medicare population. In addition, the applicant stated that several of the studies provided had significantly larger patient populations, and while the Chichra et al. (2023) and Fraccaroli et al. (2024) had small sample sizes compared to other submitted studies, they provide helpful confirmatory results comparing GRAFAPEX™-based conditioning regimens to other available regimens. The applicant also stated that these two studies focused on the specific patient population and sub-population of interest, contributing to the totality of circumstances in demonstrating GRAFAPEX™'s significant clinical value. In addition, the applicant stated that AML and MDS are life-threatening and relatively rare conditions, and that FDA granted GRAFAPEX™ orphan drug designation in April 2015. The applicant asserted that notwithstanding the realities and challenges of rare diseases, it believes that the totality of data and evidence submitted provides a robust set of peer-reviewed, published literature demonstrating GRAFAPEX™'s significant clinical benefits for AML or MDS patients.

In response to CMS's concern about the Beelen et al. (2024) study's missing data, the applicant stated it is unclear what significance this missing data has to the GRAFAPEX™ results, since it was data for the comparator arms. The applicant asserted that it seems one would have to assume that all missing data was positive for the comparators in order to undermine the results with respect to GRAFAPEX™. The applicant further stated that Beelen et al. (2022) and other submitted studies in its application do not have missing data and demonstrate that GRAFAPEX™-based conditioning demonstrates superior EFS, OS, and NRM compared to previously available conditioning regimens.

The applicant asserted that the overwhelming majority of results and prominent trends of GRAFAPEX™ reflected in the peer-reviewed published literature demonstrate superior outcomes in EFS, OS, and NRM compared to a wide range of other available conditioning regimens, despite isolated outcome measures from certain individual studies. In response to CMS's concern regarding some conflicting outcome results, the applicant stated that the nature of different studies and comparator regimens is that specific data points and outcome measures are not always fully and uniformly consistent with respect to each individual metric across all studies. The applicant further stated that it provided a large body of evidence to present a fulsome picture of GRAFAPEX™'s substantial clinical benefits compared to several other existing conditioning regimens, including conventional MAC, RIC/NMA, and other conditioning regimens that could be described as ''reduced toxicity conditioning'' or ''RTC'' regimens. The applicant stated that the proposed rule did not identify concerns regarding the provided studies that show GRAFAPEX™'s superior EFS.

The applicant reiterated its belief that GRAFAPEX™-based conditioning has shown superior outcomes for EFS, OS, and NRM as well as significant reductions in several adverse events compared to other agents and regimens used in allo-HSCT conditioning. The applicant stated that the randomized, controlled Beelen et al. (2022) clinical trial demonstrated GRAFAPEX™'s superiority in EFS, OS, and NRM compared to busulfan-based conditioning. The applicant further stated that Beelen et al. (2024) replicated these results in GRAFAPEX™-treated patients compared to registries of melphalan- and busulfan-treated patients.

The applicant asserted the overall body of evidence demonstrates that physicians and researchers consistently turn to GRAFAPEX™ for older and/or more comorbid patients, and that GRAFAPEX™ results for NRM and OS are favorable in this patient population. The applicant reiterated the Shimoni et al. (2021) study's results and highlighted that the median age for patients who received a MAC regimen was 8 years younger than those who received GRAFAPEX™-based conditioning. The applicant stated that because clinicians often administer GRAFAPEX™ to older and/or more comorbid patients, when a retrospective cohort demonstrates similar results for GRAFAPEX™ and other treatments, it may at least be in part due to the GRAFAPEX™ cohort's older age and increase in comorbidities. In response to CMS's concern regarding similar OS between GRAFAPEX™-based regimens and RIC in certain studies, the applicant asserted that the selective focus on a single metric in the Bug et al. (2023), Chichra et al. (2024), and Fraccaroli et al. (2024) studies does not account for the multiple other submitted studies in its application in which GRAFAPEX™ demonstrated significantly improved, and even superior, OS compared to other conditioning regimens. The applicant further stated that this focus fails to account for GRAFAPEX™'s superior NRM results in the Fraccaroli et al. (2024) study, significantly improved NRM in the Bug et al. (2023) study, and fewer acute toxicities and infections in the Chichra et al. (2024) study. In addition, the applicant stated that the Chichra et al. (2024) study also highlighted GRAFAPEX™'s reduced hospital LOS compared to the melphalan-based regimen.

In response to CMS's concern regarding GRAFAPEX™'s similar NRM rate compared to other technologies in some studies, the applicant again stated that this isolated analysis fails to account for these studies' positive results as well as other studies in which GRAFAPEX™ showed significantly improved or superior NRM compared to other conditioning regimens. The applicant reiterated results from Chichra et al. (2024), Gavriilaki et al. (2023), Shimoni et al. (2021), and Wedge et al. (2020).

In response to CMS's concern that some studies showed some differences in the rate of adverse effects between the GRAFAPEX™-based regimen and comparators, the applicant asserted that this analysis does not assess or account for the overall body of data and totality of circumstances reflected in its provided studies and fails to account for the positive results for GRAFAPEX-based conditioning in the noted studies. The applicant reiterated the results of studies submitted with its new technology add-on payment application. The applicant also stated that other peer-reviewed publications have

similarly recognized GRAFAPEX™'s low organ toxicity, which multiple publications have attributed to the technology's unique mechanism of action. Specifically, the applicant stated that GRAFAPEX™'s distinct non-enzymatic activation targets the drug to the bone marrow and blood, sparing organs like the brain, lungs, and liver and helps account for the clinically observed lower hepato-, pulmo-, and neurotoxicity compared to busulfan-based conditioning regimens.

The applicant concluded by emphasizing that a one-study-at-a-time, one-metric-at-a-time type of analysis does not account for the overall thrust of the complete body of data and the significant, consistent trends it demonstrates. The applicant urged CMS to evaluate the body of peer-reviewed published literature with an eye toward the overall picture it presents, which it stated overwhelmingly demonstrates that GRAFAPEX-based conditioning has shown superior outcomes for EFS, OS, and NRM and significant reductions in several adverse events compared to other existing conditioning regimens.

Response: We thank the applicant and other commenter for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree with the applicant and commenter that GRAFAPEX™ represents a substantial clinical improvement over existing technologies because GRAFAPEX™ improves overall survival with similar or lower frequencies of clinically significant adverse events compared to existing treatments for allo-HSCT conditioning in patients with AML or MDS who are ineligible for MAC.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that GRAFAPEX™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2026. Cases involving the use of GRAFAPEX™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes XW03388 (Introduction of treosulfan into peripheral vein, percutaneous approach, new technology group 8) or XW04388 (Introduction of treosulfan into central vein, percutaneous approach, new technology group 8).

In its application, the applicant stated that the anticipated cost of GRAFAPEX™ is $610 for a 1 g vial and $3,050 for a 5 g vial. Per the applicant, based on the recommended dose (10g/m^2) and estimated average body size for Medicare patients being treated, 18 g of GRAFAPEX™ per treatment (three 1 g vials and three 5 g vials) is required for each day of a three-day course of treatment, totaling an average dose per inpatient stay of 54 g. Therefore, the applicant estimated that the average cost for GRAFAPEX™ is $32,940 per inpatient stay. 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, the maximum new technology add-on payment for a case involving the use of GRAFAPEX™ is $21,411 for FY 2026.

g. 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 stated 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.

The applicant submitted a request for unique ICD–10–PCS procedure codes for IMDELLTRA® and was granted approval for use of the following procedure codes effective October 1, 2025: XW033NA (Introduction of tarlatamab-dlle antineoplastic into peripheral vein, percutaneous approach, new technology group 10) and XW043NA (Introduction of tarlatamab-dlle antineoplastic into central vein, percutaneous approach, new technology group 10). 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.

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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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18124), we noted 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 stated our belief 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 questioned the applicant's assertion that IMDELLTRA® treats a unique patient population compared to existing technology.

We invited public comments on whether IMDELLTRA® is substantially similar to existing technologies and whether IMDELLTRA® meets the newness criterion.

Comment: The applicant submitted a public comment reiterating that IMDELLTRA® meets the newness criterion because it is the first and only approved BiTE® molecule that binds the

antigen DLL3 expressed on the surface of SCLC cells and CD3 expressed on the surface of T cells causing T-cell activation, release of inflammatory cytokines, and lysis of DLL3-expressing cells for the treatment of 2L+ ES–SCLC, and IMDELLTRA® has a unique mechanism of action as the only BiTE® molecule approved for ES–SCLC. The applicant stated its continued belief that IMDELLTRA® treats a unique patient population and reiterated information presented in its application about limited research regarding outcomes of SCLC patients with treated, stable brain metastases treated with existing chemotherapy, like lurbinectedin and topotecan. The applicant also stated that, while some studies have been conducted on topotecan and SCLC patients with brain metastases, topotecan had an ORR of 10.5 percent in a Phase 2 trial, which is empirically lower than IMDELLTRA®'s reported 40 percent ORR in the phase 2 DeLLphi-301 trial. The applicant provided new evidence from the Phase 3 randomized controlled DeLLphi-304 study, which the applicant stated demonstrated a survival benefit in patients with brain metastases (untreated or treated, stable) treated with IMDELLTRA® as compared to standard of care chemotherapy.[70] The applicant stated that although other existing FDA-approved treatments for ES–SCLC may be prescribed in the real world for SCLC patients with brain metastases, given the high unmet need, these existing treatments do not have a randomized controlled Phase 3 trial demonstrating efficacy over the current standard of care. The applicant further stated that IMDELLTRA® does not treat the same or similar disease and same or similar patient population because it is the only FDA-approved treatment option for ES–SCLC patients with or without brain metastases who have progressed after initial platinum-based chemotherapy that has demonstrated improved survival outcomes.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for IMDELLTRA®, we agree with the applicant that IMDELLTRA® uses a unique mechanism of action because it is the only BiTE® therapy targeting DLL3 for the treatment of adult patients with ES–SCLC with disease progression on or after platinum-based chemotherapy. Therefore, we agree with the applicant that IMDELLTRA® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on May 16, 2024, the date on which IMDELLTRA® was FDA approved.

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.

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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.
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

[70] Mountzios G, Sun L, Cho BC, et al. Tarlatamab in small-cell lung cancer after platinum-based chemotherapy. N Engl J Med (published online ahead of print June 2, 2025). DOI:10.1056/NEJMoa2502099.

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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 invited public comments on whether IMDELLTRA® meets the cost criterion.

Comment: The applicant reiterated that IMDELLTRA® satisfies the cost criterion because the standardized charge per case exceeds the threshold for the cost criterion. The applicant also commented that a maximum new technology add-on payment amount for IMDELLTRA® should be calculated based on an average inpatient dose of 7.3 mg.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under both scenarios. Therefore, 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.[71] 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.

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[71] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.
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.

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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 summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18126 through 18127).

We stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18127 through 18128) that, after review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we had 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, we stated it was 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 noted that having limited treatment options does not demonstrate that these patients are unresponsive to 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 noted that retreatment with platinum-based chemotherapy was considered an additional line of therapy per the study. Therefore, it was unclear that the study demonstrated that patients had failed existing 2L+ treatments, including lurbinectedin and topotecan. For these reasons, we questioned 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 noted 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, we stated that 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 questioned 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.[72] However, we noted 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 questioned whether differences in treatment guidelines between countries could affect generalizability to the Medicare population. We also noted 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,[73] which are recommended as part of the initial therapy for ES–SCLC, and we therefore questioned 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 noted 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 stated that we did 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, we stated that 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.[74] The applicant also noted that lurbinectedin can be used as a 3L agent, but mOS was 5.6 months according to real world data.[75] 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,[76] with an mOS of 15.2 months after extended follow-up.[77] 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.[78] The applicant stated the registrational study for topotecan included patients with brain metastases and reported a mOS of only 5.8 months,[79] 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.[80] However, we noted 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 questioned 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®,[81] and compared it to lurbinectedin's mOS of 5.6 months according to real world

[72] Anh, 2023, *op. cit.*

[73] Anh, 2023, *op. cit.*

[74] Coutinho, 2019, *op. cit.*

[75] Desai, 2023, *op. cit.*

[76] Ahn, 2023, *op. cit.*

[77] Sands, 2024, *op. cit.*

[78] Dingemans, 2024, *op. cit.*

[79] von Pawel, 1999, *op. cit.*

[80] Desai, 2023, *op. cit.*

[81] Ahn, 2023, *op. cit.*

data,[82] but we questioned whether it is appropriate to compare clinical trial and real-world data. We noted, 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 questioned 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 [83] and 54.5 percent in patients with stable brain metastases [84]) 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 questioned the applicant's assertion of improved clinical outcomes for IMDELLTRA® compared to previously available therapy.

We stated we agreed with the applicant that head-to-head trials, while preferred, are not required for comparing currently available therapy. However, we noted 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 noted 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 noted 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 questioned 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 noted 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.

We stated that 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 noted 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 invited public comments on whether IMDELLTRA® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. 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, and that when survival is measured in months, it is clear patients need access to new, more efficacious treatments. The applicant commented that the evidence it previously submitted support that IMDELLTRA® satisfies the substantial clinical improvement criterion, and further stated that additional evidence and publications have become available, reinforcing that IMDELLTRA® is a substantial clinical improvement compared to prior therapy, with IMDELLTRA® representing the first FDA-approved therapy to demonstrate a substantial survival advantage over chemotherapy in 2L SCLC in a Phase 3 study. The applicant stated this new evidence unequivocally shows that IMDELLTRA® is a substantial clinical improvement for 2L+ ES–SCLC patients because it demonstrates that IMDELLTRA® provides statistically significant and clinically meaningful improvement in OS compared to other 2L+ approved therapies. Per the applicant, the new evidence includes results from the DeLLphi-304 trial, as well as an indirect treatment comparison (ITC) assessing the relative efficacy of IMDELLTRA® versus real-world U.S. physicians' choice of therapies in 3L+ ES–SCLC patients.[85]

Per the applicant, the DeLLphi-304 trial was a randomized, open-label, multicenter, global, Phase 3 trial of 509 patients that compared IMDELLTRA® (n=254) to standard of care chemotherapy (n=255) in patients with relapsed SCLC after platinum-based 1L chemotherapy. The applicant stated that standard of care chemotherapy was either topotecan, amrubicin, or lurbinectedin; the primary endpoint was OS; key secondary endpoints were PFS and patient-reported outcomes (PRO); and additional secondary endpoints included ORR, disease control, DOR, and safety. Per the applicant, the median age was 65. The applicant further stated that 45 percent of patients had brain metastases (current or prior), 35 percent had liver metastases at baseline, 71 percent received prior PD–L1 inhibitor therapy, and 44 percent had platinum-resistant disease. Per the applicant, the results demonstrated a higher, more durable anticancer activity for IMDELLTRA® compared to chemotherapy. Specifically, the applicant stated that IMDELLTRA® resulted in significantly longer OS compared to chemotherapy (median, 13.6 months vs. 8.3 months; [HR 0.60, 95% CI, 0.47 to 0.77; p<0.001]), significantly improved PFS (median, 4.2 months vs. 3.7 months [piecewise weighted average HR: 0.71; 95% CI: 0.59, 0.86; P < 0.002, restricted mean survival time (RMST) for PFS), improved ORR (35% vs. 20% [OR 2.13; 95% CI 1.43–3.18]), and a positive benefit:risk profile versus chemotherapy, with chemotherapy resulting in more frequent and high-grade adverse events. The applicant noted Kaplan-Meier estimates for 6-month and 12-month PFS were 30 percent and 20 percent, respectively, in the IMDELLTRA® group, compared with 23 percent and 4 percent in the chemotherapy group. In addition, the applicant stated that approximately 47 percent of responders remained on study without progression or death in the IMDELLTRA® group as compared to 15 percent in the chemotherapy group at the interim analysis; the median DOR was 6.9 months with IMDELLTRA® and 5.5 months with chemotherapy; and the Kaplan-Meier estimate of 12-month DOR was 41 percent with IMDELLTRA® and 13 percent with chemotherapy. The applicant stated that IMDELLTRA® improved PROs with statistically significant and clinically meaningful improvements over chemotherapy in

[82] Desai, 2023, *op. cit.*

[83] Ahn, 2023, *op. cit.*

[84] Dingemans, 2024, *op. cit.*

[85] Tapan U, Takundwa R, et al. (2025, March 26–29). A comparison of tarlatamab with real-world physicians' choice of therapies in patients with previously treated small cell lung cancer [Poster Presentation]. European Lung Cancer Conference, Paris, France.

dyspnea and cough after 18 weeks from baseline in DeLLphi-304, and that changes in chest pain were not statistically significant.

The applicant stated that the ITC, which was recently conducted by Tapan et al. (2025), assessed the relative efficacy of IMDELLTRA® versus real-world physicians' choice of therapies, including lurbinectedin and topotecan, in patients with previously treated ES–SCLC. The applicant stated that the ITC analysis used data from DeLLphi-301 and comparator data from the Flatiron Health Research database, which the applicant stated is a trusted real-world evidence source known for its high-quality, longitudinal, clinical information. The applicant also stated that patients included in the external control cohort from this database were treated with a variety of chemotherapies and/or immunotherapies, including lurbinectedin (18 percent), topotecan (15 percent), nivolumab (13 percent), paclitaxel (8 percent), pembrolizumab (7 percent), nivolumab + ipilimumab (5 percent), and others (34 percent). In addition, the applicant stated that the study employed best practices to enhance the reliability of the ITC assessment of treatment effects for IMDELLTRA® versus comparator regimens. To perform the ITC between balanced patient populations, the applicant stated that the study applied the DeLLphi-301 inclusion/exclusion criteria to the Flatiron Health data and adjusted for differences in a comprehensive list of key prognostic factors. The applicant further stated that E-values for hazard ratios (HRs) were estimated, ranging from 2.15 to 2.86, which suggested low likelihood of bias from potential unmeasured confounding variables.

The applicant stated that the ITC analysis demonstrated significantly longer OS, PFS, and a higher ORR for IMDELLTRA® versus comparator therapies after propensity score (PS) weighting was applied to balance baseline patient characteristics between cohorts. Per the applicant, the mOS was 15.2 months (95% CI: [10.8, NE]) in DeLLphi-301, which the applicant noted represents more than a two-fold increase in survival versus comparator regimens that had a mOS of 6.0 months (95% CI: [5.0, 7.1]) after adjusting for prognostic factors. The applicant stated the hazard ratio (HR) [95% CI] for OS was significantly in favor of IMDELLTRA® over comparator regimens at 0.45 (95% CI: [0.30, 0.68], p<0.001). The applicant stated that patients were free of progression for an extended period in the IMDELLTRA® cohort (mPFS: 4.9 months [2.9, 6.7]) compared to the comparator regimens cohort (mPFS: 3.1 [2.3, 3.7], after weighting) with a HR of 0.61 (95% CI: [0.43, 0.90], p=0.009). Additionally, the applicant noted significantly more patients treated with IMDELLTRA achieved ORR (40 percent) compared with patients receiving comparator regimens (19 percent, after weighting) and the odds of achieving ORR were 2.80 (95% CI: [1.44, 5.83], p=0.004) times higher for IMDELLTRA® versus comparator regimens. Per the applicant, the results for the prespecified sensitivity analyses (intended to examine impact on ITCs with different approaches to define real-world progression, to adjust for imbalances on more baseline variables, and to account for globally available regimens) were consistent or near identical to the primary analysis. The applicant also stated that this consistency across the primary and sensitivity analyses reinforces the robustness of the clinical benefit that IMDELLTRA® may offer over comparator regimens.

In response to CMS's concern about how IMDELLTRA™ demonstrates improved clinical outcomes relative to other current therapies without providing relapse rates or comparing outcome data, the applicant stated that IMDELLTRA® improves survival outcomes compared to previously available treatments. Specifically, the applicant stated that in SCLC, PFS is generally evaluated instead of relapse free survival, which is more commonly used in hematology oncology, and the PFS for lurbinectedin and topotecan may depend on whether there are CNS metastases, although such a difference has not been observed for IMDELLTRA®'s PFS benefit in DeLLphi-301 and DeLLphi-304. The applicant restated information from its application from the Desai et al. (2023) analyses. The applicant further stated that DeLLphi-304 demonstrated a significant PFS benefit with a 4.2 months median PFS with IMDELLTRA® and a 3.7 months median PFS with chemotherapy (piecewise weighted average HR: 0.71; 95% CI: 0.59, 0.86; P < 0.002, RMST for PFS). In addition, the applicant stated the Kaplan–Meier estimates for 6-months and 12-months PFS were 31 percent and 20 percent, respectively, in the IMDELLTRA® group, compared with 23 percent and 4 percent in the chemotherapy group. The applicant also stated that the chemotherapy group included patients on topotecan and lurbinectedin and DeLLphi-304 overall included patients with treated, stable brain metastases and untreated, asymptomatic brain metastases. Per the applicant, a subgroup comparison reported hazard ratios of PFS between IMDELLTRA® versus topotecan/amrubicin of 0.76 (95% CI: 0.62, 0.94) and versus lurbinectedin of 0.56 (95% CI: 0.34, 0.90). Additionally, the applicant stated that among responders, the DOR at 12 months was 41 percent for IMDELLTRA® and 13 percent for standard of care chemotherapies, reaffirming the substantial improvements of IMDELLTRA® in delaying progression compared to chemotherapies such as topotecan and lurbinectedin. Per the applicant, IMDELLTRA® has a significantly more durable anticancer response compared to chemotherapy treatments like lurbinectedin and topotecan, supporting that IMDELLTRA® substantially improves outcomes over previously available treatments for ES–SCLC.

In response to CMS's question about the use of OS and PFS to support improved clinical outcomes in a single-arm study, the applicant stated that DeLLphi-304 is the Phase 3 confirmatory trial needed to confirm superior survival benefit over previously available treatments. Per the applicant, the Phase 2 DeLLphi-301 OS and PFS data is very similar to that reported in the Phase 3 DeLLphi-304 trial with significantly improved OS and PFS, validating the claim that Phase 2 data represent an improved clinical outcome with IMDELLTRA® compared to previously available treatments. The applicant reiterated that based on this Phase 2 data, 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 response to CMS's questions about the generalizability of DeLLphi-301 trial data because 14 of the 134 patients treated with the target dose of IMDELLTRA® were from North America (without further specification on the country) and whether differences in treatment guidelines between countries could affect generalizability to the Medicare population, the applicant stated that IMDELLTRA®'s clinical trial data is generalizable to the Medicare population. The applicant stated it was a global multicenter trial with representation from Asia, Europe, and North America; the only trial sites in North America were in the United States; and approximately 48 percent of patients were age 65 years or older. The applicant stated that, similarly, the new DeLLphi-304 data also is generalizable to a Medicare population because the

median age is 65 years. The applicant further stated that real world survival outcomes in 2L+ ES–SCLC do not vary widely among the clinical trial regions of Asia, Europe, and North America, where the main previously available treatment options are chemotherapies like topotecan, amrubicin, irinotecan, taxanes, and lurbinectedin. The applicant also stated that standard of care therapies in these regions show consistently poor outcomes similar to the U.S. population following initiation of 2L and 3L therapy in ES–SCLC patients based on analyses of real-world treatment patterns and outcomes.

In response to CMS's questions about the small sizes of the real-world data that may limit the generalizability of these results to the Medicare population, the applicant stated that Phase 2 clinical trials examine efficacy in a specific patient population and are characterized by relatively small sample sizes of generally 50 to 200 patients. Furthermore, the applicant stated that SCLC is an orphan patient population (only 30,000 to 35,000 new cases diagnosed in the U.S. each year, of which approximately two-thirds are ES–SCLC), and thus trial size is limited by necessity. Per the applicant, as discussed previously, the FDA extrapolated clinical benefit out of the IMDELLTRA® Phase 2 DeLLphi-301 clinical trial, awarded the product Breakthrough Therapy Designation, and approved the product under Accelerated Approval. The applicant further stated that, in DeLLphi-304, the OS benefit with IMDELLTRA® versus chemotherapy was consistent across prespecified patient subgroups, including the 44 percent of patients with brain metastases that received IMDELLTRA® (asymptomatic, untreated or treated). Furthermore, the applicant stated that, given that the median age of the DeLLphi-304 patients was 65 years, it believes that the Phase 3 outcomes are generalizable to the Medicare population and sufficient to determine that IMDELLTRA® represents a substantial clinical improvement in the Medicare population.

In response to CMS's question about whether the results of DeLLphi-301 were different between the group of patients who previously received PD–L1 or PD–1 inhibitors versus those who did not, the applicant stated that IMDELLTRA®'s substantial clinical improvement is consistent regardless of prior PD–L1 therapy. The applicant further stated that DeLLphi-301 reported near identical ORR between the patients with prior PD–L1 and without prior PD–L1. The applicant stated that, in the supplement of Ahn et al. (2023), IMDELLTRA®'s ORR is 39.7 percent for patients previously exposed to PD–L1 therapy versus 40.7 percent for patients without prior PD–L1 exposure. Per the applicant, consistent with the DeLLphi-301 data, DeLLphi-304 also demonstrated a comparable overall survival benefit in patients both with (HR 0.61; 95% CI 0.45–0.82) and without (HR 0.65, 95% CI 0.42–1.03) prior PD–L1 inhibitor treatment, compared to standard of care chemotherapy.

In response to CMS's concern that the Sands et al. (2024) and Dingemans et al. (2024) evidence did not provide full detail on their study methods and therefore did not have sufficient information to evaluate these studies, the applicant stated that, as summarized in its application, Sands et al. (2024) presented efficacy and safety outcomes from a longer follow-up of the DeLLphi-301 study at the 2024 World Conference on Lung Cancer, while Dingemans et al. (2024) is an abstract of a post-hoc analysis of DeLLphi-301. Per the applicant, since both stem from the primary DeLLphi-301 study, the statistical methods are the same and the full protocol is available in the supplement to the New England Journal Medicine article.

In response to CMS's question about whether it was appropriate to compare clinical trial and real-world data, the applicant stated that comparisons to previously available therapies are limited by available evidence. The applicant further stated that its application provided literature ranging from clinical trials, real-world analyses, guidelines, to evidence reviews as treatment advancements for ES–SCLC patients have come slowly in the decades preceding IMDELLTRA®'s FDA approval. The applicant stated that it provided the clinical trial evidence that supported the FDA approvals of topotecan, lurbinectedin and IMDELLTRA® as well as multiple real-world analyses. The applicant stated that, for example, Trigo et al. (2020) reported on the pivotal single arm Phase 2 trial that was the basis for lurbinectedin's approval in 2L ES–SCLC. The applicant further stated in response to CMS's note that lurbinectedin demonstrated an OS of 9.3 months in the single arm trial, that it also provided the randomized controlled Phase 3 ATLANTIS trial where lurbinectedin failed to reach its primary endpoint of OS. In response to CMS's question about how the applicant chose the historical control it used in comparing outcomes, the applicant stated that it recognized the challenges and limitations with comparing separate trials. Per the applicant, this is why, in addition to each therapy's pivotal clinical trial data, it provided more recent evidence in the form of real-world data since topotecan's FDA approval for SCLC was in 1998. The applicant stated that the new ITC analysis from Tapan et al. (2025) as well as the new DeLLphi-304 data confirm what prior literature suggested, which is that IMDELLTRA® provides statistically significant and clinically meaningful improvement in OS compared to other FDA 2L+ approved therapies.

In response to CMS's concern about ORR data for topotecan and lurbinectedin in patients with stable brain metastases as well as in patients that are taking 3L therapy, the applicant stated that IMDELLTRA® is the only FDA-approved therapy for 2L ES–SCLC that demonstrated survival benefit compared to previously available treatments in patients with treated, stable brain metastases and untreated, asymptomatic brain metastases. The applicant stated that both the Phase 2 and 3 studies evaluating the efficacy and safety of IMDELLTRA® included patients with treated, stable brain metastases and untreated, asymptomatic brain metastases. The applicant further stated that while lurbinectedin and topotecan are also approved for 2L therapy in ES–SCLC patients, they were not extensively studied in patients with treated, stable brain metastases; therefore, the applicant stated that it could not provide ORR data for this specific patient population. For lurbinectedin, the applicant stated that patients with brain metastases were excluded from the pivotal trial. Per the applicant, while some studies have been conducted on topotecan and SCLC patients with brain metastases, low response rates were observed. The applicant stated that in a Phase 2 trial, only 2 out of 19 (10.5 percent) SCLC patients with brain metastases responded to topotecan, which did not meet the minimum response requested for study continuation. The applicant stated that, likewise, topotecan and lurbinectedin do not have registrational trial data in 3L+ ES–SCLC patients while IMDELLTRA® does. Per the applicant, while ORR data for topotecan and lurbinectedin as 3L therapy were not available in the respective registrational trials, it did provide real-world evidence of these previously available treatments being used as 3L therapy.

In response to CMS's concern that, among the clinical trial and real-world data provided there was no control for confounding variables to ensure similar patients were being compared, the

applicant stated that in addition to the clinical literature provided in its application regarding outcomes of currently available treatment, the new evidence from the ITC analysis and DeLLphi-304 addresses this concern and further supports the applicant's claims of substantial clinical improvement for IMDELLTRA®. The applicant stated that, for example, the ITC analysis from Tapan et al. (2025) controlled for potential confounding factors by selecting controls based on key DeLLphi-301 inclusion/exclusion criteria and employing propensity score matching. In addition, the applicant stated that the E-value, which measures the likelihood of unmeasured confounding to bias in the ITC estimates, showed that the likelihood of bias is low in the analysis by Tapan et al. (2025).

In response to CMS's concern 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, the applicant stated that, while registrational trial data is lacking to support its use in this specific patient population, Desai et al. (2023) evaluated the safety and efficacy of lurbinectedin in a real-world setting, focusing on its use as a 2L+ treatment in SCLC patients. The applicant reiterated findings from the Desai et al. (2023) study provided in its original application to further support its statement.

In response to CMS's question about the use of the 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 guidelines and treatment protocols for SCLC have evolved and it included some highly varied patient outcomes, the applicant stated, given the long time periods between treatment advances in this difficult to treat cancer, it provided in its application more recent real-world evidence on previously approved treatments for 2L ES–SCLC. The applicant also reiterated that it provided an ITC analysis and new data from the DeLLphi-304 randomized controlled Phase 3 trial comparing IMDELLTRA® to standard of care chemotherapy, including topotecan, that demonstrate IMDELLTRA® provides a substantial clinical improvement compared to previously available treatments using more contemporary data than the historical literature on these treatments.

In response to CMS's concern that while clinical trials of topotecan and lurbinectedin reported higher rates of ≥ Grade 3 neutropenia, they did not consider other serious adverse events such as CRS or ICANS, the applicant stated that, IMDELLTRA® has a positive benefit:risk safety profile and a low incidence of treatment-related neutropenia. The applicant stated this is further confirmed in the randomized controlled DeLLphi-304 trial, where IMDELLTRA® demonstrated a more favorable toxicity profile than standard chemotherapy, with chemotherapy associated with more frequent and higher-grade adverse events. Per the applicant, in DeLLphi-304, Grade ≥3 TRAEs were significantly lower in the IMDELLTRA® group (27 percent) compared to the chemotherapy group (62 percent). The applicant additionally stated that TRAEs led to dose interruption and/or reduction in 19 percent of patients receiving IMDELLTRA® versus 55 percent in the chemotherapy group, and to discontinuation in 3 percent and 6 percent of patients, respectively.

The applicant further stated that the most common TRAEs across both the Phase 2 and Phase 3 trial was CRS, which was mild and generally manageable with antipyretics, IV fluids and steroids with ≤ 1 percent of patients experiencing CRS ≥ Grade 3. Per the applicant, consistent with this established safety profile, in the randomized controlled DeLLphi-304 trial, CRS and ICANS were observed in 56 percent of patients and 6 percent of patients treated with IMDELLTRA®, respectively, and were mostly Grade 1–2. The applicant stated that in the IMDELLTRA® group only one percent of patients experienced a Grade 3 CRS event and CRS rarely led to treatment interruption (1.6 percent) or discontinuation (0.4 percent). The applicant also stated that all ICANS events were Grade 1 or 2 in severity except for one Grade 5 event and rarely led to treatment interruption (0.8 percent) or discontinuation (0.4 percent). The applicant stated that in DeLLphi-304, CRS and ICANS were mostly Grade 1 or 2 in severity and generally manageable for patients treated with IMDELLTRA®. Per the applicant, overall, the IMDELLTRA® group reported a 27 percent rate of TRAEs with Grade 3 or higher events while the chemotherapy group reported a 62 percent rate. In addition, the applicant stated that TRAEs led to dose interruption and/or dose reduction in 19 percent of patients in the IMDELLTRA® group and in 55 percent of those in the chemotherapy group, and to discontinuation in 3 percent and 6 percent of patients, respectively.

In response to CMS's concern that there was no control for potential confounding variables in the patient populations in the comparisons of neutropenia rates, the applicant stated that while the historical comparisons are informative, the new evidence from the randomized controlled DeLLphi-304 trial provide confirmation that rates of neutropenia are higher for chemotherapy than IMDELLTRA®. The applicant further stated that in the DeLLphi-304 trial, IMDELLTRA® had a four percent rate of Grade 3 or higher neutropenia and a two percent rate of any grade febrile neutropenia. The applicant stated that, in comparison, the chemotherapy group had a rate of 22 percent along with an 11 percent rate of any grade febrile neutropenia. The applicant also stated that, given 2L+ ES–SCLC patients have been exposed to repeated chemotherapy with cumulative toxicities, the lower incidence of neutropenia is notable as this TRAE is known to delay or prevent cancer patients from initiating treatment. Per the applicant, the randomized controlled DeLLphi-304 trial demonstrates a favorable toxicity profile for IMDELLTRA® compared to chemotherapy, with chemotherapy resulting in more frequent and high-grade adverse events. The applicant stated its belief that the safety data included in its application as well as the confirming DeLLphi-304 safety data support that IMDELLTRA® represents a substantial clinical improvement in the Medicare population. The applicant stated that it is clear that IMDELLTRA® substantially improves clinical outcomes relative to previously available treatment and, therefore, meets the substantial clinical improvement criterion.

Additionally, the applicant reiterated that IMDELLTRA® treats a patient population unresponsive to previously available technologies and provided responses to CMS concerns about this assertion from the proposed rule. In response to CMS's concern about whether ES–SCLC patients are unresponsive or ineligible for existing 2L+ treatments, such as lurbinectedin and topotecan, and that having limited treatment options does not demonstrate that patients are unresponsive or ineligible for any available therapies, the applicant stated that, while topotecan and lurbinectedin may have some response in relapsed SCLC, it is short-lived and modest at best. The applicant further stated that for the subpopulation of relapsed SCLC patients that have poor prognostic factors, such as brain metastases and platinum-resistance, this short-lived response is even more pronounced. The

applicant stated, for example, in the pivotal Phase 2 study for lurbinectedin, platinum-resistant patients had a low response rate of 22 percent and a DOR of 4.7 months. Thus, the applicant stated that the poor response supports that patients are largely unresponsive to available treatments. The applicant also stated that in the Phase 3 DeLLphi-304 trial, the median DOR was 6.9 months with IMDELLTRA® versus 5.5 months with chemotherapy. Per the applicant, given that IMDELLTRA® has shown significantly better and longer response, it is evident that IMDELLTRA® treats a patient population unresponsive to previously available technology.

Furthermore, the applicant stated that for ES–SCLC patients with brain metastases, IMDELLTRA® is the only FDA-approved therapy for 2L that has been studied in ES–SCLC patients with treated, stable brain metastases and untreated, asymptomatic brain metastases. Per the applicant, while lurbinectedin and topotecan are also approved as 2L ES–SCLC therapies, they were not extensively studied in patients with treated, stable brain metastases. The applicant reiterated that in the case of lurbinectedin, patients with brain metastases were excluded from the pivotal trial, and in addition, lurbinectedin failed to reach its primary endpoint of OS in the confirmatory Phase 3 ATLANTIS trial. The applicant further stated that, while a Phase 2 study has been conducted on topotecan and SCLC patients with brain metastases, low response rates were observed. The applicant stated new evidence from the Phase 3 randomized controlled DeLLphi-304 study demonstrates the IMDELLTRA®-treated group of SCLC patients with treated, stable brain metastases had similar safety and efficacy outcomes as those patients without brain metastases. Further, the applicant stated that the OS benefit with IMDELLTRA® versus chemotherapy was consistent across prespecified patient subgroups, including the 44 percent of patients with brain metastases who received IMDELLTRA® (asymptomatic, untreated or treated) (HR, 0.45; 95% CI 0.31–0.65). The applicant stated that, although other existing FDA approved treatments for ES–SCLC may be prescribed in the real world for SCLC patients with brain metastases, these existing treatments do not have a randomized controlled Phase 3 trial demonstrating efficacy over the current standard of care. The applicant stated that IMDELLTRA® has demonstrated improved survival outcomes for ES–SCLC patients with or without brain metastases who have progressed after initial platinum-based chemotherapy, a patient population that is effectively unresponsive to existing treatment as demonstrated by low response rates.

Response: We thank the applicant for its comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree with the applicant that IMDELLTRA™ represents a substantial clinical improvement over existing technologies because it significantly improves OS and PFS with lower rates of Grade 3 or higher TRAEs, including neutropenia, compared to existing treatment options for 2L+ ES–SCLC patients.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that IMDELLTRA® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2026. Cases involving the use of IMDELLTRA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes XW033NA (Introduction of tarlatamab-dlle antineoplastic into peripheral vein, percutaneous approach, new technology group 10) or XW043NA (Introduction of tarlatamab-dlle antineoplastic into central vein, percutaneous approach, new technology group 10).

In its application, the applicant stated that the cost of IMDELLTRA® is $1,500 for a 1 mg dose and $15,000 for a 10 mg dose. According to the applicant, the first dose of IMDELLTRA® is 1 mg and all subsequent doses are 10 mg. In its application, the applicant estimated that the weighted average dose of IMDELLTRA® for Medicare patients is 7.3 mg based on about 70 percent of inpatient Medicare administrations being for a 10 mg dose and 30 percent of inpatient Medicare administrations being for a 1 mg dose. Therefore, the average cost per patient for IMDELLTRA® is $10,950 ($1,500 per mg * 7.3 mg). 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, the maximum new technology add-on payment for a case involving the use of IMDELLTRA® is $7,117.50 for FY 2026.

h. 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.

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.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18129 through 18130), we noted the following concerns regarding the substantial similarity criteria. We noted 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 noted 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.[86] Notably, monocytes (measured for MDW) are one type of leukocyte, and the IntelliSep® Test also evaluates leukocytes in its mechanism of action.[87] While the techniques of leukocyte measurement may differ, we stated that the subject of measurement appears to be the same or similar. Therefore, we questioned 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 questioned 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 stated we were 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 noted 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[88] or NAVOY CDS®[89]). We stated that 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 questioned whether a patient's location, whether in the ED, admitted to the hospital, or in the intensive care unit (ICU) constitutes a different population. Further, we noted 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.[90] [91] Therefore, we stated it was 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 invited public comments on whether the IntelliSep® Test is substantially similar to existing technologies and whether the IntelliSep® Test meets the newness criterion.

[86] 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.*

[87] 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.*

[88] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K230386.pdf.*

[89] *https://www.accessdata.fda.gov/cdrh_docs/pdf24/K240558.pdf.*

[90] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?id=K181599.*

[91] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/DEN230036.pdf.*

Comment: A commenter submitted a comment stating that both MDW and the IntelliSep® Test quantify biophysical changes in leukocytes to flag sepsis in emergency departments, and that it did not support new technology add-on payment designation for the IntelliSep® Test.

Response: We thank the commenter for its input and have taken it into consideration in determining whether the IntelliSep® Test meets the newness criterion as discussed later in this section.

Comment: The applicant also submitted a public comment regarding substantial similarity. In response to CMS's concern that the applicant did not compare the IntelliSep® Test's mechanism of action to those of other sepsis tests or detection tools, the applicant asserted that the IntelliSep® Test is novel, provides needed information that MDW, SeptiCyte® RAPID, and the Sepsis ImmunoScore™ cannot, and supports a market segment that is underserved by these technologies. The applicant stated that in 2016, International Consensus (Sepsis–3) established a new definition of sepsis, calling the disease a life-threatening organ dysfunction caused by a dysregulated host response to infection, and stating that there is no way to measure this dysregulated host response directly. The applicant stated that, although the Sepsis-3 authors proposed proxy measures for a dysregulated host response, including the organ failure assessment scores SOFA and qSOFA, these measures reflect consequences that are not exclusive to sepsis, making them insufficient for sepsis diagnosis. The applicant further stated that MDW, SeptiCyte® RAPID, and the Sepsis ImmunoScore™ similarly rely on indirect measures or proxy indicators of immune dysfunction, rather than directly measuring immune cells' structural changes that are the hallmark of sepsis. The applicant asserted that the most profound difference between the IntelliSep® Test and other technologies is that the IntelliSep® Test interrogates and visualizes immune cells directly rather than relying on downstream biomarkers or consequences.

The applicant described the IntelliSep® Test's mechanism of action as a real-time assessment of immune dysregulation and sepsis by quantifying the structural changes in white blood cells (WBCs), specifically neutrophils and monocytes, during the formation of Neutrophil Extracellular Trap (NET) or NETosis in cells. The applicant explained that NETs are networks of extracellular fibers, primarily composed of DNA from neutrophils, which bind to pathogens. The applicant stated that the formation of NETosis in neutrophils causes specific and measurable changes in the cells' structural composition. The applicant further stated that the IntelliSep® Test, unlike other sepsis tests, has been shown to correlate strongly with NET formation markers. The applicant stated that the IntelliSep® Test examines cell morphology and immune cell activation through high-speed video imagery with automated analysis and quantification of WBC 's internal structure as they undergo hydrodynamic stress applied in a microfluidic environment, providing a direct measurement of the dysregulated immune response that underlies sepsis. The applicant asserted that, therefore, the IntelliSep® Test is unique in its capability to visualize and quantify the activation level of immune cells compared to other sepsis tests, which provide or aggregate secondary information that may correlate with sepsis.

With regard to MDW and the IntelliSep® Test's subject of measurement appearing to be the same or similar, the applicant stated that both tests examine blood cell characteristics and are used to evaluate patients presenting to the ED, aiming to provide an indication of the level of immune system activation. The applicant explained that MDW measures monocytes' external size variability and is automatically reported with a routine complete blood count, whereas the IntelliSep® Test examines both monocytes and neutrophils' fluid mechanical compression and assesses the changes in cell compliance visually using high speed imagery. The applicant stated that the IntelliSep® Test evaluation of neutrophils adds critical new information, providing a broader signal that is not available from monocytes alone, and thus, not available from MDW. The applicant further stated that differences in method of action are foundational to the IntelliSep® Test's ability to directly indicate immune dysregulation, in contrast to MDW's more indirect, or limited approach. In addition, the applicant stated that Sarani et al. (2024) conducted an independent evaluation of MDW and the IntelliSep® Test and found limited correlation in overall data and especially weak correlation in high-risk groups between the two tests' results. The applicant added that Sarani et al. (2024) asserted that this lack of correlation suggests that MDW and the IntelliSep® Test are measuring different blood cell properties.

The applicant compared the IntelliSep® Test to SeptiCyte® RAPID, the Sepsis ImmunoScore™, qSOFA, and other Systemic Inflammatory Response Syndrome (SIRS) symptoms. The applicant stated SeptiCyte® RAPID aims to indirectly assess host immune activation through proxy gene expression markers for two selected genes and compares them to a specific set of known septic and healthy patient profiles. The applicant asserted that SeptiCyte® RAPID captures only a narrow, indirect signal compared to the broader range of signals evaluated and captured by the IntelliSep® Test. The applicant added that SeptiCyte® RAPID has limitations when it comes to racial disparities and usage outside the ICU.

The applicant stated that the Sepsis ImmunoScore™ measures up to 22 other biomarkers and provides no new independent assessment of a patient's condition. The applicant further stated that Sepsis ImmunoScore™ collates and analyzes measurements from a patient's medical record, calculating a proxy score for immune activation using machine learning algorithms applied to electronic health record data. In addition, the applicant stated that the qSOFA is based on clinical and laboratory indicators of organ dysfunction and does not provide any new information beyond what is already available as the standard of care. The applicant further stated that SIRS symptoms and the sepsis markers based upon them reflect findings from initial clinical assessments and do not offer any new information. In comparison to SeptiCyte® RAPID, the Sepsis ImmunoScore™, qSOFA, and SIRS symptoms, the applicant stated that the IntelliSep® Test delivers a standalone signal of the host response based on a blood sample from the patient and directly evaluates the structure of monocytes and neutrophils under mechanical stress using high-speed video.

In response to CMS's question whether a patient's location, whether in the ED, admitted to the hospital, or in the ICU constitutes a different population, the applicant provided a table to summarize differences between the IntelliSep® Test, SeptiCyte® RAPID, Sepsis ImmunoScore™, and MDW reported by the Early Sepsis Indicator. The applicant provided comparative analyses and asserted that the IntelliSep® Test is the only test of its kind indicated for use in adult patients presenting to the ED with signs and symptoms of infection. The applicant reported the population for Sepsis ImmunoScore™ as patients admitted to the Emergency Department or hospital

with cultures drawn, and for Early Sepsis Indicator as adult patients presenting to the ED in whom a WBC differential was ordered. The applicant elaborated on implications of differences between the IntelliSep® Test and the reported population for SeptiCyte® RAPID, adult patients with SIRS within the first day of ICU admission. The applicant stated that the suspected sepsis population that has been admitted to the ICU is significantly different than the population presenting to the ED, and therefore, the IntelliSep® Test does not involve treatment of the same or similar population and disease as existing technologies, such as SeptiCyte® RAPID. The applicant stated that previous studies found that 68 percent of the IntelliSep® Test tested population were admitted to the hospital and 16.1 percent were admitted to the ICU. The applicant asserted that these findings indicate that providers judged only a small portion of those tested with the IntelliSep® Test severe enough to warrant an ICU level of care. The applicant stated that identifying sepsis early in the ED when symptoms are subtle is challenging, while diagnosing sepsis later when severe organ dysfunction necessitates ICU care is easier. The applicant concluded the value of a test, like the IntelliSep® Test, that can provide an accurate indicator of sepsis in an ED population, is much greater because the opportunity to intervene with effective care is greater.

Response: We thank the applicant and commenter for their comments. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for the IntelliSep® Test, we agree with the applicant that the IntelliSep® Test uses a unique mechanism of action for early sepsis detection because it is the only FDA-approved test that directly assesses immune dysregulation by quantifying the changes in cell compliance for WBCs to aid in the early detection of sepsis with organ dysfunction. Therefore, we agree with the applicant that the IntelliSep® Test is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on December 20, 2022, the date on which the IntelliSep® Test received FDA market authorization for use with adult patients with signs and symptoms of infection who present to the ED.

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 invited public comments on whether the IntelliSep® Test meets the cost criterion.

Comment: The applicant reiterated that the cost criterion analysis submitted with the application demonstrate that the IntelliSep® Test meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, 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,[92] 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 noted that two other articles were submitted as supporting evidence (Kraus et al., 2023; Rhee et al., 2017), which we stated we believed should be characterized as background articles because they do not directly assess the use of the IntelliSep®

[92] One of these studies (Sheybani et al., 2024) is a published abstract that was retracted.

Test.[93] 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.

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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.	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.
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.

[93] 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.*

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.

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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 summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18132).

After review of the information provided by the applicant and the public comment received in response to the New Technology Town Hall meeting, we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18132 through 18133) that we had 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 noted 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).

We stated that 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 noted 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. We stated that 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 noted 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 stated 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 noted 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 questioned 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 noted 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 stated that we were therefore unclear whether the results may be influenced by potential confounding factors, and we questioned whether they are generalizable to other EDs or geographic regions as well as to the Medicare population.

We stated that 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 noted 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 questioned whether the claim that the IntelliSep® Test reduces door-to-bed time is an appropriate proxy for timely antibiotic administration and the

potential for subsequent clinical outcomes (such as mortality). We stated that 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 was unclear. We also noted that the provided evidence did 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 stated we were unclear about the direct association between the IntelliSep® Test and antibiotic initiation for sepsis consistent with current guidelines as this was also only inferred, and the IntelliSep® Test is one tool among others used to diagnose sepsis. We also questioned 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 noted that a decrease in mortality is only inferred, and the provided evidence does not demonstrate that the IntelliSep® Test decreases mortality. We stated we were 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 noted 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 questioned 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 noted that both Early Sepsis Indicator and Sepsis ImmunoScore™ are indicated for use in the ED. We stated we were 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 noted 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 stated we were 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 questioned 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 stated we had 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 noted 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.

We stated that 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's 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 noted that the study used control and intervention cohorts that were not concurrent, and we questioned the impact from varying confounders, such as changes in clinical policy. We noted 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.[94] However, these studies did not assess the IntelliSep® Test's ability to affect LOS, rates of infection, readmission, or other clinical outcomes.

Lastly, we questioned how much capability should be attributed to the IntelliSep® Test when making clinical judgments and improving clinical outcomes, and we welcomed additional information.

We invited public comments on whether the IntelliSep® Test meets the substantial clinical improvement criterion.

Comment: A few commenters expressed support for approval of the IntelliSep® Test's new technology add-on payment, inclusive of emphasis on the importance of early sepsis recognition and rapid treatment. Another commenter did not support approval for the IntelliSep® Test, stating that O'Neal et al. (2024) found that the IntelliSep® Test's area under the receiver operating characteristic curve (AUROC) is indistinguishable from procalcitonin. The commenter also stated that head-to-head evidence of the IntelliSep® Test and MDW is even thinner, stating that the Sarani 2025 series reports IntelliSep® Test results only, leaving MDW unmeasured. The commenter also stated that for Sepsis-3 identification, FDA clearance assigned the IntelliSep® Test likelihood ratios of 0.35 (Band 1) and 2.69 (Band 3), but 28 percent of patients fall into the indeterminate Band 2. The commenter further stated MDW delivers comparable discriminatory power (≤20: LR 0.36; >20: LR 0.265) with 100 percent of patients classified, meaning it still

[94] 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.*

reports when the IntelliSep® Test cannot. According to the commenter, MDW results are available in roughly 2 minutes, widely deployed as part of complete blood counts, and reimbursed at $4.48, unlike the dedicated IntelliSep® Test instrument. The commenter added that the IntelliSep® Test's utility claims hinge on abstracts and single-center slide decks from the site that co-developed the test. The commenter stated that the applicant for the IntelliSep® Test did not offer peer-reviewed publications with robust outcome benefits and that unpublished data from one institution does not establish utility. The commenter stated that MDW, in contrast, has a substantial, peer-reviewed record of both clinical validity and real-world benefit, whereas the IntelliSep® Test shows similar or poorer analytic performance, lacks peer-reviewed utility data, and requires proprietary hardware at higher cost. The commenter, therefore, recommended that the IntelliSep® Test's new technology add-on payment application be denied.

Response: We thank the commenters for their input and have taken it into consideration in determining whether IntelliSep® meets the substantial clinical improvement criterion, discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant included a recently published paper by Thomas et al. (2025),[95] which the applicant asserted further demonstrates how the IntelliSep® Test provides a substantial clinical improvement in detecting and diagnosing sepsis compared to all other available tests. The applicant explained the article discusses a sepsis quality improvement initiative at a large academic medical center with a high-volume ED that incorporated the IntelliSep® Test into its protocol, enabling rapid diagnostic support for patients flagged by an electronic health record-based alert. The applicant asserted that, per the authors, over the course of 1 year, implementation of the IntelliSep® Test significantly reduced mortality, hospital LOS, and blood culture utilization, demonstrating improved patient outcomes and resource efficiency compared to the pre-implementation period. The applicant further stated that while the study does not have the rigor of some other study designs, it overcomes limitations related to a control population by leveraging protocolized screening, which defines a broad, consistent, and pre-specified analysis group including more than 12,000 diverse patients (median age: 66 years) with no inclusion or exclusion criteria. In addition, the applicant asserted that the article shows that the use of the IntelliSep® Test in an ED triage process enabled the care delivery in a way that was superior to the standard of care in a large population of patients.

The applicant also asserted that the article provides additional documentation regarding multiple concerns that CMS stated in the proposed rule, including those related to reductions in hospital LOS, blood culture utilization, and mortality. First, the applicant stated that it addressed CMS's concerns regarding the Thomas et al. (2024b) study, including the impact from varying confounders and several questions from CMS, specifically providing additional documentation related to reductions in hospital length of stay, blood culture utilization, and mortality. The applicant stated that, in the Thomas et al. (2025) study, the IntelliSep® Test's implementation resulted in a reduction in hospital LOS for sepsis patients of 0.64 days (9.5 percent) for the full cohort and 0.76 days (11.3 percent) for the temporally matched cohort. The applicant stated that this reduction meets the standard provided in 42 CFR 412.87(b), which states: A more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time. Second, the applicant asserted that the Thomas et al. (2025) study addresses the IntelliSep® Test's ability to reduce diagnostic exposure, because the study showed application of the IntelliSep® Test resulted in a relative reduction in blood culture utilization, from usage in 50.8 to 45.7 percent of patients. The applicant stated that this reduction in cultures meets the standard in 42 CFR 412.87(b) which describes a decreased rate of at least one subsequent diagnostic or therapeutic intervention. In addition, the applicant stated that the Thomas et al. (2025) study demonstrates that, in the temporally matched cohort, application of the IntelliSep® Test produced an absolute reduction in sepsis mortality risk by 4.2 percent (from 10.7 percent to 6.5 percent). The applicant added that this reduction is a significant improvement over the standard of care, which included SIRS symptoms, lactate measurement, and the use of cultures, that no other sepsis test has demonstrated.

In response to CMS's concern that its application lacked a comparison of the IntelliSep® Test to existing technologies used to diagnose sepsis, the applicant stated that the Sepsis ImmunoScore™, SeptiCyte® RAPID, and the Early Sepsis Indicator are not in widespread use, preventing comparative data between these sepsis diagnostic tests and the IntelliSep® Test. The applicant further stated that a 2024 New England Journal of Medicine review article confirmed that no sepsis test is in widespread use. The applicant asserted that, as such, there is no practical way to construct a comparison in sepsis diagnostic tests. The applicant additionally asserted that no other technology has conducted a comparative study documenting improvements in hospital LOS, blood culture utilization, and mortality risk relative to the standard of care as the Thomas et al. (2025) study provides.

In response to CMS's concern that the IntelliSep® Test application did not address its ability to diagnose a patient population where sepsis is currently undetectable or the ability to diagnose sepsis earlier than other technologies, the applicant stated that other sepsis diagnostic tests, including SIRS symptoms, lactate, and blood cultures, assess the symptoms or effects of sepsis, rather than sepsis's immune dysregulation, and are therefore insufficient. The applicant asserted that the IntelliSep® Test provides the novel capability to assess immune activation, which can allow for a sepsis diagnosis based on underlying cell physiology. The applicant further stated that the IntelliSep® Test shows superior performance in sepsis diagnosis (as adjudicated by a physician panel) against the current sepsis detection standards of care for sepsis detection.

Regarding the IntelliSep® Test's ability to diagnose sepsis earlier than other technologies, the applicant stated that the IntelliSep® Test's turnaround time is comparable to some other sepsis tests, such as MDW and the Sepsis ImmunoScore™. The applicant asserted that the IntelliSep® Test's ability to rapidly assess immune dysregulation allows it to identify sepsis across the range of the disease's progression continuum based on ED presentation, where patients may present early in sepsis progression with limited symptoms. In addition, the applicant asserted that, as such, the IntelliSep® Test's sensitivity allows it to identify sepsis patients at an earlier point in the disease's course than other available

[95] Thomas, C. B., Wyler, B., D'Antonio, C. M., Laperouse, M., Alwood, S., Richard, K., Grantham, A., Sheybani, R., Sorrells, M. G., Tan, W.-J., Teague, J. W., O'Neal, H., & Jagneaux, T. (2025). Impact of a Sepsis Quality Improvement Initiative on Clinical and Operational Outcomes. *Healthcare,* 13, 1273. *https://doi.org/10.3390/healthcare13111273.*

tests. The applicant stated that Sarani et al. (2024) showed that the IntelliSep® Test demonstrated improved sepsis detection capability relative to MDW.

In response to CMS's concerns about the Jagneaux et al. (2024) study, the applicant reiterated that the study showed that patients in the waiting room with a Band 3 score from the IntelliSep® Test were immediately put into an ED bed for treatment, which improved time to bed (TTB) relative to the overall mean. The applicant stated that this study did not document patient outcomes but added it demonstrated that patients with Band 3 scores had a 94 percent rate of infection and a 54 percent rate of sepsis based upon discharge, while patients with Band 1 scores had a 1.6 percent rate of sepsis. The applicant asserted that because the IntelliSep® Test results led to faster TTB for patients with Band 3 scores, the test resulted in faster treatment times for high-risk patients. The applicant also stated that while Jagneaux et al. (2024) did not document patient outcomes, Thomas et al. (2025) included these same patients and observed significant decreases in sepsis-associated mortality. The applicant further asserted that given the known association between care timeliness and mortality as well as the known waiting time decrease, it follows that some of the IntelliSep® Test's documented mortality improvement is likely attributable to the advancement in sepsis care it enabled. The applicant concluded that the application of the IntelliSep® Test in clinical practice provides evidence for its substantial clinical improvement and the approval of its new technology add-on payment application.

A commenter who employed the IntelliSep® Test at several facilities submitted a comment and an unpublished abstract to show how the test's adoption impacted patient outcomes at the facilities. The commenter stated that it tracked patient discharge and return rates following the introduction of the IntelliSep® Test, and documented a significant increase (from 14 percent to 24.9 percent) in the patient discharge rate from EDs in the first 4 months following the IntelliSep® Test's implementation. The commenter further stated that the EDs achieved this increase without an increase in the rate of patient returns. The commenter asserted that, taken together with other admission and clinical data, it observed a significant increase (26 days to 27 days) in the return-adjusted hospital free days experienced by patients. The commenter stated that the IntelliSep® Test adoption resulted in a significant clinical impact for its patients. The commenter provided an abstract describing the impact of the IntelliSep® Test use in the ED within their submission.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received and all data received to date, we continue to have concerns as to whether the IntelliSep® Test represents a substantial clinical improvement over existing technologies. Specifically, we disagree with the applicant that the evidence provided is sufficient to establish that the IntelliSep® Test offers the ability to diagnose a medical condition in a patient population where the 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. Additionally, it remains unclear that the IntelliSep® Test significantly improves clinical outcomes relative to services or technologies previously available.

Regarding the applicant's assertion that the IntelliSep® Test provides a substantial clinical improvement in detecting and diagnosing sepsis compared to all other available tests, we note the recently published and submitted Thomas et al. (2025) study did not compare the IntelliSep® Test to other available sepsis diagnostic technologies, such as the Early Sepsis Indicator and Sepsis ImmunoScore™. Furthermore, the applicant stated that Sarani et al. (2024) showed that the IntelliSep® Test demonstrated improved sepsis detection capability relative to MDW. However, the Sarani et al. (2024) study was conducted in a single medical center with a small sample size (n = 44), and we therefore question the generalizability of the results. We maintain our concern that Sarani et al. (2024) does not compare the IntelliSep® Test and MDW with respect to the ability to diagnose sepsis earlier, and the study does not define a patient population where sepsis is currently undetectable in which the IntelliSep® Test can detect sepsis. The applicant asserted that the O'Neal et al. (2024) study demonstrates that the IntelliSep® Test shows faster time to diagnosis against current standards of care including SIRS, lactate, and blood cultures. However, the applicant stated that the turnaround time of the IntelliSep® Test is comparable with that of MDW (that is, Early Sepsis Indicator) and Sepsis ImmunoScore,™ which both may also have the capability to provide a faster diagnosis of sepsis compared to SIRS, lactate, and blood cultures. Although the applicant stated that the Sepsis ImmunoScore™, SeptiCyte® RAPID, and the Early Sepsis Indicator are not in widespread use, the substantial clinical improvement criterion requires that a technology demonstrate its diagnostic ability relative to currently available methods or technology. The applicant also stated that the sensitivity of the IntelliSep® Test allows it to identify these patients at an earlier point in the patient's course of sepsis than other available tests, but the applicant did not provide evidence demonstrating sepsis identification earlier in the disease process than other diagnostic tools. In addition, the applicant cited the Jagneaux et al. (2024) study, stating that the test led to faster treatment for patients who were ultimately shown to have been at high risk, based on the rate of higher infection in the high risk band. We continue to be concerned that the Jagneaux, et al. (2024) study does not demonstrate how the IntelliSep® Test compares to other currently available diagnostic methods in TTB. Also, while the applicant concluded that because the patients from the Jagneaux, et al. (2024) study were included in the Thomas et al. (2025) patient cohort, some of the mortality improvement documented with the IntelliSep® Test in the Thomas et al. (2025) study is likely attributable to the advancement in sepsis care enabled by the IntelliSep® Test, neither the applicant nor the Jagneaux, et al. (2024) study identify or measure the asserted advancements. It is unclear if TTB resulted in changes in patient management, and if so what those changes were. Our concerns for evidence of differences in the management of patients remain. We also continue to be concerned with the lack of data comparing the IntelliSep® Test to other available sepsis diagnostics, or evidence of a patient population where sepsis is currently undetectable, in which the IntelliSep® Test can detect sepsis. We remain unclear how the IntelliSep® Test compares to other available sepsis diagnostic technology in detecting and diagnosing sepsis.

Regarding the applicant's assertion that the IntelliSep® Test significantly improves clinical outcomes relative to services or technologies previously available, we remain unclear how the IntelliSep® Test compares to other sepsis diagnostic technologies. While the applicant submitted the Thomas et al. (2025) study to show that the IntelliSep® Test demonstrated a significant reduction in mortality, LOS, and blood culture utilization, we remain concerned about the continued lack of

comparative data. We remain unclear how the IntelliSep® Test's clinical outcomes compare to those of other existing sepsis detection tests.

After consideration of all the information received from the applicant as well as the public comments, we are unable to determine that the IntelliSep® Test represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule, and therefore, we are not approving new technology add-on payments for the IntelliSep® Test for FY 2026.

i. 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.

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: 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.

The applicant submitted a request for approval for unique ICD–10–PCS procedure codes for the Neuroguard IEP® System and was granted approval to use the following procedure codes effective October 1, 2025: X2AH34B (Right common carotid artery cerebral embolic filtration, single integrated distal filter, percutaneous approach, new technology group 11), X2AJ34B (Left common carotid artery cerebral embolic filtration, single integrated distal filter, percutaneous approach, new technology group 11), X2AK34B (Right internal carotid artery cerebral embolic filtration, single integrated distal filter, percutaneous approach, new technology group 11), and X2AL34B (Left internal carotid artery cerebral embolic filtration, single integrated distal filter, percutaneous approach, new technology group 11). 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 for multiple devices, reducing catheter exchanges and procedural complexity. While traditional distal embolic protection devices have larger pores that allow micro-emboli to reach the brain, potentially 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.
Is the technology assigned	Yes	The Neuroguard IEP® System falls under the MS-DRGs related to

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18135), we stated we had 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 questioned 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 noted 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,[96] which suggests that its filter would not impact the mechanism of action of the device. We also noted 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.[97]

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

[96] 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*).

[97] 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).

dilation to streamline the procedure and increase the effectiveness of embolic protection during CAS, we questioned 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.[98] We stated it was 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, we stated that it appears these technologies may have the same or a similar mechanism of action as the Neuroguard IEP® System. We further noted 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 we stated that it appears that the Neuroguard IEP® System and existing carotid stents or stent systems, such as the GORE® Carotid Stent, RX Acculink™ Carotid Stent System, or Carotid WALLSTENT® Monorail® Endoprosthesis, or the Paladin® System with IEP used with any available carotid artery stent, may use the same or similar mechanism of action to achieve a therapeutic outcome, would be assigned to the same MS–DRG, and would treat the same or similar patient population and disease, we questioned whether these technologies may be substantially similar to one another. We noted 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, we stated 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,[99] [100] [101] the Neuroguard IEP® System would not be considered new.

We invited public comments on whether the Neuroguard IEP® System is substantially similar to existing technologies and whether the Neuroguard IEP® System meets the newness criterion.

Comment: Several commenters expressed support for the Neuroguard IEP® System. The commenters stated that the 3-in-1 design is new, often based on their clinical experience. A few of the commenters stated that the integrated design streamlines the procedure, shortens the procedure time, and eliminates multiple device exchanges, each of which represents a discrete embolic risk in and of itself. A commenter stated that the Neuroguard IEP System is a paradigm shift in the field of carotid intervention by introducing a new mechanism of action, combining targeted microembolus capture at the most vulnerable stages of the procedure with improved procedural efficiency through reduced device exchanges. A commenter stated that the Neuroguard IEP® System is a true advancement that directly addresses an unmet need posed by traditional or legacy EPDs, which are unable to capture microemboli materials less than 100 microns. Some commenters stated that these smaller particles account for more than 80 percent of the debris generated during carotid stenting and that by functioning in tandem with standard embolic protection, the Neuroguard IEP® System offers dual protection. Another commenter stated that the Neuroguard IEP® System eliminates the need to maneuver through the cervical loop to capture additional filters, thereby reducing the risks to patients and decreasing the overall procedure time. A commenter stated that the Neuroguard IEP® System introduces a novel dual embolic protection mechanism while maintaining required primary protection throughout the procedure. Per the commenter, this integrated approach creates therapeutic capabilities not available with existing technologies. A commenter stated that this technology has broader implications, particularly in the treatment of tandem occlusions during anterior circulation stroke, since these are complex cases involving both an intracranial large vessel occlusion and a proximal cervical internal carotid artery lesion, often of atherosclerotic origin. Some commenters stated that the closed-cell design of the stent enhances plaque coverage without reducing vessel conformability.

Response: We thank the commenters for their input and have taken it into consideration in determining whether the Neuroguard IEP® meets the newness criterion as discussed later in this section.

Comment: The applicant submitted a public comment asserting that the Neuroguard IEP® System represents a groundbreaking advancement in CAS with a novel 3-in-1 design combining a carotid stent, post-dilation balloon, and 40-micron pore integrated embolic filter in 1 device. The applicant reiterated that the technology's design distinctions enable a novel mechanism of action that directly addresses the root cause of procedure-related embolic events, microemboli generated during stent deployment and post-dilation, when perioperative stroke risk is highest.[102] [103] [104] The applicant reiterated that the Neuroguard IEP® System enables the placement of a 40-micron pore filter, deployment of the stent, and post-dilation ballooning all through a single catheter. Per the applicant, the Neuroguard IEP® System's revolutionary mechanism of action directly addresses the primary limitation of traditional carotid stenting technologies and offers advantages not achievable through any combination of existing devices, including (1) smaller filter size and selective deployment combined with standard embolic protection offers dual protection; and (2) integration enables usage of 40-micron pore protection and real-time filter control with no catheter exchanges.

The applicant also referred to CMS's determination in the FY 2021 IPPS/LTCH PPS final rule that the Eluvia™ Drug Eluting Stent (Eluvia™) had a unique mechanism of action (85 FR 58648) and discussed how the same approach can be applied to the determination of the Neuroguard IEP®

[98] FDA. Neuroguard IEP® 3-in-1 Carotid Stent, Post-Dilation Balloon System with Integrated Embolic Protection. Pre-market approval. October 11, 2024.

[99] 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.*

[100] 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.*

[101] 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.*

[102] Kastrup A, Gröschel K, Krapf H, et al (2003) Early outcome of carotid angioplasty and stenting with and without cerebral protection devices: A systematic review of the literature. *Stroke* 34(3) *https://doi.org/10.1161/01.STR.0000058160.53040.5F.*

[103] Müller-Hülsbeck SM, Jahnke T, Stolzmann P, et al (2003) A new concept for covered stent protected carotid angioplasty: An ex vivo study *Röfo* 175(12): 1634–1638 DOI: 10.1055/s-2003–45342.

[104] Schnaudigel S, Gröschel K, Pilgram S, et al (2008) New brain lesions after carotid stenting versus carotid endarterectomy: A systematic review of the literature. Stroke 39(6) *https://doi.org/10.1161/STROKEAHA.107.500603.*

System's mechanism of action. According to the applicant, because CMS recognized that Eluvia™'s long-term drug release profile constituted a unique mechanism of action although the device used paclitaxel like other peripheral drug-eluting stents, it asserted that CMS was stating that integrating a novel distinction to existing technology to address a critical treatment limitation such as sustained drug delivery constituted a novel mechanism of action. The applicant stated that similarly, the Neuroguard IEP® System integrates a critical function that fundamentally alters treatment for carotid stenting because it uniquely addresses the lack of micro-embolic protection during stent deployment and post-dilation.

In response to CMS's question about whether the requirement that the Neuroguard IEP® System must always be used in conjunction with an available primary distal embolic protection device suggests that its filter would not impact the mechanism of action of the device, the applicant stated that this requirement does not diminish its novel mechanism of action, but rather underscores its innovative complementary approach to solving a critical clinical limitation in carotid stenting procedures. The applicant explained that the Neuroguard IEP® System offers complementary, not redundant, protection by pairing a standard filter that protects against large emboli (>100 microns) throughout the procedure with its integrated 40-micron pore filter, which captures microemboli during the highest-risk phases of the procedure. Per the applicant, traditional filters must maintain minimum pore sizes of 100 microns to avoid filter thrombosis during prolonged use throughout the carotid stenting procedure, but that approximately 69 percent to 90 percent of embolic particles released during carotid artery stenting procedures are less than 100 microns in size, and thus may reach the cerebral circulation despite the use of these large pore distal filters. The applicant stated that the Neuroguard IEP® System's unique mechanism of action is not possible with other commercially available technologies, including first-generation embolic protection devices and FDA-approved dual-layer stents. The applicant asserted that the Neuroguard IEP® System's clinical outcomes reflect a distinct function that cannot be explained by simply combining existing technologies.

In response to CMS's question about similarity to other existing embolic protection filters used during CAS procedures that have the same 40-micron pore size, such as the Paladin® System with IEP from the same manufacturer, the applicant stated that the Neuroguard IEP® System fundamentally differs from the Paladin® System with IEP in mechanism of action and clinical utility, despite both featuring a 40-micron pore filter. The applicant explained that the key differences are related to procedural coverage and device integration, both of which set the two technologies apart and are critical for understanding why the Neuroguard IEP® System represents a novel therapeutic approach. In terms of procedural coverage differences, the applicant stated that the Paladin® System with IEP's balloon is a separate balloon catheter with integrated embolic protection (without a stent) that can provide small-pore coverage only during balloon dilation before or after a traditional carotid stent placement. According to the applicant, the Paladin® System with IEP's 2018 and 2022 510(k) clearances were limited to balloon angioplasty and post-dilation of a deployed self-expanding stent. Thus, per the applicant, the Paladin® System with IEP cannot be used with a stent during stent deployment, leaving patients unprotected during the high-risk stent deployment phase of the procedure. The applicant stated that the Neuroguard IEP® System's integrated design, in contrast, provides 40-micron pore protection during both the stent deployment and post-dilation phases. In terms of device integration and impact, the applicant stated that the Paladin® System with IEP's balloon must be used with separate stenting systems, which requires additional catheter exchanges and therefore increases embolic risk, whereas the Neuroguard IEP® System consists of a stent, balloon, and filter on a single platform, providing comprehensive protection and eliminating exchanges that increase the risk of microemboli. The applicant also stated that the Neuroguard IEP® System received FDA PMA approval as a novel device with no predicate, and that its comprehensive integrated solution not only enhances protection but also improves procedural efficiency, which was validated by the more rigorous PMA process. The applicant also added that the Paladin® System with IEP's balloon was not widely commercialized in the U.S., as company records show no to minimal sales from 2021 to 2024.

Response: We appreciate the additional information from the applicant and commenters with respect to whether the Neuroguard IEP® System is substantially similar to existing technologies. However, we remain unclear that the Neuroguard IEP® System does not use the same or a similar mechanism of action as existing technologies. While the applicant and commenters describe differences between the Neuroguard IEP® System and other technologies that require a separate EPD, stent, and post-dilation balloon, we believe that the mechanisms of action for the Neuroguard IEP® System to perform individual tasks, like capturing debris, dilating a vessel, and expanding a stent against vessel walls, remain similar to that of existing EPDs, carotid stents, and post-dilation balloons. The applicant asserted that the Neuroguard IEP® System's integrated design, which allows for simultaneous deployment, is absent in other technologies, and that this design in addition to the smaller pore size captures more microemboli. However, the amount of microembolic material captured between EPD types refers to how well each technology performs that task. Thus, the difference in pore size between the EPD of Neuroguard IEP® System and other EPDs, their differential capabilities in capturing microemboli, and the potential impact on clinical outcomes are related to performance differences rather than differences in mechanism of action. Similarly, while the applicant states that by capturing more microemboli, the Neuroguard IEP® System will likely protect patients from strokes post-procedure, this relates to the assessment of substantial clinical improvement rather than the newness criterion. We also note that while, according to the applicant, the Neuroguard IEP® System's integrated design enables the EPD to be deployed during both the stenting and post-dilation phases, reducing the risks for thrombosis, this also relates to assessment of substantial clinical improvement rather than the newness criterion. In addition, while commenters described potential benefits in terms of the Neuroguard IEP® System's closed-cell design, vessel conformability, potential applications for treating complex patients, ease of use, or improving workflow efficiency, these do not describe a new mechanism of action. Since the stent of the Neuroguard IEP® System expands the carotid luminal diameter by propping open a narrow blood vessel physically and providing structural support to the vessel walls, its mechanism of action is similar to that of existing carotid stents. By the same token, the mechanism of action by which existing EPDs and the EPD in the Neuroguard IEP® System capture debris is fundamentally similar. Similarly, regarding the Paladin®

System with IEP, the mechanism of action by which the EPD of the Paladin® System with IEP captures and removes microemboli appears to be the same as that of the EPD of the Neuroguard IEP® System, as well as existing stents and EPDs. We note that we do not believe that the volume of sales is a relevant consideration for making the determination as to whether a product is considered ''new'' for the purposes of new technology add-on payments. Consistent with the statute and our implementing regulations, a technology is no longer considered ''new'' once it is more than 2 to 3 years old, and the costs of the procedures are considered to be included in the relative weights irrespective of how frequently the technology has been used in the Medicare population (89 FR 69126).

With regard to the applicant's comment about Eluvia™, we determined in the FY 2021 IPPS/LTCH PPS final rule that the Eluvia™ Drug-Eluting Stent uses a unique mechanism of action because the sustained release of paclitaxel combats restenosis for 12 to 15 months as compared to other drug-coated balloons or drug-coated stents that deliver drug to the artery for about two months (85 FR 58649). We disagree with the applicant's conclusions that our determination of a new mechanism of action for Eluvia™ means that addressing a treatment limitation constitutes a new mechanism of action. We note that Eluvia™ allowed for gradual degradation of the polymer to control the release of paclitaxel into the bloodstream, while stents that were commercially available before Eluvia™ lacked any mechanism of sustained and controlled release of paclitaxel. Like all EPDs in the market, the EPD of the Neuroguard IEP® System is designed with a filter basket that captures and traps microembolic materials. In this way, its mechanism of action is the same as that of existing EPDs. While existing EPDs are deployed alone and remain open during the entire procedure, and the EPD of the Neuroguard IEP® System is deployed selectively, they all use a basket-like component to catch microembolic materials. Similarly, despite the differences in the pore size of this basket-like component in the Neuroguard IEP® System and existing EPDs, they use the same method to stop microembolic materials from escaping into the bloodstream. Thus, the Neuroguard IEP® System's mechanism of action is the same as that of existing technologies because the mechanism by which each of its components performs a specific task is the same as that of existing technologies.

After consideration of the comments received, and for the reasons discussed, we believe that that the Neuroguard IEP® System uses a similar mechanism of action as existing technologies by using a balloon to dilate blood vessels physically, using a stent to support the vessel wall and keep the vessels open, and using an EPD to capture embolic materials. Furthermore, as discussed previously, the Neuroguard IEP® System and existing technologies map to the same MS–DRGs and treat the same disease, carotid artery stenosis, in the same patient population as existing carotid stent technologies and EPDs. Accordingly, because the Neuroguard IEP® System meets all three of the substantial similarity criteria, we believe that the Neuroguard IEP® System is substantially similar to existing carotid artery stents. In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date as the beginning of the newness period. Because carotid artery stents and EPDs have been on the market for many years, the 3-year anniversary for the Neuroguard IEP® System occurred prior to FY 2026. Therefore, the Neuroguard IEP® System does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2026. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2026, we are not summarizing comments received or making a determination on those criteria in this final rule.

j. 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.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for RYSTIGGO® and was granted approval to use the following procedure code effective October 1, 2025: XW013TB (Introduction of rozanolixizumab-noli monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 11). 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+.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18139), 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 stated that we were unclear as to what the specific differences are and whether they rise to the level of a new mechanism of action. We noted 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.[105] [106] We welcomed additional information about how the mechanism of action for RYSTIGGO® differs from other existing FDA-approved therapies, including FcRn inhibitors such as VYVGART®. We noted 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 noted 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 questioned 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 invited public comments on whether RYSTIGGO® is substantially similar to existing technologies and whether RYSTIGGO® meets the newness criterion.

Comment: The applicant submitted a public comment regarding the newness criterion. The applicant stated that RYSTIGGO® meets the newness criterion for new technology add-on payment status because it was just recently approved by FDA on June 26, 2023, and was not available for sale until July 20, 2023 and there are no other treatments for the disease or condition that RYSTIGGO® treats or diagnoses. The applicant noted that RYSTIGGO® is the first treatment approved by FDA specifically for patients with either AChR ab+ or MuSK ab+ gMG. The applicant also reiterated information from its application regarding its claim that RYSTIGGO® does not use the same or a similar mechanism of action compared to existing technologies to achieve a therapeutic outcome and does not treat the same or similar type of disease or patient population compared to existing therapies.

In response to CMS's request for additional information about how the mechanism of action for RYSTIGGO® differs from existing FDA-approved therapies, including FcRn inhibitors such as VYVGART®, the applicant stated that while technically, both RYSTIGGO® and VYVGART® are FcRn blockers, RYSTIGGO® was specifically studied for the MuSK ab+ patient population, and FDA granted an expedited review of the product for this subset of gMG patients, for which there was previously no other indicated product. The applicant also commented that RYSTIGGO® differs from IMAAVY® in that IMAAVY® is

[105] argenx US, 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.*

[106] 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.*

immuno-selective, only targeting IgG1 levels, while RYSTIGGO® targets IgG1, IgG2, IgG3, and IgG4 levels.

The applicant commented that while several treatments have been approved by FDA for gMG, including SOLIRIS®, ULTOMIRIS®, and VYVGART®, these treatments do not adequately assist those gMG patients with anti-muscle specific tyrosine kinase antibodies. In response to CMS's concern with regards to the applicant's assertion that RYSTIGGO® does not involve the treatment of the same or similar type of disease and the same or similar patient population because there are other standard of care treatment options, the applicant stated that RYSTIGGO® is a targeted therapy with a safety and efficacy profile established in a randomized clinical trial, as well as real world evidence. The applicant further stated that at the time RYSTIGGO® was approved, there were no other available approved treatments for gMG in adult patients who are MuSK ab+, and all other treatments for gMG cited by CMS have been used off-label. According to the applicant, RYSTIGGO® is now able to meet this patient population's need and as such, it is effectively the new standard of care for the MuSK ab+ patient population.

Response: We appreciate the additional information from the applicant. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for RYSTIGGO®, we agree with the applicant that RYSTIGGO® uses a unique mechanism of action for the treatment of MuSK ab+ gMG because at the time the new technology add-on application was submitted, it was the only FcRn inhibitor FDA-approved for the treatment of adult patients with gMG who are MuSK ab+. Therefore, we agree that RYSTIGGO® is not substantially similar to existing treatment options and meets the newness criterion, specifically for the MuSK ab+ gMG indication. We consider the beginning of the newness period to commence on July 20, 2023, the date on which RYSTIGGO® became commercially available.

However, we have concerns with regard to the substantial similarity criteria for RYSTIGGO® for the treatment of AChR ab+ gMG in adults. We note that the applicant has not provided any information to differentiate RYSTIGGO®'s mechanism of action from that of VYVGART®, and we therefore believe that the two technologies have the same or a similar mechanism of action as FcRn inhibitors approved for use in patients with AChR ab+ gMG. As there are many other treatment options for patients with AChR ab+ gMG, including VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®, we also believe that RYSTIGGO® does not treat a new patient population or disease with respect to AChR ab+ gMG. In addition, we agree with the applicant that RYSTIGGO® would be assigned to the same MS–DRG as existing technologies.

Because RYSTIGGO® for the treatment of adults with AChR ab+ gMG meets all three of the substantial similarity criteria, we believe that RYSTIGGO® is substantially similar to VYVGART® for this indication. Therefore, in accordance with our policy, we consider the beginning of the newness period for RYSTIGGO® to begin on December 17, 2021, the date on which VYVGART® received FDA marketing authorization for the treatment of adults with AChR ab+ gMG. Since the 3-year anniversary date of VYVGART®'s entry onto the market occurred prior to FY 2026, RYSTIGGO® for the treatment of adults with AChR ab+ gMG does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2026. We note that because we have determined that the technology does not meet the newness criterion for the treatment of adults with AChR ab+ gMG and therefore is not eligible for approval for new technology add-on payments for FY 2026 for this indication, we are not summarizing comments received or making a determination on the cost or substantial clinical improvement criteria for the AChR ab+ gMG indication in this final rule.

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 invited public comments on whether RYSTIGGO® meets the cost criterion.

Comment: The applicant reiterated that the cost criterion analysis submitted with the application demonstrates that RYSTIGGO® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, 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.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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®, which we summarized in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18140 through 18141).

After review of the information provided by the applicant and the public comments received in response to the New Technology Town Hall meeting, we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18141 through 18142) that we had 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 noted that the applicant also stated that 3,4-diaminopyridine treatments may have a mild to moderate effect. We further noted that, as mentioned previously, other therapies such as pyridostigmine, glucocorticoid therapy, and plasmapheresis are also available options for these patients, and we therefore questioned whether 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 questioned 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.[107] 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 noted 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 questioned 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 questioned if RYSTIGGO® is the only treatment option for patients with gMG who have failed conventional therapy.

We stated that 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 a number of prior therapies, excluding acetylcholinesterase inhibitors, but including corticosteroids, non-steroidal immunosuppressants, IVIg, and plasma exchange. However, we stated that it was 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 noted 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 noted are not published or peer-reviewed. We noted 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 were uncertain as to how significant the results are. We stated that 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-steroidal immunosuppressive therapy, steroids, and pyridostigmine. However, we noted 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 questioned whether RYSTIGGO® improves clinical outcomes relative to all previously available therapies. Given the 6-week duration of the trial, we also questioned how natural changes in symptoms were accounted for since symptoms can wax and wane in patients with gMG. We further noted 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 stated that we were 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 noted 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 noted that the study considered a 2-point difference in MG–ADL as a clinically meaningful improvement. We stated that 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 noted there were 21 MuSK ab+ patients in the studies submitted by the applicant. We further noted that the FDA Integrated Review for RYSTIGGO® indicated that 16 patients tested positive for the MuSK ab+ and we stated that we would appreciate clarification regarding this discrepancy in numbers. We noted

[107] Bril, 2023a, *op. cit.*

that in its Town Hall comment, 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 FDA. However, we questioned 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.[108] We also noted 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 noted 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 questioned how this difference may have impacted the placebo group's outcomes relative to 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 questioned if this difference in background therapy could have affected the outcomes, since oral corticosteroids were a permitted concomitant medication in the trial. We also noted that the trial excluded individuals with severe oropharyngeal or respiratory weakness, and we questioned 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.

We stated that 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 noted that the same article indicated no significant difference in MG–ADL between complement inhibitors and anti-FcRn treatments. Additionally, we noted that the analysis found that VYVGART® had the highest probability of being the best treatment, followed by RYSTIGGO®.[109] We noted that we did not receive any other evidence comparing complement inhibitors or anti-FcRn treatments with RYSTIGGO® to demonstrate improved outcomes. Therefore, we requested 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 noted 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 questioned how this analysis demonstrates RYSTIGGO® improves clinical outcomes relative to previously available therapy for patients with MuSK ab+ gMG.

We also noted 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 did not provide a comparison of administration to other available therapies. We stated that 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 invited public comments on whether RYSTIGGO® meets the substantial clinical improvement criterion.

Comment: A few commenters expressed general support for RYSTIGGO®'s eligibility for new technology add-on payments. A commenter stated its belief that use of RYSTIGGO® for the FDA-labeled indications would require hospitals to incur costs that, without a new technology add-on payment, would have to be fully absorbed by the treating hospital. The commenter stated that the new technology add-on payment mechanism was created to eliminate the limitations in access to new therapies due to lack of reimbursement in the inpatient setting.

Response: We thank the commenters for their input.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant also reiterated information from its application regarding the claim that RYSTIGGO® meets the substantial clinical improvement criterion because it offers a treatment option for gMG patients unresponsive to, or ineligible for, currently available treatments, and that, RYSTIGGO® offers further clinical improvement in addition to standard of care therapies for adult patients with gMG.

In response to CMS's note that there are other therapy options for patients with MuSK ab+ gMG, the applicant reiterated RYSTIGGO® is the first approved treatment for gMG in adult patients who are MuSK ab+, and all other treatments are used off-label. In addition, the applicant discussed a case report of an adult patient with MuSK ab+ gMG that illustrated that the patient was responsive to and tolerant of 3,4-diaminopyridine (DAP). According to the applicant, the case report qualifies as Class IV evidence and is a single observational study without controls. The applicant further stated that, while in the abstract it would be ideal if the safety and efficacy of 3,4-DAP in patients with MuSK ab+ gMG were confirmed in randomized trials, the evidence to-date, along with real world data and patient reports, supports the conclusion that RYSTIGGO® is unique in being the first drug to treat the gMG MuSK ab+ population.

In response to CMS's question whether the evidence provided demonstrates that there is a population of patients with gMG with no other treatment options, which refers to the 10 to 20 percent of patients with gMG whose disease was not responsive to and not treated by conventional therapies due to inadequate response or intolerable side effects, the applicant stated that the 10 to 20 percent of patients with gMG referenced are those patients who are MuSK ab+, and thus did not have effective treatments

[108] U.S. FDA CDER, 2023, *op. cit.*

[109] Saccà, 2023, *op. cit.*

available until the approval of RYSTIGGO®.

In response to CMS's question if RYSTIGGO® is the only treatment option for patients with gMG who have failed conventional therapy, given that some standard of care treatment options for patients were excluded from the MycarinG study, including rituximab products, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®, the applicant restated that RYSTIGGO® was the first treatment option approved for the MuSK ab+ patient population and noted rituximab is not indicated for the treatment of MG even if it is sometimes used off-label in the MuSK ab+ patient population. According to the applicant, rituximab, an anti-CD20 mAb, is reserved for patients who are refractory to conventional oral immunosuppressants and used as part of an escalation therapy, which is supported in the International Consensus guidance. The applicant stated that safety concerns related to the risk of virus-related progressive multifocal leukoencephalopathy remain. Per the applicant, biologics have added to the more targeted treatment options for gMG, with SOLIRIS® being a first-in-class humanized mAb targeting the terminal complement complex, blocking the enzymatic cleaving of complement 5 (C5), and thereby preventing the activation of the complement complex. The applicant further stated that due to lack of complement involvement in the pathophysiology of MuSK ab+ patients with gMG, this difficult-to-treat subgroup of patients does not benefit from C5 inhibitor treatment. The applicant commented that immunosuppressive treatment of gMG is dominated by untargeted treatments, such as steroids and nonsteroidal immunosuppressants, and that both steroids and nonsteroidal immunosuppressants target the immune system non-specifically with the goal of reducing autoimmune reactivity in MG. The applicant stated that the treatments with these agents are associated with well-documented short-term as well as long-term toxicities, and that the delayed beneficial effect combined with early onset of tolerability issues frequently discourages patients from continuing therapy. The applicant further commented that both plasma exchange (PLEX) and IVIg are considered for patients with gMG who have exhausted all of their other treatment options, and whose clinical status is deteriorating despite ongoing immunosuppressive and acetylcholinesterase inhibitors (AChEI) therapies. According to the applicant, although treatment with PLEX or IVIg is mentioned in the International Consensus guidance for management of MG, neither treatment is approved in the U.S. for gMG. The applicant stated that the availability of IVIg (including shortages and increasing demand over supply) and repetitive cycles of IVIg and PLEX administered in a hospital setting are burdensome and time consuming for patients, caregivers, and healthcare professionals, and are not considered a viable long-term treatment option for the majority of patients with MG.

In response to CMS's question on how a subgroup analysis of the MycarinG study, in the Vu et al. (2023) abstract, provides evidence that RYSTIGGO® is the only treatment option for patients unresponsive to the prior standard of care, the applicant stated that MycarinG is a pivotal Phase III trial that led to the approval of RYSTIGGO®, and Phase III trials typically don't include head-to-head analyses. The applicant stated that the MycarinG study demonstrates that RLZ is a possible option for patients who have had or have not had prior therapies. In response to CMS's further concern about why AChEIs were excluded from this subgroup analysis even though they are part of the standard of care for MG, the applicant stated that ''prior therapies (0 1, 2 prior MG therapies excluding AChEI)'' refers to patients who had been on two therapies that did not include AChEIs, not that the patient had not received AChEIs. The applicant clarified that this includes patients who might have received three prior therapies (for example AChEI, corticosteroids, and non-steroidal immunosuppressive therapies). According to the applicant, patients in the zero prior therapy group could have received AChEI but no other treatment and 86 percent of patients in MycarinG were on AChEIs.

With regards to the concern that two poster presentations (Bril et al., 2023b and Habib et al., 2024b) do not report statistically significant results, the applicant stated that the Bril et al. (2023b) poster did not report statistical significance because the poster included pooled extension data, so there was no placebo group to compare against, and therefore, no statistical test. Similarly, the applicant stated that the Habib et al. (2024b) poster did not report statistical significance given the reported significant change from baseline at day 43 in muscle weakness fatigability and physical fatigue, confirming the Bril et al. (2023b) study. Per the applicant, the Habib et al. (2024b) poster further shows the clinical meaningfulness for those data by applying the meaningful change thresholds that were determined post hoc. However, according to the applicant, because of the novel nature of the Myasthenia Gravis Symptoms Patient Reported Outcome (MGSPRO), the threshold of responder is a range, as described in the poster. The applicant stated that because both ends of the range of the threshold were applied, statistical significance does not apply here. The applicant stated that CMS posed several questions about the MycarinG study, which allowed trial participants to remain on standard of care therapies such as non-steroidal immunosuppressive therapy, steroids, and pyridostigmine, but not on other treatments, such as rituximab products, VYVGART®, ULTOMIRIS®, ZILBRYSQ®, and SOLIRIS®. In response to CMS's questions about the lack of comparison to other treatments, the applicant stated it appreciates that it would be ideal if all study designs were identical, allowing for both head-to-head comparative results between different therapies and dose-response results in tests of identical duration. Per the applicant, there was a clearing out period for some of these therapies because, while no head-to-head studies have been conducted, continued use would potentially lead to immunosuppression that would be more severe and lead to other major side effects. In response to CMS's questions about the 6-week trial duration given patient symptom variability, the applicant stated that the reason the study included 6 weeks of administration was that IgG levels were tracked and showed a 70 percent reduction at 6 weeks. In response to CMS's questions about the difficulty in comparing results with 8-week studies (such as MycarinG and MG0004) or 16-week studies (MG0007), the applicant stated that the reason for the 8 weeks of observation in the pivotal trial and then 16 weeks in the open-label extension study is that patients were only reinitiated with therapy based on emerging symptoms, which speaks to the long-lasting durability of the product.

In response to CMS's question about whether there is a dose-response effect and the definition of a clinically meaningful improvement, the applicant stated the study considered a two-point difference in MG–ADL as a clinically meaningful improvement. The applicant reiterated that more patients achieved meaningful symptom expression (MSE) in both rozanolixizumab groups than in the placebo group, and the change from baseline to day 43 in MGII was greater in both rozanolixizumab groups than in the placebo group.

A commenter provided a response to CMS's concern on the validity of the endpoints used in the RYSTIGGO® study, including the rationale for using MG–ADL as the primary endpoint. The commenter stated that the choice of endpoints is largely driven by FDA preferences, and while sponsors may choose to select endpoints other than those outlined as acceptable within a review toward approval, few would assume the risk in doing so. The commenter stated that it is aware that FDA's preferences on specific endpoints evolves over time and could change while a study incorporating an older endpoint is in progress. The commenter asserted that, while it believes there are often flaws in FDA's determination on endpoints for specific rare and ultra-rare conditions, once a study has started (and certainly after FDA has granted approval based on that endpoint), CMS should not make an independent decision impacting access based on choice of endpoints. The commenter further stated that CMS's analyses related to RYSTIGGO® focused primarily on whether there is a particular subpopulation for which the treatment under review offers a significant improvement over other treatments. The commenter stated that these inquiries appeared to examine whether other products existed and the extent to which there was a direct comparison between those therapies and the product under review. The commenter stated the time from approval to expiration of any new technology add-on payment period is 3 years, far too short for any comparative effectiveness study. The commenter stated its belief that the expectation of data that unequivocally demonstrates superiority of a newly approved treatment over existing branded therapies is simply not realistic.

In response to CMS's question with respect to the discrepancy in numbers between 21 MuSK ab+ patients included in the MycarinG study submitted by the applicant and 16 patients tested positive for the MuSK ab+ in the FDA Integrated Review for RYSTIGGO®, the applicant clarified that the 21 MuSK ab+ patients is the number of historical MG-specific autoantibody status patients, and the baseline MG-specific autoantibody status was 16 patients.

In response to CMS's question if the results of the MycarinG study are generalizable to the Medicare population due to the small sample size,[110] the applicant commented that MuSK ab+ gMG is a rare disease, and limited U.S. enrollment is not unusual in global trials for rare conditions. The applicant commented that FDA's acceptance of the sample size and international enrollment is consistent with rare disease norms. Additionally, a commenter stated that it urges CMS to accept the manufacturers assertion that small study samples are not only common to rare disease studies but that they are accepted by FDA to support approval. The commenter stated that with respect to generalizability to the Medicare population, it urges CMS to recognize that recruitment of patients over age 65 has been a challenge for researchers regardless of patient population size, and additionally, Medicare's beneficiary population extends beyond those over age 65 to include disabled individuals. Per the commenter, approximately 10 percent of individuals qualifying for SSDI payments (and subsequently eligible for Medicare benefits) are disabled due to a condition of nervous system and sense organs such as MG.

In response to CMS's concern that in the MycarinG study not all efficacy outcomes were statistically significant within the MuSK ab+ population, the applicant stated that as a rare disease with a small patient population in the pivotal study, it is not unusual that some endpoints may not demonstrate statistical significance. The applicant acknowledged that the QMG score difference between RYSTIGGO® and placebo in the MuSK ab+ subgroup did not reach statistical significance, as the 97.5 percent CIs crossed zero. The applicant stated that the MG–ADL and MGC endpoints were statistically significant or numerically favored RYSTIGGO®. According to the applicant, the small size of the MuSK ab+ subgroup (n=21) results in limited power, but multiple endpoints consistently showed improvement. The applicant stated that this trend across endpoints supports clinical benefit, notwithstanding the absence of ideal statistical uncertainty. The applicant reiterated that as with many rare disease indications, the limited power of the studies necessarily will constrain the nature of the data, and FDA was comfortable approving the biologic and found the available statistical evidence sufficient.

In response to CMS's concern that in the MycarinG study there was a difference in the disease severity between the MuSK ab+ patients in the placebo and treatment arms, the applicant stated that patients were randomized. The applicant also stated that consistent improvements across MG–ADL, QMG, and MGC (in the context of randomization) suggest efficacy notwithstanding baseline severity differences.

In response to CMS's question on whether the difference in corticosteroid use between treatment and placebo groups in the clinical trial could have impacted the trial results, the applicant commented that this variability is inevitable in rare disease clinical trials that necessarily involve relatively small numbers of patients. The applicant further stated that the extensive data analysis that followed the trial did not produce any suggestion that corticosteroid use influenced trial results. The applicant commented that, whether or not corticosteroids could enhance response and amplify the treatment effect, RYSTIGGO® still demonstrated a benefit over placebo despite corticosteroids being allowed across arms. In response to CMS's question on the choice of the clinical study design to exclude individuals with severe oropharyngeal or respiratory weakness, and whether the trial results would apply to such patients, the applicant commented that while additional data or trials including this subgroup would enhance relevance for the Medicare population with more severe disease, the clinical trial design that was accepted by FDA did not require the inclusion of these patients to demonstrate efficacy.

The applicant commented in response to CMS's concerns about a meta-analysis comparing innovative therapies in MG. In response to CMS's question why there was no significant difference in MG–ADL between complement inhibitors and anti-FcRn treatments, the applicant stated that the meta-analysis suggests that anti-FcRn therapies, including RYSTIGGO®, are among the most promising emerging treatments for gMG based on multiple outcome measures, with statistically superior results to complement inhibitors in QMG, MG-QoL15, and a trend toward improved MGC. In response to CMS's requested additional information comparing RYSTIGGO® to other therapies, the applicant stated that, notwithstanding the conclusions of the meta-analysis, the totality of available evidence for RYSTIGGO®—the meta-analysis by Saccà et al. (2023), differentiation in patient populations treated (particularly MuSK ab+), subcutaneous route with home administration, rapid onset of effect, and favorable safety profile without the need for complement blockade monitoring—supports the conclusion that RYSTIGGO® represents a substantial clinical improvement over existing therapies for appropriate patients with gMG. In response to

[110] U.S. FDA CDER, 2023, *op. cit.*

CMS's question of how the meta-analysis demonstrates improved clinical outcomes without a comparison to current therapies in patients with MuSK ab+ gMG, the applicant stated its view that the clinical trial data in both the pivotal studies and from the meta-analysis contain sufficient evidence to conclude that RYSTIGGO® offers clinical superiority over the existing standard of care for the MuSK ab+ patients at the time of approval. Further, the applicant commented that the meta-analysis included two clinical trials with MusK ab+ patient data, MycarinG and ADAPT, while the remaining five trials primarily enrolled patients with AChR ab+ gMG. The applicant stated that it agrees that the meta-analysis, as published, does not allow for a subgroup-level indirect comparison of RYSTIGGO® with standard of care therapies specifically in the MuSK ab+ population. According to the applicant, the meta-analysis did not include trials assessing standard of care therapies (for example, corticosteroids, cholinesterase inhibitors, or non-steroidal immunosuppressants) in MuSK ab+ gMG. The applicant stated that this gap reflects a broader evidence limitation in the field but does not detract from the conclusions of the literature and clinical results demonstrating that RYSTIGGO® was the first FDA-approved treatment specifically indicated for MuSK ab+ gMG in adult patients. The applicant also stated that the evidence demonstrates that patients with MuSK Ab+ gMG often do not respond to cholinesterase inhibitors and may have intolerances or inadequate responses to corticosteroids and immunosuppressants. The applicant further stated the MycarinG study included a subgroup of 21 patients with MuSK ab+ gMG, representing a rare disease cohort. The applicant noted that these patients demonstrated rapid onset of clinical improvement in MG–ADL and MGC scores by Day 8, numerically greater improvements versus placebo across multiple endpoints (MG–ADL, MGC, QMG, PRO measures), and an MG–ADL responder rate of 100 percent in both RYSTIGGO® treatment arms compared to 14 percent in placebo. Per the applicant, these results were achieved in the context of a randomized, placebo-controlled, double-blind phase 3 trial, representing the highest level of evidence currently available for this subgroup. The applicant stated that in summary, the clinical trials reflect the clinical benefits of RYSTIGGO® for the MuSK ab+ rare disease population notwithstanding the absence of standard of care-controlled RCTs.

In response to CMS's request for additional information comparing RYSTIGGO®'s administration method to other therapies and regarding 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), the applicant commented that patient preference is directly related to an improvement in the quality of the patient's life when on therapy, § 412.87(b)(1)(ii)(C)(6), and patient preference is directly related to greater medication adherence. The applicant stated that patient preference is implicated by the regulatory factors that CMS must consider in evaluating clinical superiority. The applicant commented that RYSTIGGO®'s subcutaneous delivery with optional home administration offers potential convenience over IV therapies like IVIg or PLEX, which require clinic settings.

Response: We thank the applicant and the commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we continue to have concerns as to whether RYSTIGGO® for the treatment of MuSK ab+ gMG meets the substantial clinical improvement criterion to be approved for new technology add-on payments. We note that whether a particular treatment improves outcomes does not demonstrate that the treatment offers an option for patients with no other options. We also note that being the first treatment with a specific (narrower) indication, does not singularly demonstrate substantial clinical improvement, particularly when there are other treatments available which are considered the standard of care, and which have broader indications. Therefore, we continue to question that the evidence provided demonstrates both that there is a population of patients with MuSK ab+ gMG with no other treatment options, and that RYSTIGGO® offers further clinical improvement over currently available standard of care therapies for adult patients with MuSK ab+ gMG. We also did not receive data to indicate that potential confounders such as differences in disease severity and other therapies received among the treatment groups in MycarinG could not have impacted the study results. We also continue to question the assertion of improved clinical outcomes with RYSTIGGO® compared to other therapies without adequate comparison data to other therapies in the MuSK ab+ patient population. In addition, we question whether the clinical outcome results provided by the applicant adequately distinguish the effect of RYSTIGGO® from natural changes in symptoms.

The applicant and another commenter highlighted that the study design, including endpoints, sample size, and international enrollment, was accepted by FDA. As previously stated, while FDA has regulatory responsibility for decisions related to marketing authorization, 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 efficacy on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population. In addition, with regard to the generalizability of the MycarinG study results to the Medicare population, while we acknowledge that Medicare does include beneficiaries under the age of 65 years who are disabled, we are unclear that the MycarinG study included any patients generalizable to disabled Medicare patients since it excluded patients with more severe disease (severe oropharyngeal or respiratory weakness). Also, as stated previously, all MuSK ab+ patients in the treatment arms of the MycarinG study had mild or moderate disease. Given this, and that only one patient who received RYSTIGGO® was 65 years or older, the age of the majority of the Medicare population, we remain unclear that the patient population of the MycarinG trial represented the Medicare population that is eligible for this technology.

Finally, we note the applicant did not provide any evidence linking patient preference to greater medication adherence or greater quality of life for patients treated with RYSTIGGO®, nor any comparison of these outcomes to other treatment options. Therefore, we disagree that the administration method for RYSTIGGO® for patients with MuSK ab+ gMG demonstrates that the technology significantly improves clinical outcomes over other available treatments.

After consideration of all the information received from the applicant, as well as the public comments we received, we are unable to determine that RYSTIGGO® for patients with MuSK ab+ gMG represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule, and therefore, we are not

approving new technology add-on payments for RYSTIGGO® for FY 2026.

k. 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 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), and 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.

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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.
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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18144), we stated we had 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 stated we were 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 questioned 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 noted that the applicant stated that the mechanism of action of synthetic grafts is immediate revascularization, and we questioned whether that is not also the mechanism of action of SYMVESS™ and/or autologous vein grafts.

We invited 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.

Comment: The applicant submitted a public comment regarding the newness criterion. The applicant reiterated 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 therefore, the technology meets the newness criterion. In response to CMS's question about how SYMVESS™' composition is associated with regenerative properties and how these properties are associated with its mechanism of action, the applicant asserted that the composition of SYMVESS™ is unique amongst vascular conduits, which leads to its regenerative properties and new mechanism of action. Specifically, the applicant stated that unlike native veins and arteries, SYMVESS™ is a unique vascular conduit that lacks living cells and elastin. The applicant explained that SYMVESS™' absence of living cells prevents cellular injury and inflammatory responses upon implantation, reducing risks like fibrosis, neointimal hyperplasia, and vessel occlusion. The applicant added that the lack of elastin contributes to SYMVESS™' resistance to calcification, as calcification in native vessels often occurs near elastin proteins. The applicant further stated that SYMVESS™ contains over 40 extracellular matrix molecules typically found in the human aorta, including fibronectin, vitronectin, and collagens (types I and III), which support vascular cell adhesion, survival, migration, and integration. The applicant explained that these human extracellular matrix proteins in SYMVESS™ interact with vascular cells through specific binding motifs, facilitating cellular adhesion, migration, differentiation, and repopulation and transforming the conduit into a living blood vessel capable of consistent blood flow, long-term durability, and self-repair. The applicant further asserted that SYMVESS™' composition, which does not contain synthetic materials or xenogeneic proteins, facilitates cellular ingrowth, remodeling, and integration without triggering foreign body reactions or fibrosis. The applicant explained that because SYMVESS™ transforms into tissue resembling the patient's native vascular structure post-implantation, critical cellular repopulation occurs, as proteins like collagen have a finite half-life in vivo, and the conduit does not then mechanically fail due to foreign proteins. The applicant emphasized that this cellular integration and matrix upkeep are key to SYMVESS™' therapeutic effectiveness and mechanical resilience over time. The applicant stated that long-term follow-up from the V005 clinical study demonstrate SYMVESS™' mechanical durability and stability in treating extremity vascular trauma, with excellent limb salvage rates, low infection incidence, and no spontaneous rupture over 3 years of follow-up, across a high-risk population with many severe injuries and contaminated wounds. The applicant further stated that duplex ultrasound assessments through 36 months demonstrated stable conduit dimensions without trends toward dilation or stenosis.

In response to CMS's question as to how the association between SYMVESS™' regenerative properties and mechanism of therapeutic action differs from that of autologous vein grafts, the applicant asserted that there are important differences between SYMVESS™ and autologous vein grafts related to composition, mechanism of action, and regenerative properties after implantation. The applicant stated that SYMVESS™ has greater mechanical strength than autologous vein grafts, making it a more effective option for arterial implantation. The applicant further explained that, while autologous vein grafts have a rupture strength of approximately 1,600 mmHg, SYMVESS™ has a rupture strength exceeding 3,000 mmHg, comparable to native arteries. The applicant asserted that SYMVESS™' mechanical strength prevents over-distension and maintains its original diameter post-implantation, whereas autologous vein grafts become distended under arterial pressure, leading to cellular damage and death, which triggers inflammatory and pro-fibrotic responses, neo-intimal hyperplasia, and eventual graft occlusion. The applicant further explained SYMVESS™ avoids over-proliferation in the vascular wall due to its acellular structure, absence of an intima, and non-inflammatory protein matrix, which collectively prevent cellular over-proliferation and neo-intimal hyperplasia, ensuring long-term functionality without the need for additional interventions.

In response to CMS's question about whether physiological changes, such as arterialization, cellular repopulation, and fibrosis, that occur after a conduit is implanted should be considered part of SYMVESS™' mechanism of action, the applicant stated that these physiological changes are directly part of SYMVESS™' mechanism of action and support its ability to provide durable blood flow to injured extremities. The applicant stated that SYMVESS™' composition of human proteins drives cellular responses post-implantation and is central to its mechanism of action. The applicant also stated that multiple publications have not observed fibrosis, which can be triggered by synthetic materials and the production of foreign-body giant cells, after SYMVESS™ implantation. In addition, the applicant stated that SYMVESS™ conduits' physiological transformation after implantation closely mimics native vascular tissue, which cannot be achieved with synthetic grafts which remain inert and foreign to the body.

In response to CMS's question whether immediate revascularization is not also the mechanism of action of SYMVESS™ and/or autologous vein grafts, the applicant asserted that SYMVESS™' mechanism of action is the sustained and durable blood flow after implantation made possible by its unique human protein composition and resultant mechanical and biological properties. Per the applicant, this is inherently different from that of synthetic grafts, which cannot interact with human cells in the way that SYMVESS™ does, and from autologous vein grafts, which create extensive cellular damage and death after implantation which impairs the ability of the vein to maintain patency due to endothelial and smooth muscle damage. The applicant stated that SYMVESS™' immediate physiological effect of implantation for revascularization is restoration of blood flow, which would be similar to the effect of implanting any tubular conduit, regardless of material or composition, into arterial circulation. The applicant further explained that immediate restoration of blood flow is not the important mechanism of action and associated clinical benefit of an arterial conduit, since it may not be a durable benefit for the patient. The applicant asserted that any conduit's true therapeutic effect, and hence its mechanism of action, lies in its long-term functionality and maintained post-implantation blood perfusion within the body. The applicant reiterated that SYMVESS™' composition (both what it contains in terms of proteins that interact with cells, and what it lacks in terms of cellular content) contributes to its mechanism of action as a durable conduit that supports cellular repopulation and sustained mechanical function while avoiding cellular damage and inflammation at the time of implantation. The applicant also reiterated long-term outcomes from the V005 study regarding SYMVESS™' durability.

Several commenters also voiced support for SYMVESS™ and asserted that SYMVESS™ has a different mechanism of action than synthetic grafts. A commenter asserted that SYMVESS™ operates through a targeted mechanism of action designed to improve blood flow, vessel wall stabilization, capacity for remodeling, and long-term viability. Other commenters described its immediate availability similar to that of synthetic grafts but stated it has a unique mechanism of action which enables integration into native vasculature. Another commenter provided its personal experience that imaging of patients post-SYMVESS™ repair often reveals no visible graft. Per the commenter, this suggests natural tissue integration and effective healing, which the commenter has not seen with other conduits. Other commenters stated that due to its acellular nature, SYMVESS™' unique composition avoids cellular damage post-implantation, enabling better interaction with human cells, and maintaining patency, which drives its distinct regenerative properties compared to other vascular conduits.

Response: We appreciate the additional information from the applicant and commenters with respect to whether SYMVESS™ is substantially similar to existing technologies. However, we disagree with the applicant and commenters that SYMVESS™ has a unique mechanism of action compared to currently available synthetic grafts. While the applicant asserted that SYMVESS™ has a novel composition, we note that, as stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58847), the composition of a technology does not represent the mechanism of action. Further, we note the applicant's assertions that SYMVESS™'s mechanism of action is the restoration and maintenance of durable blood flow through the conduit post-implantation, achieved through a combination of immediate revascularization and long-term cellular repopulation and remodeling, and that SYMVESS™'s regenerative properties, including cellular repopulation, matrix remodeling and tissue integration are central to SYMVESS™'s mechanism of action and therapeutic effectiveness. However, we note that, per FDA, definitive studies that characterize the behavior of SYMVESS™ and how long it would take for cells to migrate and repopulate the graft have not been conducted, and that the exact mechanism of action has not been established.[111] [112] We remain unclear that these potential downstream effects are critical to the way SYMVESS™ provides for urgent arterial repair following extremity vascular trauma to avoid limb loss. Furthermore, we disagree with the applicant that SYMVESS™'s avoidance of cellular damage and inflammatory responses represents a novel mechanism of action. While these attributes may reduce complications such as fibrosis and neointimal hyperplasia, they do not change the fact that SYMVESS™ functions as a vascular conduit by facilitating blood flow, similar to other vascular grafts. Similarly, the long-term clinical results described by the applicant to demonstrate mechanical durability, patency, and low rates of complications relate to SYMVESS™'s clinical outcome and not mechanism of action. Similarly, with respect to the comments by several commenters that the absence of visible grafts in imaging studies post-SYMVESS™ implantation suggest natural tissue integration and effective healing, we note that this observation may reflect SYMVESS™'s biocompatibility and regenerative properties, but it does not, on its own, establish a novel mechanism of action. Tissue integration and remodeling are expected outcomes for many vascular conduits, as stated previously, and are influenced by the material and design of the graft rather than representing a new therapeutic mechanism.

After review of the information provided in the comments, including the applicant's assertions regarding SYMVESS™'s composition, post-implantation healing characteristics, and mechanism of action, we disagree with the applicant that the evidence provided demonstrates that SYMVESS™ has a unique mechanism of action compared to previously available technologies. Because we agree with applicant that SYMVESS™ will be assigned to the same MS–DRGs and used to treat the same type of disease in a similar patient population as existing technologies for treating significantly damaged arteries due to traumatic injuries, SYMVESS™ meets all three of the substantial similarity criteria. Therefore, we believe SYMVESS™ is substantially similar to currently approved or cleared synthetic grafts, and we consider the beginning of the newness period for SYMVESS™ to begin on the date on which those existing synthetic grafts received FDA marketing authorization. Since those technologies have been on the U.S. market for longer than 3 years, SYMVESS™ does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2026. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and, therefore is not eligible for approval for new technology add-on payments for FY 2026, we are not summarizing comments received or making a determination on those criteria in this final rule.

[111] SYMVESS. USPI Section 12: Clinical Pharmacology, p. 10.

[112] December 18, 2024 Clinical Review Memo—SYMVESS, *https://www.fda.gov/media/185229.*

l. 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 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.

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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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18150), we noted 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 noted that synovial sarcoma is a type of STS. Consequently, we questioned 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 invited public comments on whether TECELRA® is substantially similar to existing technologies and whether TECELRA® meets the newness criterion.

Comment: The applicant submitted a public comment reiterating that

TECELRA® meets the newness criterion because it 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, and the only therapy studied specifically in the synovial sarcoma patient population and FDA-approved for the treatment of synovial sarcoma. In response to CMS's question about whether existing treatment 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®, the applicant stated that existing treatments used for STS do not treat the same, or similar, patient population as TECELRA®. The applicant explained that STS is a broad and heterogeneous group of solid tumors with more than 50 different histologic subtypes of STS identified, differing widely in morphology, genetic aberrations, and expression of tumor antigens. The applicant submitted a review article by Beck et al. (2009),[113] which stated that synovial sarcoma is a distinct subtype of STS with a pattern of dysregulated gene expression and a cluster that separates it from other STS. Specifically, the applicant stated that Beck et al. (2009) explained that synovial sarcoma has a unique gene expression that includes increased expression of genes associated with neural differentiation, the retinoic acid pathway, and epidermal and fibroblast growth factor receptor signaling pathways. The applicant further explained that, given the lack of data and FDA-approved synovial sarcoma-specific therapies, the NCCN Guidelines recommend systemic therapies for patients with unresectable recurrent or metastatic disease while acknowledging that the benefits of systemic therapy are very limited. The applicant stated that the SPEARHEAD–1 trial studied TECELRA® in a targeted population, of which the majority (44 out of 52) of patients had synovial sarcoma. The applicant added that the SPEARHEAD–1 trial was unique in the STS field because it was designed to utilize the specific tumor antigen (MAGE–A4) expression expressed in 70 percent of the synovial sarcoma patient population. Given the results of the SPEARHEAD–1 trial, the applicant asserted that TECELRA® is the only product in the recently updated NCCN Guidelines specifically recommended for synovial sarcoma.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for TECELRA®, we agree with the applicant that TECELRA® uses a unique mechanism of action because its modified T-cells target and destroy MAGE–A4 expressing cancer cells in 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. We also agree with the applicant that TECELRA® is the only synovial sarcoma therapy assigned to MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-Cell and Other Immunotherapies). Therefore, we agree with the applicant that TECELRA® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on August 1, 2024, the date on which TECELRA® received FDA market authorization 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.

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.

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[113] Beck, A.H., West, R.B., & van de Rijn, M. (2009). Gene expression profiling for the investigation of soft tissue sarcoma pathogenesis and the identification of diagnostic, prognostic, and predictive biomarkers. *Virchows Arch* 456(1): 141–151. *https://doi.org/10.1007/s00428-009-0774-2.*

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®.
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

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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 invited public comments on whether TECELRA® meets the cost criterion.

Comment: The applicant reiterated that the four cost criterion analyses submitted with its application demonstrated that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, and therefore, TECELRA® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under all scenarios. Therefore, 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).[114] 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.

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[114] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.
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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18152), after review of the supporting evidence provided by the applicant, we stated we had 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 noted 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 noted that synovial sarcoma is a subtype of the broader STS group. According to the applicant, there were no therapies approved by 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 questioned 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 percent have been reported.[115] We noted that while patients in the SPEARHEAD–1 study received multiple

[115] 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.

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 questioned 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, we stated that 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).[116] [117] [118] [119] 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 noted that patients with unresectable or metastatic synovial sarcoma treated with TECELRA® demonstrated a mOS of 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 noted that the mOS for SPEARHEAD–1 non-responders was comparable to existing therapies, and we questioned 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 noted that TECELRA® is indicated for patients with tumors expressing the MAGE–A4 tumor antigen, and we questioned 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 noted 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 questioned 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, we stated that 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 stated we were 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 stated we were 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 questioned the basis for this claim as the applicant did not provide any supporting evidence.

We invited public comments on whether TECELRA® meets the substantial clinical improvement criterion.

Comment: Several commenters stated support for the approval of TECELRA® for the new technology add-on payment program. A few commenters further stated that approval would allow for increased patient access to this new therapy. A few commenters also underlined their support for approval by stating TECELRA® is an innovative, significantly advanced and meaningful therapy that addresses an unmet need in the treatment of synovial sarcoma, an ultrarare cancer accounting for <10 percent of all STS, and asserted that new technology add-on payments for TECELRA® would make it financially feasible for hospitals to provide innovative care that improves patient outcomes.

Response: We thank the commenters for their input and have taken it into consideration in determining whether TECELRA® meets the substantial clinical improvement criterion as discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. The applicant reiterated that TECELRA® meets the substantial clinical improvement criterion because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments and significantly improves clinical outcomes relative to previously available services or technologies. In response to CMS's concern whether 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, the applicant stated that advanced synovial sarcoma patients have limited treatment options because, as they experience disease progression, patients develop resistance, or in some cases intolerance, to treatment. The applicant also reiterated that the current treatment options listed in the NCCN Guidelines were not studied or approved specifically for the treatment

[116] 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.*

[117] 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.*

[118] 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.*

[119] 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.*

of synovial sarcoma. The applicant asserted that other current treatment options have a minimal impact on ORR and OS in this patient population. The applicant further explained that due to the broad and heterogenous subtypes of STS, clinical studies face challenges in enrolling patients for only one subtype due to limited numbers. The applicant stated that studies like PALETTE (44 out of 369 patients had SyS) and REGOSARC (27 out of 182 patients had SyS) provide limited data for synovial sarcoma, leaving clinicians reliant on limited results applicable to synovial sarcoma for treatment decisions. The applicant reiterated that the SPEARHEAD–1 clinical trial studied TECELRA® in heavily pretreated patients, many of whom had failed multiple prior therapies. The applicant asserted that, given that the SPEARHEAD–1 participants failed multiple prior lines of treatment and were no longer eligible for other treatment options due to toxicity, it is reasonable to conclude that this patient population is unresponsive to or ineligible for other currently available treatment options.

In response to CMS's concern that it was unclear whether patients with unresectable or metastatic synovial sarcoma who are unresponsive to existing systemic therapies after previous 1L treatments are unresponsive to or ineligible for other existing treatments, such as trabectedin, in which higher response rates have been reported, the applicant stated that higher response rates for other existing treatment options have not been reported. The applicant asserted that TECELRA® demonstrated a significant clinical improvement for synovial sarcoma patients by achieving a 43.2 percent ORR compared to historical controls, such as trabectedin (up to 12.3 percent) and pazopanib (up to 18.9 percent). The applicant further stated that the higher ORR rates (27 to 51 percent) referenced by CMS were not specific to synovial sarcoma, but rather pooled analyses of other sarcoma subtypes, with synovial sarcoma showing much lower response rates (5.9 percent for trabectedin). The applicant stated that a meta-analysis of trabectedin and pazopanib reported similar results in patients with metastatic synovial sarcoma, with trabectedin and pazopanib producing an ORR of 7 and 13.2 percent in clinical trials and 12.3 and 18.9 percent in real-world studies, respectively. The applicant reiterated that the SPEARHEAD–1 trial for TECELRA® used a benchmark ORR of 18 percent based on historical second-line therapies and agreed upon by FDA, and TECELRA®'s ORR significantly exceeded this benchmark, underscoring its efficacy in treating heavily pretreated synovial sarcoma patients.

In response to CMS's concern that the SPEARHEAD–1 study allowed bridging therapy including pazopanib, trabectedin, ifosfamide, or doxorubicin, between leukapheresis and lymphodepletion at the investigators' discretion putting into question whether the results can solely be attributable to TECELRA®, the applicant reiterated that TECELRA® provides a treatment option for synovial sarcoma patients who are unresponsive to or ineligible for existing therapies, which have limited efficacy and are not specifically approved for synovial sarcoma. The applicant further explained that patients in the SPEARHEAD–1 study were heavily pretreated with a median of three prior lines of therapy, including standard agents like ifosfamide, doxorubicin, and pazopanib. The applicant stated that some patients received bridging therapy to control disease progression temporarily, but these strategies required a washout period before TECELRA® treatment. The applicant also stated that patients who received bridging therapy notably had a lower ORR of 25 percent compared to 46 percent for those who did not, indicating that bridging therapies did not contribute to improved outcomes.

In response to CMS's concern that patients with unresectable or metastatic synovial sarcoma treated with TECELRA® demonstrated a similar mOS to historical benchmark results of gemcitabine/docetaxel and regorafenib, the applicant reiterated that TECELRA® offers a significant clinical improvement in OS compared to existing therapies. The applicant stated that patients with advanced synovial sarcoma who were treated with TECELRA® demonstrated a mOS of 16.9 months (95 percent CI 10.9-not estimable) in the SPEARHEAD–1 phase II clinical trial conducted at 23 sites in Canada, the U.S., and Europe. The applicant stated that the data referenced in its application for other therapies comes from studies of various designs and scientific rigor, conducted at limited treatment sites, and showed limited efficacy and no statistical benefit over placebo in trials. In contrast, the applicant stated that the SPEARHEAD–1 trial for TECELRA® was an open-label, single arm, phase II trial specifically designed to evaluate efficacy and safety outcomes in populations of advanced synovial sarcoma and MRCLS patients, with a primary endpoint of ORR, a secondary endpoint of OS, and a prespecified statistical analysis plan. The applicant highlighted that Carroll et al. (2022) conducted a meta-analysis that evaluated clinical trials and real-world studies of pazopanib and trabectedin in previously treated metastatic synovial sarcoma patients and found: an mOS of 10.3 months (95 percent CI 8.4–12.6) for 4 pazopanib studies that included 4 to 38 patients; an mOS of 10.5 months (95 percent CI 8.2–13.4) when restricted to pazopanib studies with greater than or equal to ten participants; a mOS of 10.4 months (95 percent CI 7.3–14.8) when using 4 trabectedin studies with 3 to 101 patients; and 10.8 months (95 percent CI 8.4–13.9) when restricted to 3 trabectedin studies with 10 or more participants.

As for the data supporting gemcitabine and docetaxel in synovial sarcoma, the applicant stated the data are limited and come from analyses of various designs and two studies that show partial response in only one patient. In contrast, the applicant reiterated that the SPEARHEAD–1 study demonstrated an ORR of 39 percent in patients with synovial sarcoma and a mOS of 16.9 months (95 percent CI 10.9–NE). The applicant further stated that the OS among patients who responded to TECELRA® (mOS not reached; 95 percent CI 15.4–NE) was significantly improved versus non-responders (10.9 months; 95 percent CI 5.2–20.9; $p<0.0001$). The applicant stated that, when FDA re-evaluated the efficacy information during its review of the TECELRA® BLA, the ORR was revised to 43.2 percent (19 of 44 patients) including 2 incomplete responses (4.5 percent) and 17 partial responses (38.6 percent). The applicant stated that, given the study design, it is confident that the ORR of 39 to 43.2 percent is accurate. Lastly, the applicant stated that, even though mOS was not the primary endpoint of the SPEARHEAD–1 study, the strengths of the study provide confidence that the mOS of 16.9 months represent real improvement in patients with synovial sarcoma.

In response to CMS's concern that TECELRA® is indicated for patients with tumors expressing the MAGE–A4 tumor antigen and, therefore, the provided historical benchmark results from other studies may represent different target populations from that of TECELRA®, the applicant stated that the baseline characteristics of the SPEARHEAD–1 study population, including non-responders, are consistent with those of the broader synovial sarcoma population. The applicant stated that TECELRA® targets

a novel antigen with a unique mechanism of action and biomarkers of resistance have not been observed. The applicant stated that the patient population in Carroll et al. (2022) had similar baseline characteristics to the patient population in the SPEARHEAD–1 study. The applicant explained that, although cancer-testis antigen expression in solid tumors, such as MAGE–A4 in synovial sarcoma, was not used to select patients in past studies, current evidence by immunohistochemistry shows that 70 to 82 percent of synovial sarcoma tumors express MAGE–A4. The applicant stated that, therefore, it expects to see the same prevalence of antigen expression as in prior studies. The applicant further stated that a retrospective study of adult patients with metastatic synovial sarcoma from the French Sarcoma Group NetSARC database found that expression of MAGE–A4 and HLA–A genotype did not affect prognosis in synovial sarcoma. The applicant asserted that patients with metastatic synovial sarcoma who are MAGE–A4 positive/HLA–A*02 eligible exhibited similar prognosis as the rest of the population, strengthening the absence of selection bias in TECELRA® trials.

Similarly, a commenter stated that there are no biomarkers for synovial sarcoma prognosis and that MAGE–A4 positive synovial sarcoma is not a different disease than MAGE–A4 negative synovial sarcoma. According to this commenter, there is no evidence that MAGE–A4 tumor expression is associated with synovial sarcoma prognosis, and there is no biological reason to suspect that it could be the case.

In response to CMS's question whether the applicant had compared clinical outcomes from the SPEARHEAD–1 study to historical controls without appropriate statistical adjustment to account for differences in the study designs, the applicant submitted two analyses containing indirect treatment comparisons to assess the relative efficacy of TECELRA® versus relevant comparators (pazopanib, trabectedin, gemcitabine/docetaxel, and regorafenib) in patients with advanced or metastatic synovial sarcoma. The applicant stated that, since most trials that included patients with synovial sarcoma were single-arm trials, it conducted unanchored matching-adjusted indicated comparisons (MAICs) to assess ORR and OS and a simulated treatment comparison analysis for these endpoints to serve as a sensitivity analysis to the MAICs. The applicant asserted that the point estimates from these analyses were either statistically significant or trended in favor of TECELRA® for both ORR and OS. The applicant further stated that, in those instances where point estimate results were not statistically significant, interpretation of the 95 percent CI demonstrated clinical meaningfulness in favor of TECELRA® (lower limits of CI for ORR and upper limits of CI on the HRs for OS).

In response to CMS's question as to 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, the applicant stated that it made the comparison to CAR T-cell therapies because of the unique hematological aspects of cellular therapy for any indication. The applicant also provided a side-by-side adverse event list comparing TECELRA® to other treatments for STS (pazopanib, trabectedin, and regorafenib).

In response to CMS's question about the support for the applicant's statement that, because TECELRA® is a single administration, recipients are less likely to experience repeated adverse events from the infusion, compared to treatments requiring multiple or regular continuous or cyclical administrations, the applicant stated that the most common adverse events for TECELRA® were expected, reversible, and manageable with supportive care. The applicant further stated that, unlike TECELRA®'s one-time administration, other therapies currently used for STS involve continuous or cyclical dosing with repeated or long-term AEs. The applicant noted that for trabectedin, repeated dosing may lead to rhabdomyolysis, hepatotoxicity, and cardiomyopathy; for pazopanib, continuous dosing is associated with hepatotoxicity and hypertension within 18 weeks; and for regorafenib, cyclical administration can lead to liver dysfunction due to hepatocellular injury within 2 months. The applicant asserted that TECELRA® offers a favorable benefit-risk profile with a single-dose regimen and manageable adverse events, making it a viable option for patients with contraindications to or risks associated with toxicities from other current treatments used for STS. Similarly, a few commenters stated that TECELRA® provides a safe and more tolerable treatment option for patients with synovial sarcoma. Lastly, a commenter stated that, compared to traditional therapies that require multiple cycles and prolonged exposure to toxic side effects, synovial sarcoma patients treated with TECELRA® have reported improved quality of life due to the convenience of a single treatment administration and the reduced exposure to ongoing toxicities associated with traditional therapies, representing a significant step forward in the treatment of synovial sarcoma.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree with the applicant and other commenters that TECELRA® represents a substantial clinical improvement over existing technologies because it offers an improvement in ORR of 43.2 percent compared to up to 18.9 percent for existing treatments with a single treatment for 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.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that TECELRA® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2026. Cases involving the use of TECELRA® that are eligible for new technology add-on payments will be identified by ICD–10–PCS code 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).

In its application, the applicant estimated that the cost of the one-time TECELRA® infusion is $727,000 per patient based on a single, one-time, patient-specific treatment delivered as a cell suspension for intravenous infusion containing 2.68×10^9 to 10×10^9 MAGE–A4 TCR positive T-cells. 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, the maximum new technology add-on payment for a case involving the use of TECELRA® is $472,550 for FY 2026.

m. 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 stated we were 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.

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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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18154), after review of the information provided by the applicant, we noted 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®.[120] Therefore, we stated it was unclear how ZIIHERA® treats a new patient population or disease as compared to these existing treatments.

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

Comment: A commenter submitted a public comment stating that ZIIHERA®'s bispecific design targets two non-overlapping HER2 epitopes, enhancing receptor clustering, internalization, and immune-mediated cytotoxicity. The commenter stated that this dual engagement mechanism distinguishes it from other HER2-directed agents used in BTC, such as trastuzumab deruxtecan (T–DXd), which relies on a cytotoxic payload, or trastuzumab-based combinations, which may provide less potent HER2 blockade in this disease context.

Response: We thank the commenter for its comment.

Comment: The applicant submitted a public comment regarding the newness criterion. The applicant reiterated its statements from its new technology add-on payment application in support of its assertion that ZIIHERA® meets the newness criterion, including that it is the first and only FDA-approved, HER2-directed bispecific antibody indicated for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC3+) BTC, and that it has a unique mechanism of action. The applicant reiterated that ZIIHERA®'s unique asymmetric antibody design, its biparatopic bispecific binding, and its ability to induce HER2 receptor crosslinking and internalization is hypothesized to drive multiple mechanisms of action that lead to a reduction of HER2 from the cell surface and reduction in downstream signaling as well as complement-dependent cytotoxicity (CDC), antibody-dependent cellular cytotoxicity (ADCC), and antibody-dependent cellular phagocytosis (ADCP) to destroy and eliminate HER2-express tumor cells, all of which may support its clinical activity as a single agent. The applicant provided additional information, including figures detailing its study of ZIIHERA®'s mechanism of action observed in pre-clinical trials. The applicant stated that ZIIHERA® provides an opportunity to circumvent potential resistance mechanisms from single site HER2 agents.

In response to CMS's concern about whether ZIIHERA® treats a new patient population or disease as compared to existing treatments, such as FOLFOX, FOLFIRI, STIVARGA®, or ENHERTU®, the applicant reiterated that ZIIHERA® is the first and only FDA-approved, HER2-directed bispecific antibody indicated for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC3+) BTC. The applicant stated that prior to the FDA approval of ZIIHERA® and its NCCN addition as a Category 2A treatment option for BTC, the preferred subsequent-line therapy option for patients with advanced BTC who progress was FOLFOX (fluorouracil, leucovorin, and oxaliplatin) chemotherapy, as well as other systemic therapy options recommended for 2L therapy in BTC, such as FOLFIRI (fluorouracil, leucovorin, and irinotecan) and, with Category 2B evidence, STIVARGA® (regorafenib) and liposomal irinotecan plus 5-fluorouracil plus leucovorin. The applicant reiterated that, overall, these and other regimens used in the 2L or later setting are associated with response rates of approximately 3 percent to 15 percent, median PFS of approximately 3 to 7 months, and median OS of approximately 6 to 9 months, and that historically, chemotherapies have shown modest clinical benefit in the 2L or later setting and are associated with significant toxicity burden for the patients, with up to a third reported to discontinue chemotherapy because of the toxicities. The applicant also stated that chemotherapy-related toxicity may be cumulative by the time patients make it to 2L since treatment guidelines recommend the use of cisplatin and gemcitabine with or without immunotherapy as 1L treatment for patients with metastatic BTC. The applicant stated that there is a need for a chemotherapy-free option in the 2L+ setting. The applicant further stated that HER2 is an important targetable alteration, accounting for ~20 percent of BTC and provided a study that included 122 previously treated patients with HER2-amplified solid tumors including BTC that demonstrated patients who received HER2-targeted therapy had numerical improvement in mOS compared to those who did not (18.6 vs 10.9 months; hazard ratio [HR], 0.60; 95% CI, 0.34 to 1.06; P=.07), highlighting ZIIHERA®'s potential to address the serious unmet treatment need and further provide a chemotherapy-free option. In regards to ENHERTU®, the applicant commented that the FDA approval and NCCN recommendation were based on the DESTINY-PanTumor2 basket trial including 41 patients with BTC who had received a median of 2 lines of prior therapy (range, 1–5), 16 of which were HER2+ (IHC3+) BTC, stating that ENHERTU® had a cORR of 56.3 percent (95% CI 29.9, 80.2), an observed mOS of 12.4 (2.8, NR) months, and a mDOR of 10.9 months (5.5, NE) while emphasizing that ENHERTU®'s FDA-approved indication is for the treatment of adult patients with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.

With respect to assignment to the same MS–DRG as existing technologies, the applicant stated that it agrees with CMS that ZIIHERA® will not map to MS–DRGs distinct from other treatments administered to patients with BTC.

In response to CMS's request for additional information regarding the cause of any delay in commercial availability, the applicant stated that the newness period for ZIIHERA® should begin on the date of its first market availability, December 2, 2024, and not the FDA approval date of November 20, 2024. Specifically, the applicant explained that the gap in time from FDA approval to commercial availability was to allow for final packaging with FDA-approved labels and package inserts as well as to allow time for shipment to all critical distribution points. ZIIHERA® inventory was received by specialty distributors on December 3, 2024, and was able to be ordered by end users on that date. The applicant stated its understanding that CMS's use of either date will result in the 3-year anniversary of ZIIHERA®'s entry onto the U.S. market occurring after October 1, 2027, and so long as this understanding is correct, it does not object to CMS using November 20, 2024, as the date of ZIIHERA® market availability.

Response: We thank the applicant and other commenters for their comments. Based on our review of comments received and information submitted by the applicant as part of its FY 2026 new technology add-on payment application for ZIIHERA®, we agree with the applicant that ZIIHERA® uses a unique mechanism of action because it is a bispecific HER2-directed, biparatopic antibody approved by FDA for the treatment of adults with previously treated, unresectable/metastatic HER2+ (IHC 3+) BTC. Therefore, we agree with the applicant that ZIIHERA® is not substantially similar to existing treatment options and meets the newness criterion. We consider the

[120] 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*.

beginning of the newness period to commence on December 2, 2024, the date on which ZIIHERA® became commercially available.

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).
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 invited public comments on whether ZIIHERA® meets the cost criterion.

Comment: The applicant stated that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both the primary cohort and the sensitivity cohort, and thus ZIIHERA® meets the cost criterion.

Response: We thank the applicant for its comments. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount under all scenarios. Therefore, 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.[121] 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.

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[121] Background articles and supplemental material are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments	
Applicant statements in support	**Supporting evidence provided by the applicant**
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.
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.

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In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18156), after review of the information provided by the applicant, we stated we had 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 noted 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 noted that the applicant stated that FOLFOX is the preferred subsequent line therapy option for these patients, and we also noted that NCCN guidelines list additional available therapies including: FOLFIRI, ENHERTU®, and HERCEPTIN® plus TUKYSA®. We further noted 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 questioned 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 noted that the HERIZON–BTC–01 study did not compare ZIIHERA® outcomes to outcomes for other existing treatments, and therefore we questioned the extent to which this can be relied upon for a finding of substantial clinical improvement. We noted that 63 percent of the study's patients were enrolled at clinical trial sites in Asia, and we questioned 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 questioned 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 noted 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 questioned 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 stated 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 stated we were 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 noted that since ZIIHERA® is indicated for use in patients with HER2+ (IHC 3+) BTC only, we questioned 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 questioned 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 noted 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 invited public comments on whether ZIIHERA® meets the substantial clinical improvement criterion.

Comment: We received several comments that expressed general support for new technology add-on payment approval for ZIIHERA®. Some of the commenters stated that ZIIHERA® addresses a critical unmet need in this patient population by offering a targeted, chemotherapy-free treatment option that has demonstrated meaningful and durable responses in a setting where conventional therapies have limited efficacy, and that the ability to initiate or continue ZIIHERA® in the inpatient setting may help stabilize disease, reduce symptom burden, and facilitate discharge planning, offering both clinical and health system benefits. A commenter expressed support for ZIIHERA® as a chemotherapy-free treatment option for patients with biliary obstruction, poor performance status, and comorbidities that limit chemotherapy tolerance. Many commenters also stated that in the HERIZON–BTC–01 trial, ZIIHERA® demonstrated meaningful results with an ORR of 52 percent with a mDOR of 14.9 months. One of the commenters stated that a small but clinically relevant subset of BTCs have HER2-amplification for which HER2-targeted therapy is vastly superior to traditional chemotherapy. Another commenter stated that for patients with HER2 overexpression after progression on first-line therapy, ZIIHERA® offers a singularly advantageous profile based upon a host of parameters including the lack of myelosuppression which is important in a population at high risk for cholangitis or biliary sepsis and that because ZIIHERA® does not require significant hepatic metabolism, it is also a preferred choice in patients with biliary obstruction and risk for fluctuating hepatic function. The commenter stated that alternate HER2-targeted therapies, such as trastuzumab deruxtecan or tucatinib-based regiments, are not options in these settings due to risk for hepatic toxicity or worsening infection. A commenter further stated that currently available options for patients with HER2+ (IHC3+) BTC, such as chemotherapy or ENHERTU®, have important limitations, especially in 2L where patients may already be fragile and chemotherapy-intolerant, and that ZIIHERA® represents an important option because it offers a chemotherapy-free, HER2-targeted approach. The commenter stated the availability of a well-tolerated, targeted 2L regimen such as ZIIHERA® could expand access especially for patients who might otherwise forgo treatment due to poor performance status or inability to tolerate the toxicity of current standard regimens. Additionally, another commenter stated that traditionally,

antineoplastic therapies have not been given in the inpatient setting due to them being unsafe for people that are acutely ill because they have cytotoxic mechanisms of action that can cause infection, cytopenias, bleeding and other complications and that having inpatient access to ZIIHERA® would allow patients to start it sooner or to continue treatment on schedule, rather than missing doses.

Response: We thank the commenters for their input and have taken it into consideration in determining whether ZIIHERA® meets the substantial clinical improvement criterion as discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. In response to CMS's questions regarding the applicant's assertion that ZIIHERA® offers a treatment option for a patient population unresponsive to, or ineligible for, other existing therapies, the applicant stated that prior to FDA approval of ZIIHERA® and its addition as a Category 2A treatment option for BTC, the preferred subsequent-line therapy option for patients with advanced BTC was FOLFOX chemotherapy, although survival rates remain poor (6.2 months OS and 4.0 months mPFS) and response rates are low (5 percent). The applicant asserted that among patients receiving FOLFOX, Grade 3 to 5 adverse events occurred in 69 percent of patients, and 3 chemotherapy-related deaths were reported. The applicant explained that additional treatment options recommended for 2L therapy in BTC were FOLFIRI, STIVARGA®, and liposomal irinotecan plus 5-fluorouracil plus leucovorin, and provided two tables displaying the efficacy, and safety and tolerability of select 2L therapies in BTC. The applicant commented that historically, there were no HER2-targeted therapies that were specifically studied in a trial dedicated to patients with BTC as most of these trials were basket trials. Per the applicant, with the addition of ZIIHERA®, four HER2-targeted therapies are now recommended in the NCCN guidelines. The applicant stated that ZIIHERA® was studied in the largest phase 2b clinical trial dedicated to BTC with 80 patients with HER2+ disease, 62 of which were IHC3+ and that aside from ZIIHERA®, only ENHERTU® has reported efficacy data in centrally confirmed HER2+ (IHC3+) BTC (n=16). The applicant further stated that two of the guideline-recommended HER2-targeted agents, trastuzumab + pertuzumab, which was investigated in a phase 2 basket trial (SGNTUC–019) in patients with HER2+ solid tumors, including 30 patients with HER2+ advanced BTC, and trastuzumab + tucatinib, which was investigated for the treatment of patients with previously treated, locally advance/metastatic HER2+ BTC in phase 2 multiple-basket study (MyPathway), are not FDA-approved for use in patients with HER2+ BTC. The applicant provided two figures that describe the efficacy outcomes in previously treated HER2+ BTC for fam-trastuzumab-deruxtecan, tucatinib + trastuzumab, and trastuzumab + pertuzumab, as well as the TEAEs with HER2-targeted subsequent-line therapies for treatment of BTC. The applicant reiterated that a significant and urgent unmet medical need exists for optimal and tolerable treatment options for patients with unresectable/metastatic HER2+ (IHC3+) BTC who have progressed on prior systemic therapy or for those who are ineligible for chemotherapy, and that the outcomes demonstrated by ZIIHERA® support the potential for a new standard of care for patients who progress on 1L options. The applicant further stated that ZIIHERA® offers the only FDA-approved chemotherapy-free treatment option and noted that ENHERTU® has a chemotherapeutic payload and is approved for use when no satisfactory alternative treatment option remains.

With respect to the assertion that ZIIHERA® significantly improves clinical outcomes relative to service or technologies previously available, the applicant reiterated findings from the HERIZON–BTC–01 trial and stated that the data continue to demonstrate rapid, sustained, and durable responses in comparison to FOLFOX and FOLFIRI while highlighting the clinical benefit of continued treatment with chemotherapy-free, single-agent ZIIHERA®. The applicant further commented that given the aggressive and rare nature of advanced HER2+ BTC (affecting about 4.4 per 100,000 in the U.S.), the conduct of randomized studies can be challenging in this biomarker-selected population and that HERIZON–BTC–01 is a single-arm study without comparator arm as there is no approved standard of care in this setting. The applicant stated that, acknowledging the hazards of cross-trial indirect comparison, the anti-tumor activity observed for ZIIHERA® in patients with HER2+ BTC compares favorably to historic controls from clinical studies in similar and relevant populations. The applicant provided several figures that describe the efficacy outcomes (ORR, mDOR in months, mPFS in months, and mOS in months) in previously treated HER2+ BTC for fam-trastuzumab-deruxtecan, tucatinib + trastuzumab, and trastuzumab + pertuzumab, noting that the table is for illustrative purposes only and is not intended as a direct comparison across trials. The applicant further stated that with the rarity of BTC and a further reduced subset of patients with HER2-expressing tumors, the sample size of HERIZON–BTC–01 (n=80, Cohort 1; median age 64 years [IQR 58–70]) is representative of the small BTC population, and that a sample size of approximately 75 patients in Cohort 1 was informed by Clopper-Pearson exact binomial 95 percent CIs using a historical response rate of 10 percent. The applicant reiterated that the HERIZON–BTC–01 study population represented the largest study in the 2L setting conducted in this rare disease. The applicant also stated that a conscious effort was made to target a broad range of clinical sites in wide geographic locations for the HERIZON–BTC–01 study, with study participants enrolled at sites in the U.S., Canada, Spain, France, U.K., Italy, Chile, China, and Korea. The applicant reiterated that the largest components of participants in Cohort 1 (IHC3+) were Asian (61.3 percent) and White (30.6 percent) but asserted that these demographic characteristics are representative of the target indication population of patients with BTC, which has a higher prevalence in Asian populations. The applicant stated that Harding et al. (2023) concluded that the ORRs were similar in patients enrolled in Asia compared with those enrolled in the rest of the world, indicating that geographical variation is unlikely to affect the therapeutic use of ZIIHERA®. The applicant stated these data demonstrate that HERIZON–BTC–01 results are generalizable to the U.S. BTC population, including the Medicare-age patient population. Furthermore, the applicant stated that prespecified subgroup analysis of cORR based on age (<65 or 65 or <75 or 75), sex (female or male), race (Asian or non-Asian), geographical region (North America, Asia, or other), HER2+ IHC score (2+ or 3+), anatomic site (gallbladder cancer, intrahepatic cholangiocarcinoma, and extrahepatic cholangiocarcinoma), number of previous therapies for advanced disease (<2 or 2), disease stage at baseline (stage III or stage IV), intolerance to most recent previous treatment (yes or no), and baseline ECOG performance status (0 or 1) were also examined. The applicant stated that

ZIIHERA® provided treatment benefit regardless of the anatomic subtype, geographical region, and lines of previous treatment and that the ORR results were similar across age groups (<65; 65; <75).

In regard to the claim that the overall benefit:risk assessment of ZIIHERA® is favorable and ZIIHERA® fulfills an unmet medical need and provides an option for patients to receive clinical benefit with a low risk of harm, the applicant reiterated that in contrast to chemotherapy regimens used in the 2L or later setting, ZIIHERA® as a single agent is well tolerated in the pretreated BTC patient population with AEs that are manageable and that ZIIHERA®, a HER2-directed, non-chemotherapy treatment approach, provides a clear clinical benefit, fulfills an unmet medical need for the intended patient population, and provides an option for patients to receive clinical benefit with a low risk of harm. The applicant further stated that the BLA safety analysis for ZIIHERA® was based on cohort 1 (n=80) of the pivotal, single arm Phase 2b HERIZON–BTC–01, and that for the cohort 1 subgroup of IHC3+ patients (n=62), 80.6 percent of patients experienced any TRAEs, with 59.7 percent of patients having a Grade 1 or 2 TRAE, 19.4 percent having a Grade 3 TRAE, 1.6 percent having a Grade 4 TRAE, none having a Grade 5 TRAE, and 2.3 percent having a TRAE leading to discontinuation. The applicant provided a figure with a summary of TRAEs. Furthermore, the applicant stated that the subgroup analysis by IHC status indicates that patients with IHC3+ had an ORR of 51.6 percent (32 of 62 patients) and those with IHC2+ had a response rate of 5.6 percent (one of 18 patients). The applicant stated that substantial improvements in quality of life were seen in patients who had a response, which was primarily in patients with HER2+ IHC3+ BTC (32/33 responders). The applicant also stated that the present analysis of quality of life was based on cohort 1: HER2+ patients defined as IHC3+ or IHC2+. The applicant stated that there were no responders in cohort 2 (IHC1+ or IHC0), and therefore, Cohort 2 was not included in any of the analysis. The applicant also explained that a Phase 3 clinical trial is underway investigating the use of ZIIHERA® in combination with standard of care versus standard of care alone as 1L therapy in advanced HER2+ BTC and will serve as the confirmatory trial.

Response: We thank the applicant for its comment regarding the substantial clinical improvement criterion. Based on the additional information received, we continue to have concerns as to whether ZIIHERA® meets the substantial clinical improvement criterion to be approved for new technology add-on payments.

Regarding the applicant's assertion that ZIIHERA® offers a treatment option for a patient population unresponsive to or ineligible for other existing therapies, since the information provided in the application for this assertion as well as the updated NCCN guidelines note that there are additional therapy options, we disagree that the material presented adequately supports that patients treated with ZIIHERA® have no other treatment options. Specifically, we note that the NCCN guidelines recommend other treatment options for patients with unresectable or metastatic BTC, including FOLFOX, FOLFIRI, liposomal irinotecan plus 5-fluorouracil plus leucovorin, and STIVARGA®, or targeted therapy for patients with HER2+ unresectable or metastatic BTC, including ENHERTU®, PERJETA® plus HERCEPTIN®, and TUKYSA® plus HERCEPTIN®, as well as ZIIHERA®. In addition, while ZIIHERA® may provide a treatment option for patients unable to tolerate the toxicity of current standard chemotherapy regimens as described by the applicant and commenters, it is unclear that patients who are unable to tolerate these chemotherapy regimens are also ineligible for other targeted therapies such as ENHERTU®.

We also continue to question that ZIIHERA® improves outcomes over existing targeted therapies like ENHERTU®. While the applicant provided outcomes for ZIIHERA® and ENHERTU® from their respective trials, we note the similarity of the clinical outcomes data in the information provided. For example, while the applicant stated ZIIHERA® demonstrated a cORR of 51.6 percent (95 percent CI: 38.6, 64.5) in the HERIZON–BTC–01 which the applicant stated was significantly more than the historical response rate of 7.7 percent, we note that ENHERTU® demonstrated a cORR of 56.3 percent in the DESTINY-PanTumor02 trial. We also question whether the data provided by the applicant comparing outcomes and TRAEs for the HER2-targeted therapies allows for direct comparison given there are differences in the sample size and differences in the number of prior treatments between the two studies. Therefore, we remain unclear that ZIIHERA® improves outcomes or TRAEs compared to other HER2-targeted therapies such as ENHERTU® for patients with 2L unresectable or metastatic HER2+ (IHC 3+) BTC.

After consideration of all the information received from the applicant, as well as the public comments we received, we are unable to determine that ZIIHERA® represents a substantial clinical improvement over existing technologies for the reasons discussed in the proposed rule and in this final rule, and therefore, we are not approving new technology add-on payments for ZIIHERA® for FY 2026.

6. 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 final 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, in the FY 2026 IPPS/LTCH PPS proposed rule, we noted we made available separate tables listing the ICD–10–CM codes and/or ICD–10–PCS codes that we believed 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 the 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 of the proposed rule for additional information regarding tables associated with the proposed rule.

Table 10 associated with this final rule reflects the finalized lists of ICD–10–CM codes or ICD–10–PCS codes that would be used to identify cases relevant to the Breakthrough Device-designated indication for the RECELL® Autologous Cell Harvesting Device for purposes of the new technology add-on payment for FY 2026, and is available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.*

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 the proposed rule. Subsequently, prior to the issuance of this final rule, 7 additional applicants (for the Dexcom G7 Hospital Continuous Glucose Monitoring System, DrugSorb-ATR Device, Nelli Seizure Monitoring System, PearlMatrix P–15 Peptide Enhanced Bone Graft, Provizio® SEM Scanner, Spur Peripheral Retrievable Stent System, and the Ventura® Interatrial Shunt System) withdrew their applications, or did not meet the May 1 deadline for FDA approval or clearance of the technology and therefore are not eligible for consideration for new technology add-on payments for FY 2026. We are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2026. We are addressing the remaining 22 applications. Of the remaining 22 applications, 20 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 the FY 2026 IPPS/LTCH PPS proposed rule we made a proposal to approve or disapprove each of these 22 applications for FY 2026 new technology add-on payments. Therefore, in this section of the preamble of this final rule, we provide a table summarizing background information and the cost analysis for each of the remaining alternative pathway applications and our determination on whether or not each technology is 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 left 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.

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In the proposed rule, we noted that 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 agreed with the applicant that the 4WEB Medical ATS meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the 4WEB Medical ATS. Commenters stated that the technology meets all the eligibility requirements and requested that CMS finalize the proposal to approve the new technology add-on payments for FY 2026.

The applicant also confirmed that the per-patient cost to the hospital of the device of $23,500 provided in the new technology add-on payments application has not changed. The applicant submitted a summary of relevant dates related to commercial availability, noting that 510(k) clearance was received from FDA on March 21, 2024, and a third-party distribution agreement between the applicant and Stryker Corporation (Stryker) was executed on July 26, 2024, to give

Stryker exclusive rights to distribute and sell the device. The applicant stated that there was a delay between July 26, 2024, and January 8, 2025, because manufacturing could not begin until the distribution agreement was executed, and the first batch of implants for commercial use were received on January 8, 2025. Per the applicant, it completed its inspection of the device and shipped the first batch to Stryker on January 28, 2025, and Stryker completed its processes on January 31, 2025 and made the device available for sale. The applicant noted that this date represents the date the device was commercially available and does not represent the date of first implant. The applicant stated that the first 4WEB Medical ATS implantation occurred on February 7, 2025. Given the timeline of events, the applicant requested that CMS utilize January 31, 2025, as the date of first commercial availability.

Response: We thank the commenters for their comments and support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe 4WEB Medical ATS meets the cost criterion. The technology received 510(k) clearance on March 21, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for 4WEB Medical ATS for FY 2026. We consider the beginning of the newness period to commence on January 31, 2025, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of 4WEB Medical ATS to the hospital is $23,500 per patient. Per the applicant, one 4WEB Medical ATS is used per patient per hospital discharge. 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 finalizing that the maximum new technology add-on payment for a case involving the use of 4WEB Medical ATS is $15,275 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of 4WEB Medical ATS that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: 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 left tarsal joint using open-truss design internal fixation device, open approach, new technology group 9).

(2) AeroPace® System

The following table summarizes the information provided in the new technology add-on payment application for the AeroPace® System.

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	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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In the proposed rule, we noted that 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 noted 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 stated in the proposed rule that we were 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 stated that it is not expected to be commercially available until October 1, 2025.

We agreed with the applicant that the AeroPace® System meets the cost criterion and therefore proposed 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 had not provided an estimate for the cost of the AeroPace® System at the time of the 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 stated that 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, we stated that 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 stated that we expected the applicant to submit cost information prior to the final rule, and that we would 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 invited 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.

Comment: A few commenters, including the applicant, submitted public comments expressing support for our proposal to approve new technology add-on payment for the AeroPace® System for FY 2026.

In response to CMS's request for additional information regarding the delay in the technology's market availability, the applicant stated that the company is currently manufacturing devices and anticipates first commercial use and launch beginning October 1, 2025. Regarding the delay, the applicant stated that based on average FDA PMA review times, the applicant targeted its preparation of commercial operations for manufacturing, and its fundraising to support manufacturing and hiring of sales personnel based on the anticipated FDA approval timeline of early Q2 2025. Per the applicant, the FDA review process occurred in less time than anticipated and given the lead time for manufacturing, building inventory, establishing its commercial operation, and costs, there was not sufficient time to accelerate commercialization sooner than planned.

The applicant also provided the costs for the single-patient use components that are eligible for new technology add-on payment, the AeroPace® Neurostimulation Catheter and the Airway Sensor. The applicant noted that the total per-patient cost of the AeroPace® System single-patient use components to the hospital is $36,386. Per the applicant, each AeroPace® Neurostimulation Catheter is $24,995 and each Airway Control Sensor is $995, and based on the clinical trial data, patients will use 1.4 AeroPace® Neurostimulation Catheters and Airway Sensors on average.

Response: We thank the commenters for their comments and the updated cost information.

As we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates first commercial use and launch beginning October 1, 2025, but it is unclear whether the technology would be available for sale prior to that date. In addition, we note that we do not consider the date of first sale of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale (88 FR 58802). At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be December 4, 2024.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe AeroPace® System meets the cost criterion. The technology received FDA premarket approval on December 4, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for AeroPace® System for FY 2026. Absent additional information from the applicant, we consider the beginning of the newness period to commence on December 4, 2024, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of AeroPace® System is $36,386. 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 finalizing that the maximum new technology add-on payment for a case involving the use of AeroPace® System is $23,650.90 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for a unique ICD–10–PCS procedure code for the AeroPace® System beginning in FY

2026. Therefore, cases involving the use of AeroPace® System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X2H13XB (Insertion of temporary phrenic nerve/diaphragm stimulation electrodes into superior vena cava, percutaneous approach, new technology group 11).

(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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In the proposed rule, we noted that 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.[122]

We agreed with the applicant that the AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the AGENT™ Paclitaxel-Coated Balloon Catheter. Commenters stated that the device meets all requirements for approval and requested that CMS finalize its proposal for new technology add-on payments for FY 2026. The applicant requested that CMS finalize the approval of new technology add-on payments with a maximum payment of $4,013.75 starting October 1, 2025.

Response: We thank the commenters for their comments. Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe AGENT™ Paclitaxel-Coated Balloon Catheter meets the cost criterion. The technology received FDA premarket approval on February 29, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for AGENT™ Paclitaxel-Coated Balloon Catheter for FY 2026. We consider the beginning of the newness period to commence on February 29, 2024, the date on which technology received its premarket authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of AGENT™ Paclitaxel-Coated Balloon Catheter is $6,175. 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 finalizing that the maximum new technology add-on payment for a case involving the use of AGENT™ Paclitaxel-Coated Balloon Catheter is $4,013.75 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of AGENT™ Paclitaxel-Coated Balloon Catheter that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

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

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
XW0L3LA	Introduction of paclitaxel-coated balloon technology, four or more balloons into coronary artery, three arteries, percutaneous approach, new technology group 10
XW0M3HA	Introduction of paclitaxel-coated balloon technology, one balloon into coronary artery, four or more arteries, percutaneous approach, new technology group 10
XW0M3JA	Introduction of paclitaxel-coated balloon technology, two balloons into coronary artery, four or more arteries, percutaneous approach, new technology group 10
XW0M3KA	Introduction of paclitaxel-coated balloon technology, three balloons into coronary artery, four or more 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

(4) alfapump® system

The following table summarizes the information provided in the new technology add-on payment application for the alfapump® system.

	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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In the proposed rule, we noted that 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 stated in the proposed rule that we were interested in additional information regarding any delay, such as whether the technology would be available for sale during its phased roll out plan.

We agreed with the applicant that the alfapump® system meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the alfapump® system.

In response to CMS's request for additional information regarding the delay in the technology's market availability the applicant stated that the alfapump® was not available for sale as of June 2025 and that it anticipates that the first cases and sales will now occur during the month of August 2025.

The applicant also provided updated cost information and stated that the price of the alfapump® kit will be revised from the original cost of $30,000 to a new cost of $33,000, given various commercial factors. Per the applicant, this results in a revised final average case weighted standardized charge per case of $271,692, as compared to the prior figure of $260,109, against the case weighted threshold of $130,906. The applicant requested a revised calculation using the revised cost of $33,000 for a maximum allowable new technology add-on payment of $21,450.

Response: We thank the applicant and commenters for their comments and support.

As we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates first commercial use and launch beginning August 2025, but it is unclear whether the technology would be available for sale prior to that date. At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be December 20, 2024.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe the alfapump® system meets the cost criterion. The technology received FDA marketing authorization on December 20, 2024, with an indication for use 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the alfapump® system for FY 2026. Absent additional information from the applicant, we consider the beginning of the newness period to commence on December 20, 2024, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the alfapump® system is $33,000. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the alfapump® system is $21,450 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of the alfapump® system that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code 0W1G3J6 (Bypass peritoneal cavity to bladder with synthetic substitute, percutaneous approach) in combination with 0JH80YZ (Insertion of other device into abdomen subcutaneous tissue and fascia, open approach).

(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	Per the applicant, the aprevo®-C cervical interbody fusion device will replace other implantable

	for prior technology	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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In the proposed rule, we noted that 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 noted 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 were 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 agreed with the applicant that the aprevo®-C cervical interbody fusion device meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the aprevo®-C cervical interbody fusion device. The applicant stated that the aprevo®-C cervical interbody fusion device meets the cost criterion. In response to CMS's request for additional information regarding the delay in the technology's market availability, the applicant stated that the commercial availability of the product is scheduled for October 1, 2025, to align with the new technology add-on payment start date because the higher hospital acquisition cost of the technology must be mitigated by the new technology add-on payment to secure the hospital value analysis committee approval.

Response: We thank the commenters for their comments. As we have discussed in prior rulemaking (86 FR 45132 and 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates commercial availability beginning October 1, 2025, but it is unclear whether the technology would be available for sale prior to that date. At this time, there is not sufficient

information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be November 15, 2024.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the aprevo®-C cervical interbody fusion device meets the cost criterion. The technology received 510(k) clearance from FDA on November 15, 2024, with an indication for use 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the aprevo®-C cervical interbody fusion device for FY 2026. We consider the beginning of the newness period to commence on November 15, 2024, the date on which the technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the aprevo®-C cervical interbody fusion device is $32,500. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the aprevo®-C cervical interbody fusion device is $21,125 for FY 2026 (that is, 65 percent of the average cost of the technology). The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the aprevo®-C cervical interbody fusion device beginning in FY 2026. Therefore, cases involving the use of the aprevo®-C cervical interbody fusion device that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

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ICD-10-PCS Code	Description
XRG10RB	Fusion of cervical vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 11
XRG13RB	Fusion of cervical vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 11
XRG14RB	Fusion of cervical vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 11
XRG20RB	Fusion of 2 or more cervical vertebral joints using custom-made anatomically designed interbody fusion device, open approach, new technology group 11
XRG23RB	Fusion of 2 or more cervical vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 11
XRG24RB	Fusion of 2 or more cervical vertebral joints using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 11
XRG40RB	Fusion of cervicothoracic vertebral joint using custom-made anatomically designed interbody fusion device, open approach, new technology group 11
XRG43RB	Fusion of cervicothoracic vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous approach, new technology group 11
XRG44RB	Fusion of cervicothoracic vertebral joint using custom-made anatomically designed interbody fusion device, percutaneous endoscopic approach, new technology group 11

(6) CERAMENT® G

The following table summarizes the information provided in the new technology add-on payment application for CERAMENT® G.

	CERAMENT® G	
Technology Info	**Applicant**	BONESUPPORT, 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.

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In the proposed rule, we noted 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, we noted that only the use of CERAMENT® G for open fractures, and the FDA Breakthrough Device designation it received for that use, were relevant for purposes of the new technology add-on payment application for FY 2026. We noted 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 the proposed rule, we proposed to discontinue making new technology add-on payments for FY 2026 for use of CERAMENT® G for bone infections. We believed 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 invited 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 agreed with the applicant that CERAMENT® G meets the cost criterion and therefore proposed 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 the 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.[123] We noted 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 proposed 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 invited 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.

Comment: We received comments expressing support for technologies under consideration for new technology add-on payments for FY 2026. We also received comments expressing general support of the proposed ICD–10–CM codes for which CMS specifically sought input.

Response: We thank the commenters for their comments. Based on the information provided in the application for new technology add-on payments, we believe CERAMENT® G meets the cost criterion. The technology received FDA 510(k) clearance on March 13, 2024, with an indication 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. Therefore, we are finalizing our proposal to approve new technology add-on payments for CERAMENT® G for FY 2026. As noted earlier in this section, 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 consider the beginning of the newness period to commence on March 13, 2024, the date on which technology received its 510(k) clearance for the indication of open fractures covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of CERAMENT® G is $8,750. 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 finalizing that the maximum new technology add-on payment for a case involving the use of CERAMENT® G is $5,687.50 for FY 2026 (that is, 65 percent of the average cost of the technology).

As noted, 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 final rule, we are finalizing our proposal to discontinue making new technology add-on payments for FY 2026 for use of CERAMENT® G for bone infections. Therefore, cases involving the use of CERAMENT® G that are eligible for new technology add-on payments in FY 2026 will be identified by ICD–10–PCS procedure code XW0V0P7 (Introduction of antibiotic-eluting bone void filler into bones, open approach, new technology group 7) without any of the ICD–10–CM diagnosis codes in category M86 (Osteomyelitis).

(7) 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).

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[123] 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.

	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.

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In the proposed rule, after review of the information provided by the applicant, we noted 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, we noted that 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, were relevant for purposes of the new technology add-on payment application for FY 2026.

We noted the following concerns with respect to the cost criterion. We were 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 were 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 noted 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 questioned 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, we noted that it appeared 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 questioned the assumptions used in the cost analysis regarding the potential Medicare volume for the technology. As we noted, in the FDA clearance letter for this device,[124] its intended patient population is newborns, including preterm, and infants. We stated that the applicant asserted 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 agreed that infants may be eligible for Medicare if they have ESRD and need regular dialysis or have had a kidney transplant,[125] we noted 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).[126]

Furthermore, we were 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 were also unclear as to the applicant's methodology for calculating the average charge per case (unstandardized with case weight), as it appeared 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 noted that the applicant stated that targeted fortification leads to a decreased length of stay (LOS) by 2.5 days, and we questioned if charges should be removed to account for the decreased LOS for patients using this technology.

We were 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 stated in the proposed rule that we were interested in additional information regarding the basis for using this inflation factor and how it corresponded to the source data and year used for the cost analysis.

We noted 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, we stated it was 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 had 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 proposed 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 were to receive updated information to establish that the Emily's Care Nourish Test System (Model 1) meets the cost criterion, we provided the following information regarding the new technology add-on payment.

We noted the applicant stated that the technology, which received FDA clearance on May 3, 2024, was expected to be commercially available May 1, 2025, and we stated that we would appreciate more information about the cause for any delay in the commercial availability of the device following FDA clearance.

We believed 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:

[124] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K234088.pdf.*

[125] Centers for Medicare & Medicaid Services. End-stage renal disease (*https://www.medicare.gov/basics/end-stage-renal-disease*, accessed 1/16/2024).

[126] 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
P05.01	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, 1000-1249 grams
P05.05	Newborn light for gestational age, 1250-1499 grams
P05.11	Newborn small for gestational age, less than 500 grams
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, 1000-1249 grams
P05.15	Newborn small for gestational age, 1250-1499 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, 1000-1249 grams
P07.15	Other low birth weight newborn, 1250-1499 grams

We invited 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 the 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 noted 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.

We stated that, as we had 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 stated that 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). We stated that the costs to lease the lightbox and iPhone are capital costs. As such, we noted that 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 stated we were 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.[127] We stated it was unclear how potential discounts would affect the relevant estimated operating costs of the device. We also stated we would be interested in additional information regarding the current or anticipated average cost of the technology to the hospital per inpatient stay.

We invited 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 invited public comments on the operating costs for the device, in the event we received updated information to establish that the Emily's Care Nourish Test System (Model 1) meets the cost criterion.

Comment: We received a comment from Prolacta Biosciences stating that subsequent to submission of the new technology add-on payment application for Emily's Care Nourish Test System (Model 1), Prolacta Bioscience acquired Lactation Lab Inc. and that Prolacta Bioscience should now officially be considered the applicant, and asked that all correspondence regarding the new technology add-on payments for FY 2026 application and any questions be directed to Prolacta Biosciences.

Response: We thank the commenter for its comment and note that for this final rule Prolacta Biosciences is identified as the applicant in the following section.

Comment: Multiple commenters, including the applicant, expressed support for approving new technology add-on payment for the Emily's Care Nourish Test System (Model 1). Some commenters shared their personal experiences as practicing clinicians or as mothers who had infants in the NICU. A few commenters submitted citations and studies that emphasized the importance of human milk and targeted fortification for VLBW infants in the NICU. Other commenters stated that Medicare-eligible mothers may have disabilities which raise the risk of

[127] 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.*

preterm birth, low birth weight, and NICU admission. Several commenters stated that during these admissions, Emily's Care Nourish Test System (Model 1) may be used by the hospital at the point of care to test the mother's milk.

In response to CMS's concerns regarding the potential Medicare volume for this technology and the eligible Medicare patient population, the applicant stated that testing with the device impacts both maternity-related admissions (as the subject of the nutritional analysis is the mother's breast milk) and neonatal care (as the results of the nutritional analysis guide treatment for the infant). The applicant and other commenters referenced maternal testing, measures such as the Maternal Morbidity Structural Measure in the Hospital Inpatient Quality Reporting (IQR) Program and the Exclusive Breast Milk Feeding electronic clinical quality measure, and Medicare designation of Birthing-Friendly hospitals as evidence for CMS's role in maternal and infant care. A few commenters urged CMS to approve the application for infants regardless of the insurance they hold.

The applicant stated that it agrees with the proposed rule analysis that there is an extremely low volume of Medicare claims for MDC 15 (Newborns & Other Neonates with Conditions Originating in Perinatal Period). However, the applicant maintained that since extremely low-volume MS–DRGs are active, Medicare payment for newborn and neonatal services should accurately reflect resource utilization, regardless of claims volume. Based on these examples cited, the applicant stated that new technology add-on payment eligibility for Emily's Care Nourish Test System is consistent with prior CMS policy with regard to Medicare IPPS reimbursement for maternal services and neonatal care.

Response: We thank the applicant and other commenters for their comments. While we share commenters' interests in improving maternal and infant outcomes, we do not believe that maternal care is relevant to this technology, which received a Breakthrough Device designation to measure the concentration of fat, carbohydrate, and protein in human milk to aid in the nutritional management and treatment of VLBW in the NICU, for both neonates and infants less than 6 months of age. We note that after the infant is delivered, items and services furnished to the infant cannot be covered and reimbursed under Medicare on the basis of the mother's eligibility.[128] Therefore, an infant would need to meet Medicare eligibility criteria, regardless of the mother's Medicare eligibility. As we noted in the proposed rule, infants may be eligible for Medicare if they have ESRD and need regular dialysis or have had a kidney transplant.[129] Therefore, we believe the relevant patient population for the purpose of the new technology add-on payment are VLBW neonates and infants less than 6 months of age with ESRD that need regular dialysis or have had a kidney transplant. Furthermore, the Breakthrough Device designation does not limit the sample source of the device to human milk from the mother. For example, donor human milk may be used in the NICU, as noted by a commenter.

Comment: In response to CMS's concerns with respect to the cost criterion, the applicant submitted a revised cost analysis, updated cost criterion codes, and a calculation narrative. The applicant stated that it conducted three different cost calculations. Per the applicant, the first, and most restrictive, calculation used the diagnosis codes suggested by CMS in the proposed rule discussion and MS–DRGs identified by the applicant related to childbirth or potential maternal nutritional issues. The applicant then identified cases that contained at least one code from the diagnosis code list and were also on the list of MS–DRGs. In this analysis, the applicant identified less than 11 claims mapping to each of two MS–DRGs: 641 (Miscellaneous Disorders of Nutrition, Metabolism, Fluids and Electrolytes without MCC) and 807 (Vaginal Delivery without Sterilization/D&C without CC/MCC), and therefore imputed a value of 11 cases for its cost analysis. The applicant calculated a final inflated average case-weighted standardized charge per case of $39,225, which exceeded the average case-weighted threshold amount of $32,060.

The applicant stated that the second analysis used a diagnosis code list with four additional diagnosis codes that it had identified could be appropriate. These codes are P07.21 (Extreme immaturity of newborn, gestational age less than 23 completed weeks), P07.24 (Extreme immaturity of newborn, gestational age less than 25 completed weeks), P07.25 (Extreme immaturity of newborn, gestational age less than 26 completed weeks) and P07.26 (Extreme immaturity of newborn, gestational age less than 27 completed weeks). The applicant stated that these diagnosis codes for extreme immaturity may be used in place for birthweight diagnosis. The applicant further stated these additional diagnosis codes expanded the number of claims and produced a selection of MS–DRGs unrelated to childbirth. Per the applicant, one hypothesis for the additional MS–DRGs present is that early childbirth may have been induced as the result of the mother's illness. The applicant provided rationale that medical coders and billers preferentially use gestational age over birth weight for coding and reimbursement due to clinical, regulatory, and practical considerations. Per the applicant, the claims data provides some merit for this hypothesis as it contained several claims which appeared to be outliers. The applicant stated the presence of likely outliers for non-neonate patients implies the mother was quite ill, and standardized charges for these outlier cases far exceeded CMS's MS–DRG thresholds. Therefore, the applicant calculated the second analysis two ways: with and without the apparent outlier claims. For the scenario with outlier claims, the applicant calculated a final inflated average case-weighted standardized charge per case of $175,383, which exceeded the average case-weighted threshold amount of $53,328. For the scenario without outlier claims, the applicant calculated a final inflated average case-weighted standardized charge per case of $49,284, which exceeded the average case-weighted threshold amount of $46,604.

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 Emily's Care Nourish Test System (Model 1) meets the cost criterion.

Response: We thank the applicant for its comments and updated cost analysis. We disagree that the additional ICD–10–CM diagnosis codes proposed by the applicant are relevant because gestational age is preferentially used over birthweight for coding and reimbursement due to clinical, regulatory, and practical considerations. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the indication for use of the Emily's Care Nourish Test System (Model 1) that is covered by the FDA Breakthrough Device designation is relevant for

[128] Medicare Benefit Policy Manual Chapter 1—Inpatient Hospital Services Covered Under Part A (Rev. 10892, 08–06–21) *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c01.pdf.*

[129] Centers for Medicare & Medicaid Services. End-stage renal disease (*https://www.medicare.gov/basics/end-stage-renal-disease*, accessed 1/16/2024).

purposes of the new technology add-on payment application. Therefore, we continue to believe that the birthweight-related ICD–10–CM diagnosis codes are most appropriate to identify the use of the technology for VLBW neonates and infants that is relevant to the Breakthrough Device designation for the purposes of new technology add-on payment.

However, we note that the analyses using these additional gestational age-related diagnosis codes were provided as additional analyses. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in the most restrictive scenario. Therefore, the Emily's Care Nourish Test System (Model 1) meets the cost criterion.

Comment: In response to CMS's requests for information about discounts to hospitals, length of stay, and cost breakdown, the applicant stated it does not anticipate providing routine discounts off the cost of the device and any discounts would be a volume discount and should not impact the calculation of new technology add-on payment. The applicant stated that the reference to expected reductions in length of stay was included in error, as it was not included in the labeled claims and resulted from the applicant's misunderstanding of the factors that are relevant to the device cost calculations. The applicant stated the length of stay for maternal cases is not expected to be materially impacted by testing via the Emily's Care Nourish Test System (Model 1). The applicant provided a revised cost of $5,150 per patient, per inpatient stay. The applicant stated that the costs for consumables and single-use disposables is due to an increase in the cost of raw materials and increased cost of control solutions.

In response to CMS's request for additional information regarding the delay in the technology's market availability the applicant stated that as a startup in the maternal and child health sector, Lactation Lab encountered typical early-stage funding obstacles. The applicant stated there was a delay due to restricted access to capital and establishment of the essential infrastructure for achieving scalable manufacturing. Per the applicant, it consequently acquired Lactation Lab and will be manufacturing the device. The applicant expected to be fully commercial by Q4 of 2025.

Response: We thank the applicant for its comment. As we have discussed in prior rulemaking (86 FR 45132 and 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates that the device will be fully commercial by Q4 of 2025, but it is unclear whether the technology would be available for sale earlier, in limited quantities. At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be May 3, 2024.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Emily's Care Nourish Test System (Model 1) meets the cost criterion. The technology received FDA clearance on May 3, 2024, with an indication for use to aid in the nutritional management of newborns, including preterm, and infants. As noted earlier in this section, Emily's Care Nourish Test System (Model 1) has received FDA clearance for multiple indications, and only the use of the Emily's Care Nourish 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. Therefore, we are finalizing to approve new technology add-on payments for the Emily's Care Nourish Test System (Model 1) for FY 2026. Absent additional information from the applicant, we consider the beginning of the newness period to commence on May 3, 2024, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation. Based on the information available at the time of this final rule, the cost per case of Emily's Care Nourish Test System (Model 1) is $5,150 per patient, per inpatient stay. 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 finalizing that the maximum new technology add-on payment for a case involving the use of Emily's Care Nourish Test System (Model 1) is $3,347.50 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for a unique ICD–10–PCS procedure code for the Emily's Care Nourish Test System (Model 1) beginning in FY 2026. Therefore, cases involving the use of Emily's Care Nourish Test System (Model 1) that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XXEZXAB (Measurement of macronutrient content, computer-aided assessment for nutrition management, new technology group 11) in combination with one of the following ICD–10–CM diagnosis 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, 1000-1249 grams
P05.05	Newborn light for gestational age, 1250-1499 grams
P05.11	Newborn small for gestational age, less than 500 grams
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, 1000-1249 grams
P05.15	Newborn small for gestational age, 1250-1499 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, 1000-1249 grams
P07.15	Other low birth weight newborn, 1250-1499 grams

(8) 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

BILLING CODE 4120–01–P

	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.

BILLING CODE 4120–01–C

In the proposed rule, we noted that 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.[130]

We agreed with the applicant that the Esprit™ BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: Multiple commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the Esprit™ BTK Everolimus Eluting Resorbable Scaffold.

The applicant also requested that CMS increase the maximum new technology add-on payments for FY 2026. To support this request, the applicant described two-year data from its randomized controlled trial,[131] stating that among trial subjects, the clinical success of the treatment was not based on a specific number of scaffolds used, but rather on the clinical treatment protocol, which required scaffolds to be placed along the entire length of the diseased artery, also known as ''healthy-to-healthy'' vessel treatment. The applicant stated that while two scaffolds per case were implanted on average to treat the average lesion length of 44 mm, as indicated in its application, a range of one to six scaffolds were implanted depending on the length of the lesion being treated and the corresponding healthy-to-healthy clinical need of the patient. The applicant stated that it also summarized 16 recent studies evaluating infrapopliteal lesions in patients with chronic limb-threatening ischemia, and that lesion lengths ranged from 41 mm to 244.7 mm, with a calculated weighted average of 135.1 mm based on the analyses reflecting real-world clinical practice. In addition, the applicant stated that data in the RECCORD registry showed 40.4 percent of lesions were <10 cm (100 mm), 40.4 percent were 10–20 cm (100 − 200 mm), and 19.2 percent were >20 cm (200 mm) in length, among patients treated solely for infrapoliteal lesions.

Therefore, the applicant requested that CMS revise the maximum new technology add-on payment to $6,933 to reflect a conservative average of 3.55 scaffolds needed to cover the real-world average lesion length of 135.1 mm (65 percent of 3.55 scaffolds, priced at $3,000 each).

Response: We thank the commenters for their comments and for the additional cost and trial information. We note that, based on the information provided by the applicant about the estimated average cost of the technology, the maximum new technology add-on payment for a case would be $6,922.50. Specifically, the applicant stated that an average of 3.55 scaffolds would be used, priced at $3,000 each. Therefore, the estimated average cost per case would be $10,650 and 65 percent of the average cost of the technology ($10,650) is $6,922.50.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe Esprit™ BTK Everolimus Eluting Resorbable Scaffold meets the cost criterion. The technology received FDA marketing authorization on April 26, 2024, with an 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for Esprit™ BTK Everolimus Eluting Resorbable Scaffold for FY 2026. We consider the beginning of the newness period to commence on April 26, 2024, the date on which the technology received its FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of Esprit™ BTK Everolimus Eluting Resorbable Scaffold is $10,650.00. 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 finalizing that the maximum new technology add-on payment for a case involving the use of Esprit™ BTK Everolimus Eluting Resorbable Scaffold is $6,922.50 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of Esprit™ BTK Everolimus Eluting Resorbable Scaffold that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

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

[131] DeRubertis, Brian (2024, November 3–6) Two-Year Outcomes of the LIFE–BTK Randomized Controlled Trial Evaluating the Esprit BTK Drug-eluting Resorbable Scaffold for Treatment of Infrapopliteal Lesions. VIVA 2024 Conference, Las Vegas, NV, United States.

ICD-10-PCS Code	Description
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

(9) 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.

BILLING CODE 4120–01–P

	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.

BILLING CODE 4120–01–C

In the proposed rule, we noted that 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.

We noted in the proposed rule that 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 stated in the proposed rule that we were interested in additional information regarding the cause of any delay in the technology's market availability.

We agreed with the applicant that the EUROPA™ Posterior Cervical Fusion System meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: We received comments, including from the applicant, expressing support for our proposal to approve new technology add-on payment for the EUROPA™ Posterior Cervical Fusion System.

In response to CMS's request for additional information regarding the delay in the technology's market availability, the applicant stated that following FDA clearance of the EUROPA™ Posterior Cervical Fusion System on November 19, 2024, the company initiated final steps toward market release, with product availability anticipated around August 2025. The applicant stated that the EUROPA™ Posterior Cervical Fusion System is manufactured using its proprietary MoRe alloy, which requires a different manufacturing process compared to conventional spinal implant materials. Per the applicant, the raw materials have a long lead time and are further complicated by the current macro-economic conditions, and the MoRe alloy is 3 to 4 times more expensive to produce and requires specialized tooling, extended machining time, and rigorous quality processes. Per the applicant, scaling up production while maintaining consistency and compliance with FDA cleared specifications also contributes to the extended timeline. The applicant stated that finalizing the production capabilities has taken additional time with current market considerations including supplier reliability, global tariff impacts, affecting increased demand on local manufacturing companies and delays in timeline. Per the applicant, additional time is needed to finalize regulatory labeling, sterilization, and transportation validation requirements. The applicant stated that all documentation must undergo internal review, printing, and packaging verification processes. To support commercialization, the applicant stated that it has begun conversations with large hospitals and other organizations to add the products to contracts, and that approvals have taken longer than expected. The applicant stated that it will continue communicating with CMS regarding any additional delays or updates in this timeline as the launch date approaches. The applicant stated that this timing ensures appropriate product training, manufacturing capacity, packaging readiness, and hospital system and facility approvals are in place to support a safe and successful launch.

Response: We thank the commenters for their comments and the applicant for its detailed explanation for delay in commercial market availability. As we have discussed in prior rulemaking (86 FR 45132 and 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates first commercial use and launch beginning around August 2025, but it is unclear whether the technology would be available for sale prior to that date. At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be November 19, 2024.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe the EUROPA™ Posterior Cervical Fusion System meets the cost criterion. The technology received FDA clearance on November 19, 2024, with an indication 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), which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the EUROPA™ Posterior Cervical Fusion System for FY 2026. Absent additional information from the applicant, we consider the beginning of the newness period to commence on November 19, 2024, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the average cost per case of the EUROPA™ Posterior Cervical Fusion System is $123,920, 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). 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 finalizing that the maximum new technology add-on payment for a case involving the use of the EUROPA™ Posterior Cervical Fusion System is $80,548 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the EUROPA™ Posterior Cervical Fusion System beginning in FY 2026. Therefore, cases involving the use of the EUROPA™ Posterior Cervical Fusion System that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
XRH10GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervical vertebral joint, open approach, new technology group 11
XRH13GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervical vertebral joint, percutaneous approach, new technology group 11
XRH14GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervical vertebral joint, percutaneous endoscopic approach, new technology group 11
XRH20GB	Insertion of molybdenum rhenium alloy spinal stabilization device into 2 or more cervical vertebral joints, open approach, new technology group 11
XRH23GB	Insertion of molybdenum rhenium alloy spinal stabilization device into 2 or more cervical vertebral joints, percutaneous approach, new technology group 11
XRH24GB	Insertion of molybdenum rhenium alloy spinal stabilization device into 2 or more cervical vertebral joints, percutaneous endoscopic approach, new technology group 11
XRH40GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervicothoracic vertebral joint, open approach, new technology group 11
XRH43GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervicothoracic vertebral joint, percutaneous approach, new technology group 11
XRH44GB	Insertion of molybdenum rhenium alloy spinal stabilization device into cervicothoracic vertebral joint, percutaneous endoscopic approach, new technology group 11
XRH60GB	Insertion of molybdenum rhenium alloy spinal stabilization device into thoracic vertebral joint, open approach, new technology group 11
XRH63GB	Insertion of molybdenum rhenium alloy spinal stabilization device into thoracic vertebral joint, percutaneous approach, new technology group 11
XRH64GB	Insertion of molybdenum rhenium alloy spinal stabilization device into thoracic vertebral joint, percutaneous endoscopic approach, new technology group 11

(10) 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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In the proposed rule, after review of the information provided by the applicant, we noted 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, we noted that it appeared that this indication was 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 the proposed rule for the list of ICD–10–PCS procedure codes that we believed would be appropriate to exclude when reported in combination with use of the iFuse TORQ TNT™ Implant System. We invited 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 we stated would not be eligible for new technology add-on payment, if approved.

We agreed with the applicant that the iFuse TORQ TNT™ Implant System meets the cost criterion and therefore proposed 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 the 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.

We noted that it appeared that the TNT Implant and Washers are components of the Breakthrough device. However, we noted that the Drill Bit, Guide Pin, and Blunt Pin are instrumentation used for the implantation of the TNT Implant. We stated that 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). We noted it appeared 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, we stated it was 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, we noted it appeared 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 noted 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 proposed 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 invited 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.

Comment: Multiple commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the iFuse TORQ TNT™ Implant System for FY 2026. Several commenters described their positive experience with the technology in their clinical practice and in enabling their elderly patients to return home instead of being discharged to skilled nursing facilities. Commenters stated that the technology enhances patient quality of life, reduces the need for revision surgeries, and facilitates earlier mobilization. A few commenters stated that the initial cost of the iFuse TORQ TNT™ Implant System may present a barrier to broader adoption, but that new technology add-on payment designation would help address this challenge, encourage wider use among surgeons, and enable quicker adoption in hospitals to care for Medicare patients.

Response: We thank the commenters for their comments.

Comment: We received comments expressing general support of the proposed ICD–10–PCS codes for which CMS specifically sought input. Some commenters, including the applicant, submitted public comments regarding the exclusion of new technology add-on payment for cases reporting iFuse TORQ TNT™ Implant System in combination with certain ICD–10–PCS codes noted in Table 10.2 of the proposed rule describing lumbar or thoracolumbar fusion procedures. The applicant stated that the iFuse TORQ TNT™ Implant System has marketing authorization by FDA for placing the implant in a specific trajectory (sacro-alar iliac, or SAI) when adjacent to pelvic fixation screws during the thoracolumbar fusion procedures extending to the pelvis. Per the applicant, this authorization is a ''pre-clearance'' function of a Predetermined Change Control Plan (PCCP) as part of the iFuse TORQ TNT™ Implant System 510(k) application, so that the applicant may conduct future work in this trajectory without the need for submitting another 510(k). The applicant stated that it would be inappropriate to exclude new technology add-on payment for a case using iFuse TORQ TNT™ Implant System as part of a lumbar or thoracolumbar fusion procedure in the same encounter because it is part of iFuse TORQ TNT™ Implant System's approved use and is in-line with its BDD application and pre-cleared indications. Another commenter also questioned whether there was the potential for a multiple level fusion that would involve the sacroiliac fusion using the iFuse TORQ TNT™ Implant System simultaneously with lumbar or thoracolumbar fusion and that it would be inappropriate to exclude cases

simply because the patient is receiving two levels of fusion in the same surgical encounter. The applicant encouraged CMS not to finalize its proposal to exclude ICD–10–PCS procedure codes noted in Table 10.2 in the proposed rule.

Response: We thank the applicant and other commenters for their comments. We agree with the commenters that there may be cases in which a lumbar or thoracolumbar fusion procedure may occur in the same encounter as sacroiliac joint fusion using the iFuse TORQ TNT™ Implant System. We agree that the use of the device for sacroiliac joint fusion is covered by its Breakthrough Device designation, whether it is used to treat sacroiliac joint dysfunction as a standalone procedure or when it is used for sacroiliac joint fusion that also occurs in the setting of other simultaneous procedures (such as lumbar or thoracolumbar fusions). Therefore, we are not finalizing to exclude cases reporting the ICD–10–PCS procedure codes listed in Table 10.2.-iFuse TORQ TNT™ Implant System associated with the proposed rule in combination with use of the iFuse TORQ TNT™ Implant System.

C*omment:* In response to CMS's proposed maximum new technology add-on payment, the applicant requested that CMS increase the per-case maximum amount. Per the applicant, while some of the instruments within the iFuse TORQ TNT™ Implant System may not be unique or part of the Breakthrough Device (that is, Blunt Pin and Drill Bit), the TNT Guide Pins are single-use instruments that were noted in the Breakthrough Device designation application with FDA as new and unique, as they were developed specifically for the iFuse TORQ TNT™ Implant System to support navigation compatibility. The applicant stated that the TNT Guide Pins used in both Pelvic Fixation cases (2.5 units) and SI Joint Fusion cases (3.5 units) are a part of the Breakthrough Device technology, as they are navigational aids, enabling surgeons to accurately position implants, drills, or other tools while minimizing risks to surrounding tissues. Per the applicant, taking into consideration the costs of the new and unique TNT Implant, Washers, and Guide Pins, the weighted average cost per pelvic fixation case (80 percent of mix) and cost per sacroiliac joint fusion case (20 percent of mix), the new technology cost increases to $6,363. The applicant proposed an updated maximum new technology add-on payment for a case of $4,135.95 for FY 2026 (65 percent of the average cost of the technology).

Response: We thank the applicant for its comment and cost information. We agree that the TNT Guide Pins are also a new and unique component of the iFuse TORQ TNT™ Implant System and should be included in the maximum new technology add-on payment.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe the iFuse TORQ TNT™ Implant System meets the cost criterion. The technology received FDA clearance on August 12, 2024, with an indication 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. Therefore, we are finalizing our proposal to approve new technology add-on payments for the iFuse TORQ TNT™ Implant System for FY 2026. We consider the beginning of the newness period to commence on August 19, 2024, the date on which technology received its FDA clearance for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the average cost per case of the iFuse TORQ TNT™ Implant System is $6,363, based on the weighted average cost per pelvic fixation case and cost per sacroiliac joint fusion case of the TNT Implant, Washers, and Guide Pins. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the iFuse TORQ TNT™ Implant System is $4,135.95 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the iFuse TORQ TNT™ Implant System beginning in FY 2026. Therefore, cases involving the use of the iFuse TORQ TNT™ Implant System that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
XRGE0HB	Fusion of right sacroiliac joint using bone-density-specific thread and porosity pattern internal fixation device, open approach, new technology group 11
XRGE3HB	Fusion of right sacroiliac joint using bone-density-specific thread and porosity pattern internal fixation device, percutaneous approach, new technology group 11
XRGF0HB	Fusion of left sacroiliac joint using bone-density-specific thread and porosity pattern internal fixation device, open approach, new technology group 11
XRGF3HB	Fusion of left sacroiliac joint using bone-density-specific thread and porosity pattern internal fixation device, percutaneous approach, new technology group 11
XNSN0HB	Reposition right pelvic bone with bone-density-specific thread and porosity pattern internal fixation device, open approach, new technology group 11
XNSN3HB	Reposition right pelvic bone with bone-density-specific thread and porosity pattern internal fixation device, percutaneous approach, new technology group 11
XNSP0HB	Reposition left pelvic bone with bone-density-specific thread and porosity pattern internal fixation device, open approach, new technology group 11
XNSP3HB	Reposition left pelvic bone with bone-density-specific thread and porosity pattern internal fixation device, percutaneous approach, new technology group 11
XNH60HB	Insertion of bone-density-specific thread and porosity pattern internal fixation device into right pelvic bone, open approach, new technology group 11
XNH63HB	Insertion of bone-density-specific thread and porosity pattern internal fixation device into right pelvic bone, percutaneous approach, new technology group 11
XNH70HB	Insertion of bone-density-specific thread and porosity pattern internal fixation device into left pelvic bone, open approach, new technology group 11
XNH73HB	Insertion of bone-density-specific thread and porosity pattern internal fixation device into left pelvic bone, percutaneous approach, new technology group 11

(11) 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).

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	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 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: $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.

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In the proposed rule, we noted that 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 noted that the application stated that commercialization of the device was initiated on January 2, 2025, with 3 purchase orders in 3 days. We were 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 agreed with the applicant that the Merit Wrapsody® CIE meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the Merit Wrapsody® CIE and agreed with the proposed maximum new technology add-on payment.

In response to CMS's request for additional information regarding the delay in the technology's market availability, commenters stated that the date of the first sale was January 2, 2025, and that sales were delayed due to the holiday season. Per the commenters, the date of FDA clearance on December 19, 2024, occurred before the holiday week and the sales team had completed product training based off the approved indication for use. Per the commenters, in compliance with FDA marketing rules, sales communication about the Merit Wrapsody® CIE did not commence until PMA FDA approval. The commenters stated that manufacturing and production time was needed to assemble finished goods to fulfill customer purchasing. Per the applicant, approval within customers facilities and meetings were scheduled after the Christmas holiday, which led to a delay in purchasing decision until January 2, 2025.

Response: We thank the commenters for their comments and for the additional information.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Merit Wrapsody® CIE meets the cost criterion. The technology received PMA approval on December 19, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Merit Wrapsody® CIE for FY 2026. We consider the beginning of the newness period to commence on January 2, 2025, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Merit Wrapsody® CIE is $5,800. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the Merit Wrapsody® CIE is $3,770 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the Merit Wrapsody® CIE beginning in FY 2026. Therefore, cases involving the use of the Merit Wrapsody® CIE that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes:

ICD-10-PCS Code	Description
X27535B	Dilation of right subclavian vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27635B	Dilation of left subclavian vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27735B	Dilation of right axillary vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27835B	Dilation of left axillary vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27935B	Dilation of right brachial vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27A35B	Dilation of left brachial vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27B35B	Dilation of right basilic vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27C35B	Dilation of left basilic vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27D35B	Dilation of right cephalic vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11
X27E35B	Dilation of left cephalic vein with cell impermeable intraluminal device, percutaneous approach, new technology group 11

12. Minima Stent System

The following table summarizes the information provided in the new technology add-on payment application for the Minima Stent System.

	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.

In the proposed rule, we noted that 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.[132]

With respect to the cost criterion, we noted 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. We noted that, 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 questioned 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 agreed that the technology meets the cost criterion and proposed 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 the proposed rule, the applicant anticipated the total cost of the Minima Stent

[132] 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant expressed support for our proposal to approve new technology add-on payment for the Minima Stent System.

In response to CMS's concern about using the total charges for the Medicare claims within the six identified MS–DRGs to estimate eligible cases in a pediatric patient population, the applicant stated that the Minima Stent System was FDA-approved ten months ago and that given the newness of the procedure and absence of pediatric cases in Medicare data and other available claims data, its approach of using Medicare claims within six identified MS–DRGs was reasonable. The applicant stated that while Medicare coverage is expected to be rare with fewer than 10 cases during the new technology add-on payment period, there are circumstances where medically complex children will be covered under Medicare, citing precedent with the new technology add-on payment approval for the MAGEC® Spinal Bracing Distraction system for pediatric use in FY 2017. The applicant stated that in its original cost analysis, using Medicare cases, the new charge per case of $135,000 for the device alone surpassed the case-weighted threshold of $128,762 without including other inpatient stay charges, and that since the Minima Stent device is not replacing an existing technology, it would meet the cost criterion regardless of the applicability of Medicare charges to eligible pediatric cases.

To verify if the Medicare threshold might be too low, the applicant also reviewed data from the Healthcare Cost and Utilization Project (HCUP) Kids' Inpatient Database (KID) and HCUP National Inpatient Sample (NIS) to evaluate case distribution threshold. The applicant identified 6,855 HCUP KID cases compared to 75,638 cases Medicare cases across the six MS–DRGs used in its cost analysis. The applicant noted that pediatric cases were distributed differently compared to Medicare cases, resulting in a higher case-weighted threshold of $141,341. The applicant also stated that pediatric inpatient stays had a higher average length of stay, higher average charges, and higher average costs per stay. Based on the distribution of pediatric cases, the applicant conducted an additional cost analysis and calculated a final inflated average case-weighted standardized charge per case of $281,314, which exceeded the average case-weighted threshold amount of $141,341.

Per the applicant, data from HCUP NIS and HCUP KID suggest that for the six identified MS–DRGs, pediatric inpatient stays have higher average length of stay, higher average charges and higher average costs per stay compared to inpatient stays across all ages. Per the applicant, this suggests that using total Medicare charges in the cost criterion analysis likely resulted in an underestimated inflated case-weighted standardized charge per case for the Minima stent and that while Medicare charges are not a perfect estimate, they are a reasonable and conservative substitute.

Response: We thank the applicant and other commenters for their comments. We acknowledge the challenges of estimating charges related to use of a pediatric device using Medicare data and agree that the Medicare charges used in this analysis are reasonable based on the additional information provided by the applicant.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Minima Stent System meets the cost criterion. The technology received PMA approval on August 28, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Minima Stent System for FY 2026. We consider the beginning of the newness period to commence on August 28, 2024, the date on which the technology received its premarket approval for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Minima Stent System is $34,900. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the Minima Stent System is $22,685 for FY 2026 (that is, 65 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the Minima Stent System beginning in FY 2026. Therefore, cases involving the use of the Minima Stent System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: X27339B (Dilation of right pulmonary artery with expandable intraluminal device, percutaneous approach, new technology group 11), X27439B (Dilation of left pulmonary artery with expandable intraluminal device, percutaneous approach, new technology group 11), X27W39B (Dilation of thoracic aorta, descending with expandable intraluminal device, percutaneous approach, new technology group 11), or X27X39B (Dilation of thoracic aorta, ascending/arch with expandable intraluminal device, percutaneous approach, new technology group 11).

(12) 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.

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In the proposed rule, we noted that 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.[133]

We noted in the proposed rule that according to the applicant, the MY01 Mobile Application was not yet available for use because the applicant was completing final testing of the application before it is available for download. We stated that we were 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 agreed with the applicant that the MY01 Continuous Compartmental Pressure Monitor meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: We received comments expressing support for technologies under consideration for new technology add-on payments for FY 2026.

The applicant submitted a public comment in response to CMS's request for additional information regarding the delay in the technology's market availability. The applicant stated that there was a slight market availability delay for the MY01 Mobile App due to launch and distribution orchestration and post approval compliance documentation. Per the applicant, the MY01 Mobile App was available on the Apple App Store and the Google Play Store on April 29, 2025.

Response: We thank the commenters for their comments. Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe MY01 Continuous Compartmental Pressure Monitor meets the cost criterion. The technology received FDA marketing authorization on March 13, 2025, with an indication for real-time and continuous measurement of the muscle compartment pressure, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for MY01 Continuous Compartmental Pressure Monitor for FY 2026. We consider the beginning of the newness period to commence on April 29, 2025, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of MY01 Continuous Compartmental Pressure Monitor is $3,250. 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 finalizing that the maximum new technology add-on payment for a case involving the use of MY01 Continuous Compartmental Pressure Monitor is $2,112.50 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of MY01 Continuous Compartmental Pressure Monitor that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XX2F3W9 (Monitoring of musculoskeletal muscle compartment pressure, micro-electro-mechanical system, percutaneous approach, new technology group 9).

(13) 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

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

	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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In the proposed rule, we noted that 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 agreed with the applicant that the PBC Separator with Selux AST System meets the cost criterion and therefore proposed 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 the 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 noted that according to the applicant, the Selux AST System has been granted multiple previous FDA clearances for a different indication and sample type.[134] However, we stated that per the applicant, the Breakthrough Device designation is for the Selux Positive Blood Culture Separator and Selux [AST] System. We stated that the previous FDA clearances for the Selux AST System were not considered Breakthrough Devices. Therefore, we noted that it appeared 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 noted 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 noted 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 proposed 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 invited 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.

Comment: We received comments expressing support for technologies under consideration for new technology add-on payments for FY 2026.

Response: We thank the commenters for their comments. Based on the information provided in the application for new technology add-on payments, we believe the PBC Separator with Selux AST System meets the cost criterion. The technology received 510(k) clearance on February 15, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the PBC Separator with Selux AST System for FY 2026. We consider the beginning of the newness period to commence on February 15, 2024, the date on which technology received its premarket approval for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the PBC Separator with Selux AST System is $135.04. As noted earlier in this section, the Selux AST System has been granted multiple previous FDA clearances for a different indication and sample type.[135] 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. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the PBC Separator with Selux AST System is $87.78 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of the PBC Separator with Selux AST System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XXE5XY9 (Measurement of infection, other positive blood/isolated colonies bimodal phenotypic susceptibility technology, new technology group 9).

(14) 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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[134] *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211759.pdf* and *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211748.pdf.*

[135] *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211759.pdf* and *https://www.accessdata.fda.gov/cdrh_docs/pdf21/K211748.pdf.*

	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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In the proposed rule, after review of the information provided by the applicant, we noted 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 noted 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, we noted that only the use of the RECELL® Autologous Cell Harvesting Device for acute nonthermal full thickness skin wounds after traumatic avulsion, surgical excision (for example, necrotizing soft tissue infection), or resection (for example, skin cancer), and the FDA Breakthrough Device designation it received for those uses, were 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 the proposed rule for the list of relevant ICD–10–CM diagnosis codes that we believed 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 the proposed rule for the list of relevant ICD–10–PCS procedure codes that we believed 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 invited 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 agreed with the applicant that the RECELL® Autologous Cell Harvesting Device meets the cost criterion and therefore proposed 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 the 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 noted 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, proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the RECELL® Autologous Cell Harvesting Device. We received comments expressing general support of the proposed ICD–10–CM/PCS codes for which CMS specifically sought input. The applicant further stated its support for the use of the ICD–10–CM diagnosis codes listed in Table 10.1.A and the ICD–10–PCS procedure codes listed in Table 10.1.B to identify cases eligible for new technology add-on payments for FY 2026, and agreed that new technology

add-on payment eligibility is limited to the Breakthrough-designated indication for nonthermal full-thickness wounds. The applicant also supported CMS's proposal to establish a maximum payment of $4,875 per case, based on the cost of $7,500 per device.

A commenter requested more clarity regarding the circumstances in which a hospital is eligible to receive new technology add-on payments for the RECELL® Autologous Cell Harvesting Device. Per the commenter, the technology's use in combination with another procedure (meshed autografting) is atypical and stated that it would expect that such a claim must include: (i) an ICD–10–PCS code for the use of the RECELL® Autologous Cell Harvesting Device; (ii) an ICD–10–PCS code for meshed autografting; and (iii) an ICD–10–CM code to reflect use for patients with acute nonthermal full thickness skin wounds. The commenter stated that the need for the latter two seemed to be implicit in CMS's development of Table 10.1.B and Table 10.1.A, respectively, in connection with the proposed rule. However, the commenter stated that the messaging should not be implicit, but that CMS should issue a clear statement in the final rule, or consider communicating it in an implementing transmittal, or in a Medicare Learning Network (MLN) issuance.

The commenter also recommended that CMS reassess the scope of the new technology add-on payments for FY 2026 to ensure that we had identified the appropriate ICD–10–PCS and ICD–10–CM codes to capture what would be appropriate to report in combination with the use of the RECELL® Autologous Cell Harvesting Device and that would identify the pertinent Breakthrough Device indication. Per the commenter, the listed ICD–10–PCS codes in Table 10.1.B are all for excision procedures and should be removed so that CMS can populate the table with procedures for meshed autografting. The commenter also stated its concern with the listed ICD–10–CM codes in Table 10.1.A as it stated many of the listed codes are for lacerations and lacerations typically do not correlate to full thickness wound. Accordingly, the commenter stated that it is important for CMS to ensure that Table 10.1.A be populated with diagnosis codes that capture nonthermal, full thickness wounds.

Response: We thank the applicant and other commenters for their comments.

We disagree that the procedure codes for meshed autografting should be included in Tables 10.1.A or 10.1.B. Table 10.1.A.-RECELL® Autologous Cell Harvesting Device associated with the proposed rule provided the list of relevant ICD–10–CM diagnosis codes that we believed would identify the Breakthrough Device-designated indication of acute nonthermal full thickness skin wounds after traumatic avulsion. Table 10.1.B.-RECELL® Autologous Cell Harvesting Device associated with the proposed rule provided the list of relevant ICD–10–PCS procedure codes that we believed 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 had listed ICD–10–PCS procedure codes in Table 10.1.B.-RECELL® Autologous Cell Harvesting Device to identify use of the technology after surgical excision or resection because these describe procedures, not diagnoses. Either a code from Table 10.1.A or Table 10.1.B. associated with the proposed rule may be used to identify the Breakthrough Device-designated indication for the RECELL® Autologous Cell Harvesting Device.

As we noted in the proposed rule, although the RECELL® Autologous Cell Harvesting Device is also indicated for acute partial-thickness thermal burn wounds and acute full-thickness thermal burn wounds, only the use of the 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, were relevant for purposes of the new technology add-on payment application for FY 2026. According to its FDA indication for use, the RECELL® Autologous Cell Harvesting Device is used for application in combination with meshed autografting for both acute full-thickness thermal burn wounds and full-thickness skin defects. Therefore, it is not possible to differentiate between use of the device for acute full-thickness thermal burn wounds and full-thickness skin defects using the procedure codes for meshed autografting, and these codes are not relevant to our proposal.

Although we agree with the commenter that some of the listed diagnosis codes in Table 10.1.A associated with the proposed rule may not correlate to full thickness skin wounds after traumatic avulsion in all instances, we note that these diagnosis codes must be reported in combination with use of the RECELL® Autologous Cell Harvesting Device to be eligible for new technology add-on payment. The RECELL® Autologous Cell Harvesting Device is FDA market authorized for use in full-thickness skin defects. Therefore, we believe that when these diagnosis codes are used in combination with the list of procedure codes that uniquely identify procedures involving the use of the RECELL® Autologous Cell Harvesting Device, they would describe full thickness skin defects. Therefore, we are finalizing the lists of codes in Tables 10.1.A.- and 10.1.B.-RECELL® Autologous Cell Harvesting Device associated with the proposed rule as proposed. We note that Tables 10.A.- and 10.B.-RECELL® Autologous Cell Harvesting Device associated with this final rule are the same as Tables 10.1.A.- and 10.1.B.-RECELL® Autologous Cell Harvesting Device associated with the proposed rule, respectively, but the names of the tables were updated for this final rule.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the RECELL® Autologous Cell Harvesting Device meets the cost criterion. The technology received FDA marketing authorization on June 7, 2023, with an indication for use 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), which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the RECELL® Autologous Cell Harvesting Device for FY 2026. We consider the beginning of the newness period to commence on June 7, 2023, the date on which the technology received its FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the RECELL® Autologous Cell Harvesting Device is $7,500. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the RECELL® Autologous Cell

Harvesting Device is $4,875 for FY 2026 (that is, 65 percent of the average cost of the technology). As noted earlier in this section, 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 for FY 2026.

Therefore, cases involving the use of the RECELL® Autologous Cell Harvesting Device that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes, in combination with any of the ICD–10–CM diagnosis codes listed in Table 10.A.-RECELL® Autologous Cell Harvesting Device or ICD–10–PCS procedure codes listed in Table 10.B.-RECELL® Autologous Cell Harvesting Device associated with this final rule.

ICD-10-PCS Code	Description
0HR0X72	Replacement of scalp skin with autologous tissue substitute, cell suspension technique, external approach
0HR1X72	Replacement of face skin with autologous tissue substitute, cell suspension technique, external approach
0HR2X72	Replacement of right ear skin with autologous tissue substitute, cell suspension technique, external approach
0HR3X72	Replacement of left ear skin with autologous tissue substitute, cell suspension technique, external approach
0HR4X72	Replacement of neck skin with autologous tissue substitute, cell suspension technique, external approach
0HR5X72	Replacement of chest skin with autologous tissue substitute, cell suspension technique, external approach
0HR6X72	Replacement of back skin with autologous tissue substitute, cell suspension technique, external approach
0HR7X72	Replacement of abdomen skin with autologous tissue substitute, cell suspension technique, external approach
0HR8X72	Replacement of buttock skin with autologous tissue substitute, cell suspension technique, external approach
0HR9X72	Replacement of perineum skin with autologous tissue substitute, cell suspension technique, external approach
0HRAX72	Replacement of inguinal skin with autologous tissue substitute, cell suspension technique, external approach
0HRBX72	Replacement of right upper arm skin with autologous tissue substitute, cell suspension technique, external approach
0HRCX72	Replacement of left upper arm skin with autologous tissue substitute, cell suspension technique, external approach
0HRDX72	Replacement of right lower arm skin with autologous tissue substitute, cell suspension technique, external approach
0HREX72	Replacement of left lower arm skin with autologous tissue substitute, cell suspension technique, external approach
0HRFX72	Replacement of right hand skin with autologous tissue substitute, cell suspension technique, external approach
0HRGX72	Replacement of left hand skin with autologous tissue substitute, cell suspension technique, external approach
0HRHX72	Replacement of right upper leg skin with autologous tissue substitute, cell suspension technique, external approach
0HRJX72	Replacement of left upper leg skin with autologous tissue substitute, cell suspension technique, external approach
0HRKX72	Replacement of right lower leg skin with autologous tissue substitute, cell suspension technique, external approach
0HRLX72	Replacement of left lower leg skin with autologous tissue substitute, cell suspension technique, external approach
0HRMX72	Replacement of right foot skin with autologous tissue substitute, cell suspension technique, external approach
0HRNX72	Replacement of left foot skin with autologous tissue substitute, cell suspension technique, external approach

(15) 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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In the proposed rule, we noted that after review of the information provided by the applicant, we agreed with the applicant that the restor3d TIDAL™ Fusion Cage meets the cost criterion and therefore proposed 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 the 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). We noted that based on the information provided by the applicant, the cost of the Instrument Kit was 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, we noted it appeared that the TTC Fusion Nail and Bone Graft were not new and unique components for this technology and could be purchased separately in support of other technologies. Furthermore, we noted that the Instrument Kit was not included in the Breakthrough Device designation, and it therefore appeared 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, we stated it appeared any add-on payment for the restor3d TIDAL™ Fusion Cage would include only the cost of the restor3d TIDAL™ Fusion Cage ($27,995).

We noted 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 proposed 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 invited 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.

Comment: We received comments expressing support for technologies under consideration for new technology add-on payments for FY 2026.

The applicant submitted a public comment noting that the restor3d TIDAL Fusion Cage received FDA 510(k) clearance (K242356) effective March 24, 2025, and that the Indications for Use are a subset of the Breakthrough Device designation indications.

Response: We thank the commenters for their comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe restor3d TIDAL™ Fusion Cage meets the cost criterion. The technology received 510(k) clearance from FDA on March 24, 2025, with an indication for use as part of a tibiotalocalcaneal fusion construct in a salvage procedure following failed ankle arthrodesis or failed ankle arthroplasty for patients at risk of limb loss, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for restor3d TIDAL™ Fusion Cage for FY 2026. We consider the beginning of the newness period to commence on March 24, 2025, the date on which technology received its 510(k) clearance for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of TIDAL Fusion Cage System is $27,995. 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 finalizing that the maximum new technology add-on payment for a case involving the use of TIDAL Fusion Cage System is $18,196.75 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of TIDAL Fusion Cage System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: 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), or XRGL0CA (Fusion of right tarsal joint using gyroid-sheet lattice design internal fixation device, open approach).

(16) ShortCut™

The following table summarizes the information provided in the new technology add-on payment application for the ShortCut™.

	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.

After review of the information provided by the applicant, we agreed with the applicant that the ShortCut™ meets the cost criterion and therefore proposed 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 the proposed rule, the applicant anticipated the total cost of the ShortCut™ to the hospital to be $15,000 per patient. We noted 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 proposed 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 invited 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.

Comment: Multiple commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the ShortCut™ device for FY 2026. Some commenters provided their perspectives regarding the clinical need for the device. Several commenters, including the applicant, noted that the device enabled splitting of pre-existing valve leaflets after insertion of the transcatheter heart valve to allow blood flow into the adjacent or ''at risk'' coronary artery. Per commenters, approving new technology add-on payments for ShortCut™ would make it economically feasible for hospitals to offer this breakthrough technology to Medicare patients without incurring steep losses

The applicant further reiterated that the ShortCut™ device received FDA

Breakthrough Device Designation on January 18, 2024, and FDA market clearance on September 27, 2024. The applicant also noted that CMS created a new ICD–10–PCS procedure code (X28F3VA) effective October 1, 2024, responding to the growing need for leaflet splitting in patients undergoing valve-in-valve transcatheter aortic valve replacement.

Response: We thank the commenters for their comments.

Based on the information provided in the application for new technology add-on payments, we believe the ShortCut™ meets the cost criterion. The technology received FDA marketing authorization on September 27, 2024, with an indication for use as a splitting device of bioprosthetic aortic valve leaflets to facilitate valve-in-valve procedures for patients at risk of coronary obstruction, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the ShortCut™ for FY 2026. We consider the beginning of the newness period to commence on September 27, 2024, the date on which technology received its FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the ShortCut™ is $15,000. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the ShortCut™ is $9,750 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of the ShortCut™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X28F3VA (Division of aortic valve using intraluminal bioprosthetic valve leaflet splitting technology in existing valve, percutaneous approach, new technology group 10).

(17) The WiSE CRT System

The following table summarizes the information provided in the new technology add-on payment application for The WiSE CRT System.

	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.

In the proposed rule, we noted that after review of the information provided by the applicant, we agreed with the applicant that the WiSE CRT System meets the cost criterion and therefore proposed 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 the proposed rule, the applicant anticipated the total cost of the WiSE CRT System to the hospital to be $63,300 per patient. The components included the electrode

and catheter ($21,970), the delivery sheath ($2,590), the battery ($12,870), and the transmitter ($25,870). We noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the WiSE CRT System. The applicant further stated that the WiSE CRT System received FDA approval on April 11, 2025, and that the approved indications are consistent with the Breakthrough Device designation indications. The applicant also noted that the total price of the technology is unchanged.

Response: We thank the commenters for their comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the WiSE CRT System meets the cost criterion. The technology received premarket approval from FDA on April 11, 2025, with an indication for adult patients who are at least 22 years of age, are indicated for CRT, have an existing or are eligible for an implanted right ventricular pacing system, and are in one of the following two categories: •Patients in whom previous coronary sinus (CS) lead implantation was unsuccessful, or where an implanted lead has been turned off, referred to as ''previously untreatable''; •Patients with previously implanted pacemakers or Implantable Cardioverter-Defibrillators (ICDs) 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,'' which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the WiSE CRT System for FY 2026. We consider the beginning of the newness period to commence on April 11, 2025, the date on which the technology received premarket approval for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the WiSE CRT System is $63,300. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the WiSE CRT System is $41,145 for FY 2026 (that is, 65 percent of the average cost of the technology). The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for the WiSE CRT System beginning in FY 2026. Therefore, cases involving the use of the WiSE CRT System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X2HN37B (Insertion of endocardiac pacing electrode into left ventricle, percutaneous approach, new technology group 11) in combination with XHH80HB (Insertion of ultrasound transmitter and battery for endocardiac pacing electrode into chest subcutaneous tissue and fascia, open approach, new technology group 11).

(18) TriVerity Test

The following table summarizes the information provided in the new technology add-on payment application for the TriVerity Test.

	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.

In the proposed rule, after review of the information provided by the applicant, we noted the applicant stated that the technology was not commercially available immediately after FDA clearance. We stated in the proposed rule that we were 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, we stated that 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, we noted that the applicant included diagnosis codes related to sepsis of newborn in the second cost criterion analysis. We questioned whether diagnosis codes related to newborns were applicable to this technology because it is indicated for use in adult patients, and whether the applicant should have removed these diagnosis codes to identify eligible cases more accurately.

Subject to the applicant adequately addressing this concern, we agreed that the technology meets the cost criterion and proposed 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 the 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). We noted that 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 noted 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.[136] Therefore, we stated that it appeared that only the cost of the TriVerity Cartridge was appropriate for consideration for new technology add-on payment. We noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, expressed support for our proposal to approve new technology add-on payment for the TriVerity Test for FY 2026.

In response to CMS's request for additional information regarding the delay in the technology's market availability, the applicant stated that the TriVerity Test was cleared by FDA on January 10, 2025, and commercial product inventory became available for hospital customers on March 13, 2025. The applicant stated that Inflammatix manufactures TriVerity cartridges at their headquarters in Sunnyvale, CA and has both an active cartridge production line and storage facilities of TriVerity cartridge inventory. The applicant stated that it affirms it has built up cartridge inventory to meet hospital customer demand for routine use of the TriVerity test.

In response to CMS's question about including diagnosis codes related to sepsis of newborn in the second cost criterion analysis, the applicant stated that while these codes were included in the algorithm to select cases for the analysis, it did not actually identify any cases with the newborn sepsis ICD–10–CM diagnosis codes. Per the applicant, removal of those codes from the case selection algorithm does not affect the results of the cost criterion analysis and the final inflated case weighted

[136] *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/denovo.cfm?id=DEN050003.*

standardized charge per case of $81,393 exceeded the case weighted threshold of $73,258 by $8,135. The applicant reiterated that the other cost criterion analysis scenario had a final inflated case weighted standardized charge per case of $70,025, which exceeded the case weighted threshold of $67,984 by $2,041 and that the TriVerity Test meets the cost criterion under both scenarios.

The applicant also agreed with CMS's statement that only the cost of the TriVerity Cartridge should be included in the new technology add-on payment calculation.

Response: We thank the applicant and other commenters for their comments. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, the TriVerity Test meets the cost criterion.

We stated in the proposed rule that we were 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. Although the applicant affirmed that it has built up cartridge inventory to meet demand for routine use of the TriVerity Test, we note that we did not receive any information regarding the cause of any delay in the technology's commercial availability. Therefore, at this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we consider the beginning of the newness period to commence on January 10, 2025, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the TriVerity Test meets the cost criterion. The technology received FDA marketing authorization on January 10, 2025, with an indication 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. Therefore, we are finalizing our proposal to approve new technology add-on payments for the TriVerity Test for FY 2026. We consider the beginning of the newness period to commence on January 10, 2025, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the TriVerity Test for the TriVerity Cartridge component is $375. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the TriVerity Test is $243.75 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of the TriVerity Test that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XXE5XBB (Measurement of infection and immune response, gene expression testing system, new technology group 11).

(19) 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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	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.

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In the proposed rule, we noted that 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.[137]

We noted 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 stated that we were 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 was not clear how lead times in the supply chain affected its availability on the market and what system modifications were required.

We agreed with the applicant that the VITEK® REVEAL™ AST System meets the cost criterion and therefore proposed 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 the 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 noted 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 proposed 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 invited 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.

Comment: A few commenters, including the applicant, submitted public comments expressing support for our proposal to approve new technology add-on payment for the VITEK® REVEAL™ AST System for FY 2026. The applicant also stated that the technology meets the newness criterion for FY 2026, does not have to demonstrate substantial clinical improvement in order to qualify for new technology add-on payments, reiterated that it met the cost criterion, and agreed

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

with the proposed maximum new technology add-on payment of $81.25.

In response to CMS's request for additional information regarding the delay in the technology's market availability, the applicant stated the VITEK® REVEAL™ received FDA clearance in June 2024, but the technology was not commercially available until October 21, 2024. Per the applicant, the basis for the delay was due to the implementation of a software requirement from FDA that could not be validated until a validation panel was available. The applicant stated that an external entity was not able to provide the aforementioned panel until September 2024, and that validation was initiated upon receipt of the panel and completed in October. Per the applicant, it had to delay commercial availability until this step was completed.

Response: We thank the commenters for their comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the VITEK® REVEAL™ AST System meets the cost criterion. The technology received 510(k) clearance on June 20, 2024, with an indication 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, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the VITEK® REVEAL™ AST System for FY 2026. We consider the beginning of the newness period to commence on October 21, 2024, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the VITEK® REVEAL™ AST System is $125. 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 finalizing that the maximum new technology add-on payment for a case involving the use of the VITEK® REVEAL™ AST System is $81.25 for FY 2026 (that is, 65 percent of the average cost of the technology). Cases involving the use of the VITEK® REVEAL™ AST System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XXE5X4A (Measurement of infection, positive blood culture small molecule sensor array technology, new technology group 10).

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).

	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.

In the proposed rule, we noted that 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 noted that the applicant stated that the technology is expected to be commercially available by Q3 of CY 2025 due to product availability. We stated we were 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 agreed with the applicant that EMBLAVEO™ meets the cost criterion and therefore proposed to approve EMBLAVEO™ for new technology add-on payments for FY 2026 for use in patients 18 years and older who have limited or no alternative options for the treatment of cIAI.

The applicant had not provided an estimate for the cost of EMBLAVEO™ at the time of the proposed rule. We stated that we expected the applicant to submit cost information prior to the final rule, and that we would provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. We stated that 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 invited public comments on whether EMBLAVEO™ meets the cost criterion and our proposal to approve new technology add-on payments for EMBLAVEO™ for FY 2026.

Comment: A few commenters, including the applicant submitted public comments expressing support for our proposal to approve new technology add-on payment for EMBLAVEO™ for FY 2026, with the applicant further reiterating that the product meets the cost criterion.

In response to CMS's request regarding the cause for delay in the technology's market availability, the applicant stated that it expected that EMBLAVEO™ would be commercially available for use and purchase in the United States by quarter 3 (Q3) of calendar year (CY) 2025 due to delays related to first run manufacturing for the product and packaging and other processes such as securing an export license to ship the drug to the U.S., followed by customs clearance. The applicant stated that the product will not be commercially available in the U.S. until after these processes are complete and that it would notify CMS of the date when EMBLAVEO™ is first available in the U.S. The applicant requested that the newness period for the product begin on that date.

The applicant also provided the cost for EMBLAVEO™ at $327 per vial as of June 9, 2025. The applicant stated that the anticipated cost of EMBLAVEO™ in the hospital setting is $12,000.90, which was calculated using data from the clinical trials and accounted for the loading dose, patients' estimated creatinine clearance, and treatment duration. The applicant requested that CMS set the maximum new technology add-on payment for cases involving the use of EMBLAVEO™ at $9,000.68 for FY 2026 (that is, 75 percent of the average cost of the technology), because EMBLAVEO™ is a designated QIDP.

Response: We thank the commenters for their support and additional information.

As we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that EMBLAVEO™ is expected to be commercially available by Q3 of CY 2025 due to product availability, but it is unclear whether the technology would be available for sale prior to that date. At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be February 7, 2025.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe EMBLAVEO™ meets the cost criterion. The technology received NDA approval on February 7, 2025, with an indication for use in patients 18 years and older who have limited or no alternative options for the treatment of cIAI, which is covered by its QIDP designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for EMBLAVEO™ for FY 2026. Absent additional information from the applicant, we consider the beginning of the newness period to commence on February 7, 2025, the date of FDA marketing authorization for the indication covered by its QIDP designation.

Based on the information available at the time of this final rule, the cost per case of EMBLAVEO™ is $12,000.90. Under § 412.88(a)(2), we limit new technology add-on payments 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. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of EMBLAVEO™ is $9,000.68 for FY 2026 (that is, 75 percent of the average cost of the technology).

The applicant submitted a request and was granted approval for unique ICD–10–PCS procedure codes for EMBLAVEO™ beginning in FY 2026. Therefore, cases involving the use of EMBLAVEO™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033PB (Introduction of aztreonam-avibactam anti-infective into peripheral vein, percutaneous approach, new technology group 11) or XW043PB (Introduction of aztreonam-avibactam anti-infective into central vein, percutaneous approach, new technology group 11).

(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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In the proposed rule, after review of the information provided by the applicant, we noted that the applicant stated that the technology is expected to be commercially available within 3 months of FDA approval, and we stated that we would appreciate more information on the reasons for any delay in the commercial availability of CONTEPO™ following FDA approval.

We agreed with the applicant that CONTEPO™ meets the cost criterion and therefore proposed 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. We stated that 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). We stated that 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 the proposed rule, the applicant anticipated 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 noted 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 payment 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 proposed 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 invited 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.

Comment: We received comments expressing support for technologies under consideration for new technology add-on payments for FY 2026.

The applicant submitted a public comment in response to CMS's request for additional information regarding the expected delay in the commercial availability of CONTEPO™ following FDA approval. The applicant stated that once CONTEPO™ receives marketing authorization from FDA, the final label needs to be implemented and printed, and product packaging needs to be finalized and produced. The applicant stated that logistics in the supply chain and proper loading of product information in the supply chain systems would altogether take an anticipated three months from approval. The applicant stated that this was the basis of its assessment of product availability 3 months after FDA approval.

Response: We thank the commenters for their comments. As we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that it anticipates three months from FDA approval for commercial availability, but it is unclear when the technology would be available for sale. At this time, there is not sufficient information to determine a newness date based on a documented delay in the technology's availability on the U.S. market.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe CONTEPO™ meets the cost criterion. Therefore, we are granting a conditional approval for CONTEPO™ for new technology add-on payments for FY 2026, subject to the technology receiving FDA marketing authorization before July 1, 2026 (that is, before July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2026)). In the proposed rule we stated that 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) (90 FR 18217). 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 will be made for cases involving the use of CONTEPO™ for FY 2026.

Based on the information available at the time of this final rule, the cost per case of CONTEPO™ is $11,700. Under § 412.88(a)(2), we limit new technology add-on payments 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. As a result, we are finalizing that, subject to CONTEPO™ receiving FDA marketing authorization before July 1, 2026, the maximum new technology add-on payment for a case involving the use of CONTEPO™ is $8,775 for FY 2026 (that is, 75 percent of the average cost of the technology). Cases involving the use of CONTEPO™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033WB (Introduction of fosfomycin anti-infective into peripheral vein, percutaneous approach, new technology group 11) or XW043WB (Introduction of fosfomycin anti-infective into central vein, percutaneous approach, new technology group 11).

7. Other Comments

We received several public comments requesting changes to the new technology add-on payment policies such as, but not limited to: modifying or removing the requirement for a complete and active FDA marketing authorization request, changing the deadline for an applicant for new technology add-on payments to receive FDA marketing authorization, and establishing a more frequent (such as quarterly or biannual) process to apply for new technology add-on payment. We also received comments on technologies that were not under consideration for new technology add-on payments for FY 2026. These comments were outside the scope of the proposals included in the FY 2026 IPPS/LTCH PPS proposed rule and we are therefore not addressing them in this final rule.

III. 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 FY 2026 hospital wage index based on the statistical areas appears under section III.B. of the preamble of this final 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 have submitted the information collection request to OMB for reapproval. 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 adjustment for FY 2026 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final 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 budget neutrality adjustment for FY 2026 is discussed in section II.A.4.b. of the Addendum to this final 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 January 31, 2026, expiration date. We plan to submit the information collection request to OMB for reapproval in the near future. A discussion of the occupational mix adjustment that we are applying to the FY 2026 wage index appears under section III.E. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the 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 final 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 continuing to use the new OMB delineations that we adopted beginning with FY 2025 to calculate the area wage indexes and the transition periods.

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 continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2026, Tables 2 and 3 associated with this final 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 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 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 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 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 through 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 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 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. However, we stated that 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. After we

issued the proposed rule, for the final FY 2026 wage index, we restored the data of 15 hospitals to the wage index, because their data was either verified or improved and removed the data of 2 hospitals with aberrant data. Thus, 66 hospitals with aberrant data remain excluded from the FY 2026 wage index (79 − 15 + 2 = 66).

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 stated in the proposed rule (90 FR 18219) that 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. We did not receive any comments with regard to this proposal, and we are finalizing as proposed to exclude hospitals that have subsequently converted to CAH and/or REH from the wage index calculation. Since we issued the proposed rule, we learned of 6 more hospitals that converted to CAH and/or REH status on or after January 24, 2024, and through and including January 24, 2025. We removed these additional hospitals from the FY 2026 wage index due to their conversion to CAH and/or REH status. In summary, we calculated the FY 2026 wage index using the Worksheet S–3, Parts II and III wage data of 3,036 hospitals.

For the 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 final 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
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.

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) was 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, was 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 were given the opportunity to examine Table 2 associated with the 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 contained 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 noted in the proposed rule that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by late January 2025.

We posted 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 was required to send its request to CMS and to the MAC so that it was received no later than May 30, 2025. May 30, 2025, was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital was 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 were 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 were 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 final 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 will correct that data error, and the hospital's average hourly wage will 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 FY 2026 Unadjusted Wage Index

The method used to compute the 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 did not propose any changes to this methodology. We have restated our methodology in this section the preamble of this final 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 will 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 did not propose 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 final 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 will 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 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 final 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 this final 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 did not propose 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 final FY 2026 unadjusted national average hourly wage is the following:

Final FY 2026 Unadjusted Average Hourly Wage: $57.92

D. 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 proposed 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 final rule (which is available via the internet on the CMS website), which contains the final 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 final 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 was $57.63.

We did not receive any comments on our proposed calculation of the occupational mix adjustment to the FY 2026 wage index. Thus, for the reasons discussed in this final rule and in the FY 2026 IPPS/LTCH PPS proposed rule, we are finalizing our proposal without modification to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index and to apply the occupational mix adjustment to 100 percent of the FY 2026 wage index.

For the final FY 2026 wage index, we are using the Worksheet S–3, Parts II and III wage data of 3,036 hospitals, and we are using the occupational mix surveys of 2,952 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (2,952/3,036). For the final FY 2026 wage index, we are applying 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 final FY 2026 occupational mix adjusted national average hourly wage is the following:

Final FY 2026 Occupational Mix Adjusted National Average Hourly Wage: $57.86

3. Occupational Mix Adjustment and the FY 2026 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final 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 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	$35.05
National Nurse Aide, Orderly, and Attendant	$23.53
National Medical Assistant	$23.16
National Nurse Category	$50.12

The 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[138] 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 will 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 will 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 will 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 will remain in effect for any period that the original PPS hospital remains in operation with an active CCN. For REH qualification requirement purposes, this will include the date of enactment of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), which was December 27, 2020.

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

[138] 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.

(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 465 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 309 hospitals approved for wage index reclassifications in FY 2024 that will continue for FY 2026, and 335 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, 1,109 hospitals (approximately 30 percent of IPPS hospitals) are in a MGCRB reclassification status for FY 2026 (with 258 of these hospitals reclassified back to their urban geographic location). We noted in the proposed rule that several hospitals approved for MGCRB reclassifications may opt to withdraw this status after the proposed rule,[139] and in some cases prior year reclassification would become effective in its place. There are 88 fewer hospitals in MGCRB reclassification status in this final rule than in the proposed rule due to withdrawals and terminations of MGCRB status. We refer readers to section III.F.3.b. of the preamble of this final 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 final 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.

Comment: A commenter stated that the MGCRB decisions for FY 2026 were rendered earlier than in the past, which prevented hospitals from submitting rural or rural referral center (RRC) approval letters prior to the MGCRB's decision. The commenter stated that while the Administrator reversed the MGCRB ruling on appeal, it did not do so in time for the approved reclassification to be reflected in the proposed rule datasets. Therefore, the

[139] We note that in the FY 2026 IPPS/LTCH PPS proposed rule (82 FR 18228), we inadvertently stated that hospitals approved for MGCRB reclassifications beginning in FY 2026 may opt to withdraw this status after the final rule. This was an error, and the correct statement should have read ''after the proposed rule''.

commenter contended that the FY 2026 proposed rule included inaccurate or incomplete information that hospitals relied upon for withdrawal decisions. Consequently, the commenter requested that CMS allow hospitals a 15-day window following the release of the final rule to withdraw MGCRB reclassification requests without penalty after reassessing their decisions using the corrected and finalized data.

Response: As we stated in response to a comment in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58983), we believe hospitals should submit applications complete with supporting documentation at the time MGCRB applications are due. We stated that hospitals taking advantage of the MGCRB's practice of accepting supporting documentation to supplement applications until the date of the MGCRB's review are aware that the review is not held on the same date annually. Furthermore, rural reclassification may be obtained at any time, and hospitals seeking the benefits of rural status for MGCRB reclassification purposes should plan accordingly.

In response to the commenter's specific request for CMS to allow hospitals a 15-day window following the release of the final rule to withdraw MGCRB reclassification requests, we stated in response to a similar comment in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58769 through 58770) that we maintain that the information provided in the proposed rule constitutes the best available data to assist hospitals in making reclassification decisions. In addition, section 1886(d)(8)(D) of the Act requires the Secretary to adjust the standardized amounts to ensure that aggregate payments under the IPPS after implementation of the provisions of certain sections of the Act, including section 1886(d)(10) of the Act for geographic reclassifications by the MGCRB, are equal to the aggregate prospective payments that would have been made absent these provisions. If hospitals were to withdraw or terminate reclassification statuses after the publication of the final rule, as the commenter suggested CMS permit, any resulting changes in the wage index would not have been taken into account when calculating the IPPS standardized amounts in the final rule in accordance with the statutory budget neutrality requirement. Therefore, it is necessary that the values published in the final rule represent the final wage index values reflective of reclassification decisions.

b. 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 proposed 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 stated in the proposed rule that we continue to believe this is the appropriate policy. However, we also stated that 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 proposed 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 proposed 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 also specified 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 also proposed 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 noted that this process is widely referring to as a request for ''reinstatement.'' To provide clarity and consistency, we proposed to modify several references in

§ 412.273(d) from ''cancelling'' or a ''cancellation'' to ''reinstating'' or ''reinstatement.'' As we proposed that withdrawals be limited to applications prior to approval, a proposed reinstatement will only apply to the proposed modified definition of a termination. Therefore, we proposed 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 will 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). In the proposed rule, we stated that 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 will 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 proposed 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 proposed 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 stated that 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 also proposed 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 stated in the proposed rule that 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 proposed specifically to 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 proposed 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 noted 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 would require system changes to the OH CDMS, and there could be some delay in revising certain terminology. However, these changes are not intended to significantly modify current policies and practices. Instead, they serve to clarify and simplify the process of determining whether an approved reclassification should be accepted and applied in a given fiscal year. We also stated that we believe that in making these changes, the regulation will provide clearer instructions to hospitals.

Finally, we noted 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 stated that 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.

We did not receive any comments regarding the proposed changes to § 412.273 and are finalizing the proposed changes without revision. These changes, including the revised definitions, will be effective for all reclassification requests made on or after October 1, 2026 (FY 2026).

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 will 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 will 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 will 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 will 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 will be denied, and the hospital will 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 will 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 will be ineligible to receive the county outmigration adjustment under section 1886(d)(13)(G) of the Act.

We received two timely requests from hospitals to accept the county out-migration adjustment in lieu of its Lugar reclassification. The requests were from CCNs 180056 and 320033. When applicable, we informed the hospital that for the request to be approved, the hospital must withdraw or terminate any active MGCRB reclassification. All requests have been approved and will remain in effect for the remainder of the 3-year county outmigration adjustment period.

We receive one timely request from CCN 390183 to reinstate its Lugar reclassification. This request was approved, and the hospital will be reclassified to CBSA 39740 for FY 2026.

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 finalizing as proposed to discontinue the low wage index hospital policy. Because we are finalizing as proposed to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we are no longer applying 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 final 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 961 hospitals will receive the rural floor in FY 2026. The budget neutrality impact of the application of the rural floor is discussed in section II.A.4.e. of Addendum A of this final 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).)

Comment: Some commenters expressed continued support for CMS's treatment of urban hospitals reclassified as rural under § 412.103 in the same manner as geographically rural hospitals for the rural wage index and rural floor calculations. These commenters stated that restoring equality between a state's rural floor and its rural wage index is an appropriate and fair implementation of the statute.

Conversely, several commenters expressed concern that the current rural floor methodology and associated budget neutrality adjustment exacerbates inequities. A commenter stated that the rural floor magnifies Medicare underpayment to hospitals in high-cost regions, since payments to such hospitals are reduced due to the budget neutrality adjustment. Several commenters stated that hospitals in low-wage states are hurt when their payments are reduced to drive inflated reimbursement to hospitals in states gaming the rural floor. These commenters cited examples of states with high-wage urban hospitals reclassifying to rural to set the rural wage index for the state. The commenters urged CMS to reverse its current policy and calculate the rural wage index using wage data only from geographically rural hospitals in the state.

Response: While we did not propose any changes to the rural floor policy in the FY 2026 IPPS/LTCH PPS proposed rule, we appreciate the commenters' continued support.

We understand the commenters' concerns regarding the effect that the rural floor budget neutrality factor has on some hospitals as other hospitals make reclassification decisions to take advantage of the rural floor policy. As we noted in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58975 through 58976) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69299), we expect that the number of IPPS hospitals assigned their State's rural wage index will increase in future years as hospitals adjust to the policy and as the relative value of States' rural wage index values increase due to the inclusion of hospitals that strategically obtain § 412.103 reclassification. As a result, the majority of hospitals (if not all) will be assigned identical wage index values within their states. For example, in FY 2025, 58 percent of geographically urban hospitals received a wage index equal to their State's rural floor, imputed floor, or frontier floor prior to any outmigration, or 5 percent decrease cap adjustments. For FY 2026, approximately 70 percent of geographically urban hospitals will receive a wage index equal to their State's rural floor, imputed floor, or frontier floor prior to any outmigration, or 5 percent decrease cap adjustments. As we stated in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58975) and the FY 2025 IPPS/LTCH PPS final rule (89 FR 69299), as substantially more hospitals receive the rural floor, there will be a consequently greater budget neutrality impact. However, we believe this result would be unavoidable given the requirement of section 1886(d)(8)(E) of the Act to treat § 412.103 hospitals 'as being located in the rural area' of the state, as well as the requirement at sections 4410(b) of the BBA 1997 and 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) that a uniform, national budget neutrality adjustment be applied in implementing the rural floor.

Comment: Several commenters disagreed with CMS' current application of the rural floor and rural floor budget neutrality adjustment. These commenters asserted that section 4410(b) of the Balanced Budget Act of 1997 (BBA) exempts urban and reclassified rural hospitals that receive the rural floor from having their wage indexes reduced through the application of the rural floor budget neutrality adjustment. According to these commenters, the rural floor budget neutrality adjustment should be applied only to the wage indexes of hospitals not receiving the rural floor (that is, non- reclassified rural hospitals, and urban hospitals with wage indexes above the rural floor).

Response: As we stated in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69299) in response to similar comments that we had received, we disagree with the commenters' assertion that urban and reclassified rural hospitals that receive the rural floor should be excluded from the application of the rural floor budget neutrality factor. We considered this approach in the FY 2008 IPPS proposed and final rules (72 FR 24787 and 72 FR 47325) and believe we have applied the rural floor budget neutrality adjustment in a manner consistent with the statute. Specifically, in the FY 2008 IPPS proposed rule, we rejected a reading of section 4410(b) of the BBA requiring that the budget neutrality adjustment would be applied only to those hospitals that do not receive the rural floor, because urban hospitals receiving the rural floor would receive a higher wage index than the rural hospitals within the same State (because hospitals receiving the rural floor would not be subject to budget neutrality, whereas rural hospitals would be) (72 FR 24787). We continue to believe that such a reading would not be consistent with the best reading of the statute. The statute sets a floor for urban hospitals. The statute does not instruct CMS to pay urban hospitals a wage index higher than the wage index applicable to rural hospitals and contains no suggestion that the general budget neutrality provisions of section 1886(d)(8)(D)—which expressly apply to the adjustments made in section 1886(d)(C)—should not apply. In the FY 2008 IPPS final rule, we adopted the current approach to implement rural floor budget neutrality by applying a uniform, national adjustment to the wage index (72 FR 47325). Since then, Congress specifically endorsed our approach in section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), which requires that the rural floor budget neutrality adjustment be applied ''in the same manner as the Secretary administered such [adjustment] for discharges occurring during fiscal year 2008 (through a uniform, national adjustment to the area wage index).'' In addition, we note that section 4410 of the BBA to which the commenters refer provides

that the rural floor is equal to ''the area wage index applicable under [section 1886(d)(3)(E) of the Social Security Act] to hospitals located in rural areas in the State.'' Under our existing policy, the rural floor and the rural wage index for the state are the same after application of the rural floor budget neutrality adjustment factor, and nothing in section 4410 of the BBA requires otherwise. Put differently, CMS' methodology amounts to merely calculating the amount of the rural floor such that it is the same as the final rural wage index for the state, rather than reducing the wage indices of low wage urban hospitals or reclassified rural hospitals that receive the rural floor relative to what they would be otherwise—in that way it appropriately implements both section 4410 of the BBA and section 3141 of the ACA. Thus, consistent with our longstanding methodology for implementing the rural floor, we believe it is appropriate to continue to apply a budget neutrality adjustment to all hospitals' wage indexes.

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 final 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 final rule. States with a value in the column titled ''State Imputed Floor'' are eligible for the imputed floor.

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).

Comment: We received comments supporting the application of the imputed floor.

Response: We thank the commenters for their input. As discussed earlier, the imputed floor is a statutory requirement under section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2) which requires the Secretary to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. We did not propose any changes to the methodology for calculating the imputed floor as set forth in § 412.64(e)(1) and (4) and (h)(4) and (5). Therefore, in accordance with the statute and existing regulations, we are applying the imputed floor for hospitals in all-urban States for FY 2026.

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).) In the FY 2026 IPPS/LTCH PPS proposed rule, we did not propose any changes to the frontier floor policy for FY 2026. In the proposed rule we stated 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 did not receive any public comments on the application of the State frontier floor for FY 2026. In this final rule, 23 hospitals will receive the frontier floor value of 1.0000 for their FY 2026 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 final FY 2026 wage index are identified in Table 3 associated with this final rule, which is available via the internet on the CMS website.

4. 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 will consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate.

As discussed previously 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.[140] 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 will be obtained from a complete count.

In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69301), we finalized that for FY 2025 and subsequent years, the out-migration adjustment will 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 did not propose any changes to the methodology or data source for calculating the out-migration adjustment. Specifically, we proposed 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 did not receive any comments on this proposal. We are finalizing as proposed 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 final rule (which is available on the CMS website) lists the out-migration adjustments for the FY 2026 wage index. In addition, Table 4A associated with this final 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 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 final rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this final 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

[140] 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.

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.[141] 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 proposed to discontinue the low wage index hospital policy. Because we proposed to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we stated that we would no longer apply a low wage index budget neutrality factor to the standardized amounts.

Comment: Many commenters supported the discontinuation of the low wage index hospital policy in light of the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra.* Commenters agreed with the court that the FY 2020 low wage index hospital policy is unlawful. These commenters stated that ending the low wage index hospital policy, under which the wage indexes of hospitals in the bottom quartile were raised at the expense of all hospitals nationwide due to a budget neutrality adjustment, would restore fairness and consistency to the wage index and align the true cost of care within an area.

Other commenters strongly urged CMS to continue the low wage index hospital policy. While most commenters acknowledged the court's decision, they expressed concern regarding the impact of ending the policy on low wage hospitals. They stated that the rationales for implementing the low wage index hospital policy remain, and discontinuing the policy will end critical support to vulnerable low wage and often rural hospitals. Two commenters specifically asked CMS to explore the impacts of discontinuing the low wage index hospital policy on other policies and hospital payment programs before finalizing, report on the effects of this policy change, and examine how concurrent wage index adjustments may compound or offset the effects. Similarly, another commenter supported the discontinuation of the low wage index hospital policy but expressed concern regarding the impact of ending the policy on rural hospitals. The commenter believes that other programs such as the low volume payment adjustment should provide support.

Response: We thank the commenters for their support for our proposal. With regard to the commenters opposing the discontinuation of the low wage index hospital policy, we understand the commenters' concerns that the rationales for implementing the low wage index hospital policy remain. However, as discussed in the FY 2025 IFC (89 FR 80407), although we respectfully disagree with the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra* and believed that the low wage index hospital policy and the related budget neutrality adjustment should be effective for at least three more years for the reasons stated in the FY 2025 IPPS rulemaking, after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* we proposed to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years. In response to concerns regarding the impact of ending the policy on low wage hospitals, we believe we have addressed those concerns with policies to mitigate any large decline in wage indexes. We refer readers to Section III.F.5 and III.F.6 for detailed discussions of the cap on wage index decreases and transition for the discontinuation of the low wage index hospital policy. With regard to comments requesting that we explore and report on the effects of discontinuing the low wage index hospital policy, we believe that Table 2 associated with this final rule (which is available on the CMS website) provides a clear analysis. Specifically, Table 2 contains columns with each hospital's FY 2026 wage index without and with the 5 percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, and the value with the transitional payment exception for the discontinuation of the low wage index hospital policy, if applicable. With regard to examining how concurrent wage index adjustments and payment programs like the low volume payment adjustment may compound or offset the effects of discontinuing the low wage index hospital policy, we believe this is a payment analysis best performed by each hospital individually considering each hospital's unique circumstances and eligibility for different adjustments.

Comment: Many commenters urged CMS to consider alternative policies to help low wage hospitals, specifically permanent solutions that address wage index inequities. Some commenters cited reports from the Office of Inspector General (OIG), the Institute of Medicine (IOM), and MedPAC that recognize flaws in the current wage

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

index system, and emphasized that comprehensive reform is necessary to protect care in rural and underserved communities in the absence of the low wage index hospital policy. Commenters requested that CMS develop a permanent, statutory solution to address the circularity affecting low wage hospitals by working with Congress to codify the low wage index hospital policy in a manner that complies with the court's decision. A commenter specifically asked CMS to expand on its administrative discretion to assist low wage hospitals. Another commenter encouraged CMS to continue developing policies that address low wage index hospitals without negatively impacting other hospitals by soliciting input from the hospital community. Similarly, many commenters also encouraged CMS to further investigate the specific factors causing wage disparities as part of developing a solution. A few commenters suggested that CMS establish a wage index floor for all hospitals.

Response: We appreciate the varied solutions suggested by commenters to help low wage hospitals and reduce wage index disparities. We note that many of the suggested solutions may require changes to the Medicare statute. We also note that exercising CMS's administrative discretion in a manner that would help low wage hospitals must consider the recent decision and analysis of the D.C. Circuit in *Bridgeport Hosp.* v. *Becerra.* Regarding the commenters' suggestions to solicit input from the hospital community and investigate the causes of wage index disparities, we refer readers to the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372), in which we invited the public to submit comments, suggestions, and recommendations for regulatory and policy changes to the Medicare wage index, and to the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19393 through 19394) for a summary of the responses received from that request for information (RFI). In response to the commenters' suggesting that CMS establish a wage index floor for all hospitals, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326), where we considered that alternative. Specifically, we stated that we believe the rank order of wage indexes generally reflects meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas.

Comment: Many commenters requested that CMS implement a less restrictive reclassification mechanism for the lowest wage index hospitals (for a MGCRB reclassification). Specifically, commenters suggested regulatory changes to § 412.230(d) to allow a low wage index hospital that is within 50 miles of a higher paid wage area (urban or rural) to reclassify to that area and receive the wage index that is paid to hospitals in that area. The commenters also suggested CMS add a low wage hospital exception as § 412.230(d)(6) for any hospital that was in the lowest quartile of wage indexes nationally in any of the FYs 2020 through 2025. As a policy justification, the commenters stated that 50 miles reflect real-world commuting standards, and that altering the average hourly wage comparison test for low wage hospitals advances health equity. Overall, the commenters posited that their suggested regulation text and policy change would reduce disparities and enhance access to care.

Response: We thank the commenters for their suggested policy and regulation changes to implement a less restrictive reclassification mechanism for the lowest wage index hospitals (for a MGCRB reclassification). We did not propose any changes to § 412.230 in the FY 2026 IPPS/LTCH PPS proposed rule. Additionally, 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. Any changes that would allow more hospitals to reclassify would increase the budget neutrality adjustment under section 1886(d)(8)(D) of the Act and would further increase the adjustment made to the standardized amount for all hospitals. We believe it is important to receive public comments with regard to such changes.

We note that we received comments that were out of scope with regard to our proposal to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years. Therefore, we are not responding to these comments in this final rule.

After consideration of the public comments received and the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra,* in this final rule, we are finalizing without modification for FY 2026 and subsequent fiscal years, our proposal to discontinue the low wage index hospital policy. Because we are finalizing our proposal to discontinue the low wage index hospital policy for FY 2026 and subsequent fiscal years, we will 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 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 will 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 will be applied irrespective of the FY 2025 transitional payment exception. We finally note, as discussed later in this section, that for FY 2026 we proposed a transitional payment exception that addresses the effects of the removal of the low wage index hospital policy. We proposed that this transitional payment exception would be applied after the application of the 5-percent cap.

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 will 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 refer readers to the Addendum of this final rule for further information regarding the budget neutrality calculations.

Comment: Commenters, including MedPAC, supported the policy to cap wage index decreases. MedPAC urged CMS to apply a cap to wage index increases as well. Many commenters thanked CMS for recognizing that significant year-to-year changes in the wage index can occur due to external factors beyond a hospital's control and stated that this policy increases predictability in IPPS payments. However, many commenters urged CMS to apply this policy in a non-budget neutral manner.

Response: We thank the commenters for their support. We note that we did not propose any changes to this policy in the FY 2026 IPPS/LTCH PPS proposed rule. We appreciate MedPAC's suggestion that the cap on wage index changes should also be applied to increases in the wage index. However, as we stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49021), one purpose of the policy is to help mitigate the significant negative impacts of certain wage index changes. That is, we cap decreases because we believe that a hospital would be able to more effectively budget and plan when there is predictability about its expected minimum level of IPPS payments in the upcoming fiscal year. We do not have a policy to limit wage index increases because we do not believe such a policy is needed to enable hospitals to more effectively budget and plan their operations. Therefore, we believe it is appropriate for hospitals that experience an increase in their wage index value to receive that wage index value. With regard to the commenters requesting that CMS apply this policy in a non-budget neutral manner, we refer readers to our response to similar comments in the FY 2024 IPPS/LTCH PPS final rule (88 FR 58981).

7. Transition for the Discontinuation of the Low Wage Index Hospital Policy

As discussed previously, 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 proposed to discontinue the low wage index hospital policy. Because we proposed 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.

We stated in the proposed rule 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 (that is, approximately 5 percent or more per year over that time period). Similar to how 42 CFR 412.64(h)(7) operates, and how our interim transitional policy established in the FY 2025 IFC for these hospitals operates in FY 2025, we proposed to establish a narrow transitional exception to the calculation of FY 2026 payments for these hospitals.

As described previously, 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.[142] 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

[142] 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).

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 proposed 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, we proposed the FY 2026 transition policy through the normal course of our annual rulemaking for the IPPS, which allows both for advance notice of the policy and for us to consider issues interested parties might raise in comments on the proposed rule. We proposed 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 previously 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 noted 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 proposed to use our authority under section 1886(d)(5)(I)(i) of the Act twice. First, we proposed 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 proposed to exercise our authority again to do so in a budget neutral manner.[143] [144] We refer the reader to section II.A.4.g. of the Addendum of this final rule for complete details regarding the application of the transition for the discontinuation of the low wage index hospital policy budget neutrality factor.

The transitional exception policy we proposed applies to hospitals that benefitted from the FY 2024 low wage index hospital policy. For those hospitals, we stated that we would 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 [145] 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 [146] of its FY 2024 wage index.[147] We noted this proposed transitional payment exception would be applied after the application of the 5-percent cap described at 42 CFR 412.64(h)(7). We provided the following example in the proposed rule: 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 noted that 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 noted that 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 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 will experience

[143] We note that even more so than was the case for the FY 2025 interim transition policy, the scope and magnitude of the FY 2026 transitional policy are much smaller than the low wage index hospital policy. As discussed in section VI. of the preamble of this final rule, we estimate only 54 hospitals out of the over 3,000 hospitals paid under the IPPS will receive FY 2026 transitional exception payments, and the total payment impact of the 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).

[144] 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 transitional exception can be alternatively considered a transitional adjustment.

[145] 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 will 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 proposed 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.

[146] 90.25 percent = 95 percent for FY 2025 * 95 percent for FY 2026.

[147] 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 will be applied as a separate step only for purposes of determining the hospitals' FY 2026 IPPS payments.

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 proposed to make a budget neutral equivalent exception under the capital IPPS.

Comment: Commenters generally supported a transition for the discontinuation of the low wage index hospital policy. However, a few commenters expressed concern that CMS's proposed transition for FY 2026 is too narrow in scope and duration and suggested that CMS extend the transition for more years.

Response: We thank the commenters for their support. For FY 2026, as discussed later in the section, we are finalizing as proposed without modification the transitional payment exception for FY 2026 in a budget neutral manner. With regard to extending the transition for additional years, we may consider this in future rulemaking.

Comment: Regarding the budget neutrality adjustment for the transition, a commenter was supportive and explained that the budget neutrality adjustment will have only a very narrow impact. Most commenters, however, urged CMS to adopt the transition policy on a non-budget neutral basis. Some of these commenters stated that the statute does not require CMS to implement the policy in a budget neutral manner, and CMS could apply the transition in the same manner as in FY 2025. A few commenters maintained that CMS does not have the authority under 1886(d)(5)(I)(i) to apply budget neutrality, stating that the only authority for budget neutrality is under section 1886(d)(5)(I)(ii) of the Act when making adjustments for transfer cases. Multiple commenters maintained that a budget neutrality adjustment to fund the transition perpetuates the same issue the courts rejected by increasing payments to low wage hospitals at the expense of other hospitals. Similarly, a commenter stated that if CMS lacks the authority to implement the low wage index hospital policy, the burden should be on CMS to pay for a transition for hospitals benefiting from the unlawful policy, not on other hospitals. Other reasons given by commenters for a non-budget neutral transition included avoiding additional instability and the modest cost due to the relatively small number of hospitals benefiting from the policy.

Response: We thank the commenter supportive of the budget neutrality adjustment. In response to the commenters urging CMS to finalize the transition without a budget neutrality adjustment like the FY 2025 transition, we continue to believe that the circumstances that caused us to decline to budget neutralize the interim FY 2025 transition policy are not applicable in FY 2026, and that the reasons we stated in the proposed rule for budget neutralizing the transition continue to apply.

Regarding the comments challenging CMS's authority under 1886(d)(5)(I)(i) to apply the transition for FY 2026 in a budget neutral manner, we disagree with the commenters that we are not permitted to make budget neutral exceptions under section 1886(d)(5)(I)(i) of the Act. Consistent with our response to similar comments about the authority for budget neutrality in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58767), we believe that we have authority under section 1886(d)(5)(I)(i) of the Act to promulgate a budget neutrality adjustment to the national standardized amount and that this authority is not limited to transfer cases.

In response to the commenters asserting that CMS should not budget neutralize a transition from a policy that a court ruled exceeded the Secretary's statutory authority, and other reasons given by commenters in support of a non-budget neutral transition, we continue to believe as we have stated in the past (89 FR 19398) that transition policies should not increase estimated aggregate Medicare payments beyond the payments that would have been made had we never proposed these transition policies. Also, as noted earlier, this is a narrow transition and the scope and magnitude of the FY 2026 transitional policy are much smaller. This is an appropriate budget neutral transition for hospitals.

After consideration of the public comments we received, we are finalizing as proposed without modification 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 that benefitted from the FY 2024 low wage index hospital policy and are 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 through an adjustment applied to the standardized amount for all hospitals. We are also finalizing our proposal to make a budget neutral equivalent exception under the capital IPPS.

G. FY 2026 Wage Index Tables

In this FY 2026 IPPS/LTCH PPS final 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 final rule for a discussion of the wage index tables for FY 2026.

H. 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 final rule, effective beginning FY 2026, in the FY 2026 IPPS/LTCH proposed rule, we proposed to rebase and revise the IPPS market basket to reflect a 2023 base year. We also proposed 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 final rule, we proposed this rebased and revised labor-related share in a budget neutral manner. However, consistent with section 1886(d)(3)(E) of the Act, we stated that 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 final rule, beginning with FY 2026, we proposed 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 measured in the proposed 2023-based IPPS market basket. Therefore, for FY 2026, we proposed to use a labor-related share of 66.0 percent for discharges occurring on or after October 1, 2025.

As discussed in section VI.B. of the preamble of this final 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 did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Comment: A commenter stated that while they understood that the rebasing of the market basket to a 2023 base year requires recalibrating cost weights, CMS is not required to reweight the labor related share under section 1886(d)(2)(H) as part of that rebasing. They urged CMS to maintain the current 67.6 percent labor-related share in light of rising labor costs borne by essential hospitals. Some commenters were concerned that the reduction to the labor-related share from 67.6 percent to 66 percent would disproportionally negatively impact hospitals with a wage index greater than 1.000.

Response: We thank the commenters for their comments. As stated previously, 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 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). 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. In order to meet the statutory requirement of ''time to time'', when we rebase and revise the IPPS market basket it is our longstanding practice to also recalculate the labor-related share using the rebased and revised IPPS market basket. Finally, we believe it is appropriate for FY 2026 to update the labor-related share to reflect the more recent cost structures of IPPS hospitals from the 2023-based IPPS market basket rather than continue to use the 2018-based IPPS market basket.

After consideration of public comments, as discussed in section IV. of the preamble of this final rule, we are finalizing the rebasing of the 2023-based IPPS market basket without modification and the derivation of a labor-related share of 66.0 percent based on the final 2023-based IPPS market basket. Therefore, we are finalizing a labor-related share of 66.0 percent based on the 2023-based IPPS market basket. We refer the reader to section IV. of the preamble of this final rule for complete details regarding the rebasing of the labor-related share.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2026 IPPS/LTCH PPS final 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 final 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 finalizing 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 finalizing 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 the proposed rule, we proposed 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. Effective for FY 2026, we proposed 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 final rule. We also proposed to rebase and revise the Capital Input Price Index (CIPI) as described in section IV.D. of the preamble of this final rule.

In the following discussion, 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. In each section, we describe any comments received, responses to these comments, and our final policies for this final rule. Then, we present the FY 2026 market basket update and labor-related share based on the 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 the proposed rule, we proposed 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 proposed 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 note that comments we received on the overall market basket method (including frequency of rebasings), transparency of the method, and resulting market basket updates are discussed in section IV.B.2. of the preamble of this final rule and comments we received on the labor-related share are discussed in section IV.B.3. of the preamble of this final rule.

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 proposed 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/ManuFals/Paper-Based-Manuals-Items/CMS021935*).

The major types of costs underlying the 2023-based IPPS market basket are derived from the Medicare cost reports (Form 2552–10, OMB Control Number 0938–0050). Specifically, we proposed 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 final rule, we proposed 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 the proposed rule, we proposed to 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 proposed 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 proposed to first calculate total unadjusted wages and salaries costs as reported on Worksheet S–3, Part II, column 4, line 1. We then proposed 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 proposed 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 proposed to only include the proportion attributable to the Medicare-allowable cost centers. Specifically, we proposed 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 proposed 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 proposed 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 proposed 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 final rule for wages and salaries costs). The same methodology was used in the 2018-based IPPS market basket.

Therefore, we proposed 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 final rule. We proposed 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 proposed 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 proposed 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 proposed 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 final 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 proposed 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 final 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 proposed 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 proposed 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 proposed 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 5 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 proposed 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 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.

We received the following comments on our proposed methodology for deriving the major cost weights of the proposed 2023-based IPPS market basket.

Comment: A commenter stated that contract labor has been substituted for employed labor in recent years and accelerated with the COVID–19 PHE, and as a result their expectation would be that any decrease in labor costs for employee benefits would be more than offset by the increased costs for contract labor. The commenter requested that CMS reexamine its methodology for allocating home office costs to contract labor to ensure that it is appropriately resulting in an increase that offsets the decline in employee benefits as contract labor now represents a significantly higher share of total hospital labor costs. The commenter stated that the Employee Benefits cost weight is the largest factor in the decreasing labor-related share (1.2 percentage points).

Response: We note that the discussion of the labor-related share as mentioned by the commenter is provided in section IV.B.3. of the preamble of this final rule. Our analysis of the Medicare cost report data indicates that the increase in the Home Office/Related Organization Contract Labor cost weight of 0.8 percentage point from 2018 to 2023 is more than offset by the estimated overhead compensation cost weight (excluding Home Office/Related Organization Contract Labor costs), which decreased about 1.4 percentage points over the same period. Overhead

compensation costs (as indicated in the FY 2026 IPPS/LTCH proposed rule (90 FR 18238)) would be reflected in the Wages and Salaries and Employee Benefits cost weights. Therefore, it is possible that hospitals are substituting some of their in-house administrative compensation costs for Home Office/ Related Organization administrative compensation costs as the commenter alluded. We note that direct patient care contract labor costs are allocated to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions for employed labor under the assumption that direct patient care contract labor costs are comprised of both wages and salaries and employee benefits and then these cost weights are proxied by the ECI for All Civilian Workers in Hospitals. As stated in the FY 2026 IPPS/LTCH proposed rule (90 FR 18245 through 18246), we proposed to allocate the Home Office/ Related Organization Contract Labor cost weight to the Professional Fees: Labor-Related and Professional Fees: Nonlabor-related cost weights (both of which are proxied by ECI for Total Compensation for Private Industry Workers in Professional and Related).

After consideration of public comments, we are finalizing the major cost weights without modification. We note that comments we received on the overall market basket method (including frequency of rebasings), transparency of the method, and resulting market basket updates are discussed in section IV.B.2. of the preamble of this final rule and comments on the labor-related share are discussed in section IV.B.3 of the preamble of this final rule. Table IV–01 shows the resulting proposed and final cost weights for these major cost categories of the 2023-based IPPS market basket compared to the 2018-based IPPS market basket.

TABLE IV-01.—MAJOR COST CATEGORIES AS DERIVED FROM THE MEDICARE COST REPORTS

Major Cost Categories	2018-based IPPS Market Basket	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
All Other	32.4	33.2

Note: Weights rounded to one decimal for presentation purposes.

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 proposed 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 proposed 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. We received no comments on the proposed methodology to allocate the Contract Labor cost weight to the Wages and Salaries cost weight and Employee Benefits cost weight and therefore, are finalizing this methodology without modification.

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 and final 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	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 proposed 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.[148] 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 proposed 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 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 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 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 proposed to derive 17 detailed cost categories from the 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.

We received a few specific comments on our derivation of the Professional Fees: Labor-related and Professional Fees: Nonlabor-related cost weights as they relate to the proposed labor-related share. Those comments are summarized and responded to in section IV.B.3. of the preamble of this final rule.

2. Selection of Proposed Price Proxies

After computing the 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 proxy for professional liability insurance (PLI), all the proxies we proposed 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 final rule, we present a detailed explanation of the price proxies that we proposed for each cost category weight.

[148] *https://www.bea.gov/papers/pdf/IOmanual_092906.pdf.*

a. Wages and Salaries

We proposed 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 proposed 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 2023-based IPPS market basket, we proposed 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 proposed 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 2023-based IPPS market basket.

d. Electricity and Other Non-Fuel Utilities

We proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed to use a four-part blended PPI as the proxy for the Chemicals cost category in the 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 2023-based IPPS market basket, we proposed 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). We did not receive comments on the proposed methodology to derive the blended Chemicals price proxy using the 2017 Benchmark I–O and therefore are finalizing this methodology without modification.

Table IV–03 shows the proposed and final 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	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 proposed 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 proposed 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 proposed using the PPI Commodity for Surgical and medical instruments (BLS series code WPU1562). To proxy the price changes associated with NAICS 339113, we proposed 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 proposed 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. We did not receive comments on the proposed methodology to derive the blended Medical Instruments price proxy using the 2017 Benchmark I–O data and therefore are finalizing this methodology without modification.

TABLE IV-04.—BLENDED MEDICAL INSTRUMENTS PPI WEIGHTS

NAICS	Name	2018-Based IPPS Weights	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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

We received the following comments on our proposed price proxies for the 2023-based IPPS market basket.

Comment: Several commenters urged CMS to adjust its methodology for calculating the annual payment update (including the adoption of additional data elements in the IPPS market basket) to ensure it provides a robust payment update that adequately incorporates the effects of rising workforce costs on hospitals, which they believe is not being captured by the ECI used in the IPPS market basket. The commenters stated that the use of the ECI may not be adequately capturing employment

and labor cost growth. Commenters stated that CMS should identify and use data inputs that better capture these price increases—for example, incorporating more recent wage data that include contract labor expenses, which the ECI currently does not fully reflect. They stated that they continue to stand ready to work with CMS to examine the market basket compensation indices and proxies to improve the accuracy of these measures.

Response: We believe that the ECI for wages and salaries for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care. The ECI appropriately does not reflect other factors that might affect the rate of price changes associated with labor costs, such as a shift in the occupations that may occur due to increases in case-mix or shifts in hospital purchasing decisions (for instance, to hire or to use contract labor). We believe that the prices of employed staff and contract labor are influenced by the same factors and should generally grow at similar rates. In most periods when there are not significant occupational shifts or significant shifts between employed and contract labor, the data has shown that the growth in the ECI for wages and salaries for hospital workers has generally been consistent with overall hospital wage trends. For example, our more recent analysis of the Medicare cost report data shows from 2018 to 2023, the compound annual growth rate of IPPS Medicare allowable salaries, benefits and contract labor costs per hour was about 4 percent, consistent with the growth rate of the compensation price increases in the 2023-based IPPS market basket as measured by the ECIs for hospital workers over the same period. For this final rule, based on the more recent IGI second quarter 2025 forecast with historical data through the first quarter of 2025, the projected 2023-based IPPS market basket increase factor for FY 2026 reflects a projected increase in compensation prices of 3.4 percent.

After consideration of public comments, we are finalizing the price proxies for the 2023-based IPPS market basket as proposed without modification. Table IV–05 sets forth the 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.

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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	2023-Based IPPS Market Basket Cost Weights	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	--

Cost Categories	2018-Based IPPS Market Basket Cost Weights	2023-Based IPPS Market Basket Cost Weights	2023-Based IPPS Market Basket Price Proxies
(1.) Professional Fees: Nonlabor-Related	7.0	7.0	ECI for Total Compensation for Private Industry Workers in Professional and Related
(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 3 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.

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Table IV–06 compares both the historical and forecasted percent changes in the 2018-based IPPS market basket and the final 2023-based IPPS market basket. The forecasted growth rates in Table IV–06 are based on IHS Global Inc.'s (IGI's) second quarter 2025 forecast with historical data through first quarter 2025.

TABLE IV-06.--2018-BASED AND 2023-BASED IPPS HOSPITAL MARKET BASKET PERCENT CHANGE, FY 2021 THROUGH FY 2028

Fiscal Year (FY)	2018-Based IPPS Market Basket Percent Change	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	3.5	3.5
FY 2026	3.3	3.3
FY 2027	3.0	3.0
FY 2028	3.0	3.0
Average FYs 2025-2028	3.2	3.2

Source: IHS Global, Inc., 2nd Quarter 2025 forecast.

The average historical percent change of the 2023-based IPPS market basket is slightly lower than the average percent change of the 2018-based IPPS market basket over the FY 2021 through FY 2024 time period. The average projected percent change of the 2023-based IPPS market basket is equal to the average percent change of the 2018-based IPPS market basket over the FY 2025 through FY 2028 time period. For FY 2026, the 2023-based IPPS market basket is projected to increase 3.3 percent, which is the same as the FY 2026 projected increase of the 2018-based IPPS market basket. This is 0.1 percentage point higher than the FY 2026 projected increase of 3.2 percent that we proposed in the FY 2026 IPPS/LTCH PPS proposed rule. We note that while there are multiple offsetting factors contributing to differences in the forecasts underlying the proposed and final rules, the final FY 2026 IPPS market basket increase is slightly higher due to economic uncertainty.

We summarize and respond to the public comments we received on the adequacy of the proposed IPPS market basket increase in section VI.B.1. of the preamble of this final rule. In this section, we summarize and respond to comments we received regarding the proposal to rebase the IPPS market basket.

Comment: A commenter appreciated CMS' efforts to rebase the IPPS market basket this year, as scheduled, but the commenter expressed concern that CMS' analyses are not fully representative of the input costs for providing care. Another commenter requested CMS rebase the market baskets more frequently and at least

every 3 years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.

Several commenters stated that the 3.2 percent market basket increase is lower than what it would have been absent the rebasing and revising of the hospital market basket. They stated that based on the growth in their costs that they expect to experience in the coming federal fiscal year, they are concerned that this rebasing has incorrectly lowered the calculated rate of growth of hospital costs.

Response: We appreciate the commenters' support for the rebasing and revising of the IPPS market basket, which we believe appropriately reflects a more recent input cost structure for IPPS hospitals for providing care. The major cost weights (accounting for about 70 percent of the proposed 2023-based IPPS operating market basket) were derived using 2023 Medicare cost report data for IPPS hospitals. We then supplement these data with Benchmark Input-Output data for NAICS 622000, Hospitals from ''The Use Table (Supply-Use Framework)'' to derive more detailed cost weights that reflect the complex cost structure of hospitals (reflecting costs such as compensation, food, and medical supplies/equipment). We believe both of these data sources are representative of the cost weights for IPPS hospitals providing services to Medicare beneficiaries.

As discussed in the proposed rule, 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 based on our evaluation of data and methods at the time of the FY 2006 IPPS final rule and we continue to believe a rebasing frequency of every 4 years is appropriate. We refer readers to the FY 2006 IPPS final rule (70 FR 47404 through 47407) for the research we conducted at the time to determine this, which included reviewing the frequency and availability of the data needed to produce the market basket and analyzing the impact on the market basket of determining the market basket weights under various frequencies. Therefore, we proposed 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). Despite this established frequency, we regularly monitor the Medicare cost report data to assess whether a rebasing is technically appropriate, and we will continue to do so in the future.

The IPPS market basket is designed to measure price inflation for IPPS hospitals and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As noted by the commenters and stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18244), based on IGI's fourth quarter 2024 forecast with historical data through third quarter 2024, the proposed 2023-based IPPS market basket rate-of-increase was 0.1 percentage point lower (after rounding to a tenth of a percentage point) compared to the 2018-based IPPS market basket rate-of-increase. Based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2025), we estimate that the FY 2026 IPPS market basket update used to determine the applicable percentage increase is 3.3 percent (the same percentage increase of the 2018-based IPPS market basket after rounding to a tenth of a percentage point).

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.* We proposed 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 we did in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204).

Similar to the 2018-based IPPS market basket, for the 2023-based IPPS market basket we proposed 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 2023-based IPPS market basket, we proposed 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 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 will be reflected in our labor-related measure. Therefore, we proposed 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 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 proposed 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 proposed 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 proposed to classify as professional fees costs from the 2017 Benchmark I–O data. The impact of this proposed change is an increase in the 2023-based Professional Fees: Labor-Related cost weight of about 1 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 proposed 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 final rule.

For the 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 proposed 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 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.[149] 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 Professional Fees: Nonlabor-related cost weight of 7.0 percent. The resulting 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.

Using the proposed 2023-based IPPS market basket cost weights, we derived a proposed labor-related share of 66.0 percent based on the proposed 2023-based IPPS market basket. We summarize and respond to the public comments we received on our proposed methodology for deriving the proposed labor-related share for FY 2026 here.

Comment: A commenter was supportive of the proposed update to the labor-related share and encouraged CMS to review the labor-related share of all states to ensure that the labor proportion is accurate to current costs incurred by hospitals. Several commenters were concerned about the downward adjustment of the labor-related share from 67.6 percent to 66

[149] *Note:* The cost weights are calculated using 3 decimal places. For presentational purposes, we are displaying one decimal and therefore, the detail may not add to the total due to rounding.

percent in FY 2026 stating that they believe it does not reflect hospital labor and non-labor cost pressures. They stated that per-discharge labor costs have dramatically increased in recent years, citing that according to one study, 37 percent from 2019 to 2022.

A few commenters noted the labor-related share has declined in five of the last six rebasings of the hospital market basket. The commenters stated that this continued decline only negatively impacts hospitals with a wage index over 1.0 without a clearly delineated budget neutrality adjustment to ensure overall Medicare hospital reimbursement is maintained. The commenters stated that given the current healthcare workforce crisis and the growing wage demands on hospitals, labor costs as a share of total hospital costs have grown since the 2018 base year, not declined.

A few commenters stated that they understood the need for rebasing the labor share but requested that CMS release additional information on how it arrived at its proposed estimate for the national labor-related share for FY 2026. Commenters stated that to accurately replicate and verify the labor related share, they requested CMS publish a table of their intermediate steps reflective of the numerators and denominators utilized in each cost category and calculation step. These commenters requested CMS include the dollar values used to calculate the percentage of each cost category.

A commenter stated that the proposed reduction in the national labor-related share could lead to lower payments for hospitals with higher wage indexes, as a smaller share of the payment rate will reflect local labor costs. Accordingly, the commenter requested that CMS, at a minimum, reconsider labor expense calculations to provide a more appropriate update based on growing and unsustainable costs.

Response: The purpose of the labor-related share is to reflect the proportion of the national IPPS standardized amount that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). We proposed to derive the labor-related share using the 2023-based IPPS market basket, reflecting average national cost weights for IPPS hospitals. As stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18239), for each cost weight included in the 2023-based IPPS market basket we utilized reported data from all IPPS hospitals reporting Medicare IPPS payments and facility operating costs with proposed trims to the data to remove outliers. For each of the cost weights, we evaluated the distribution of providers and costs by ownership-type and by urban/rural status to make sure they were nationally representative.

We appreciate the commenters' request to explain the decrease in the labor-related share in more detail. The decrease in the labor-related share from 67.6 percent to 66.0 percent is primarily due to the lower compensation cost weight (calculated using the Medicare cost report data) in the 2023-based IPPS market basket (51.1 percent) compared to the compensation cost weight in the 2018-based IPPS market basket (53.0 percent) as these costs increased at a slower rate than total operating costs. Our analysis of the Medicare cost report data showed that on a per inpatient day basis, compensation costs, which largely reflect direct patient care salaries, grew by about 4 percent per year from 2018 to 2023 while total operating costs grew by about 5 percent per year. The slower growth in compensation costs also reflected slower growth in employee benefit costs (particularly qualified defined benefit plan costs) and overhead employee salaries at about 3 percent per year. Contract labor costs for direct patient care, on the other hand, offset some of this experience as costs grew nearly 18 percent per year over this same period. For noncompensation costs, which grew nearly 6 percent per year from 2018–2023, key contributors were costs for home office contract labor (about 8 percent growth per year) and pharmaceuticals (about 6 percent growth per year). Consistent with some of the commenter's findings, our analysis of the Medicare cost report data shows that compensation costs have been increasing at a faster rate between the 2018 to 2023 time period compared to the prior 4-year period; however, these compensation costs have been growing slower than noncompensation costs, which results in a decrease in the compensation cost weight. In addition, from 2018 to 2023, we have seen faster growth in the Professional Fees costs and Home Office/Related Organization costs resulting in an increase in the professional fees cost weights and Home Office/Related Organization cost weight, which are partially offsetting the decrease in compensation cost weight as shown in Table IV–05.

In response to commenters' request for additional information on the methodology for calculating the labor related share, as stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18240), we derive the Professional Fees cost weight using the 2017 Benchmark I–O, ''The Use Table (Supply-Use Framework),'' for NAICS 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). First, to obtain an amount for the Professional Fees costs subject to the allocation percentage from the Medicare cost reports, we calculated the sum of I–O expenses for Professional, Scientific, and Technical Services (NAICS 54) excluding Veterinary services (which we include in the Professional Fees: Nonlabor-Related), I–O expenses for Business Support Services (NAICS 5614), Data Processing, Hosting and Related services (NAICS 5182) and I–O expenses for Lessors of Nonfinancial Intangible Assets (NAICS 533). In addition, we also are adding in 34 percent of Employment Services (NAICS 5613) as Census and BEA data indicate that these expenses reflect more than just direct patient care contract labor (which we directly obtain from Worksheet S–3, Part II, column 4, lines 11, 13, and 15 from the Medicare cost report as noted in the proposed rule). The sum of these costs reflect total Professional Fees from the 2017 Benchmark I–O data that are subject to the allocation percentage from the Medicare cost reports, or 30.2 percent of total ''All Other'' costs from the 2017 Benchmark I–O data. The ''All Other'' costs are equal to the sum of the Benchmark I–O data for the detailed cost categories as described in section IV.B.c. of the preamble of the FY 2026 IPPS/LTCH proposed rule.

Second, we proposed 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 (for instance, for the Professional Fees category we applied the growth in the ECI for Total Compensation for Private industry workers in Professional and Related). After inflating the 2017 costs to 2023 and calculating the cost shares we determined that the resulting cost share was 29.5 percent of ''All Other'' costs in 2023 dollars.

Third, 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, we apply the Professional Fees cost share (29.5 percent of total ''All Other'' costs) to the residual ''All Other'' cost weight of 33.2 percent, resulting in a total Professional Fees cost weight from the Benchmark I–O data of approximately 9.8 percent of the 2023-based IPPS market basket.

Lastly, this is then allocated between Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related as

described later in this section. As stated in the FY 2026 IPPS/LTCH proposed rule (90 FR 18245) for 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 (all of which are reported in NAICS 54). However, for the 2023-based IPPS market basket, since we proposed to revise the methodology to use the data as reported on the Medicare cost reports (Worksheet S–2, Part I), we proposed to apply the allocation percentage of 59 percent obtained from the Medicare cost reports to all of the professional fees costs we identified from the 2017 Benchmark I–O data as described previously. This proposal to apply the percentage to all of the professional fees costs is a result of the revised scope of expenses captured in the question when we switched to using the Medicare cost report data. Specifically, the professional fees question on Worksheet S–2, Part I of the Medicare cost report stated a wider range of types of costs as an example (legal, accounting, tax preparation, bookkeeping, payroll, advertising, and management/consulting services) while the survey conducted by CMS in 2009 was more limited and had specific questions for each type of cost (legal services, accounting and auditing, engineering, and management consulting). The impact of this proposed methodology change in order to be consistent with the Medicare cost report professional fees question is an increase in the proposed 2023-based Professional Fees: Labor-Related cost weight of about 1 percentage point.

For even greater transparency, as requested by the commenter, we are posting a table providing the calculations of the detailed cost category weights for the 2023-based IPPS market basket using the publicly available I–O data. This table along with other market basket information can be found at *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*.

We believe it is technically appropriate to update the labor-related share to reflect the cost structures of IPPS hospitals from the 2023-based IPPS market basket rather than continue to use the less recent 2018-based IPPS market basket.

Comment: A few commenters were grateful that CMS proposed to use Medicare cost report data to inform the determination of the proportion of expenses classified as professional fees that are purchased within the local area labor market rather than relying on survey data as had been done in previous calculations of the labor-related share. However, the commenters were disappointed that CMS has not revised the calculation to reflect that professional fees purchased outside the local area labor market are also ''related to, influenced by, or vary with the local market.'' They believe the cost of professional fees purchased outside of the hospital's local area market should be considered labor-related, because providers of these professional services must adjust their pricing to reflect what local markets are able to bear. Commenters stated that an accounting firm will not necessarily charge a hospital located in a major urban area the same that it would charge a hospital in a small rural area for the same services. Several commenters recommended CMS increase the labor-related portion of professional fees from 59 percent (which reflects CMS's estimate of the proportion of professional fees purchased within hospitals' local area labor markets) to a higher percentage. Another commenter stated that CMS should revise its methodology for rebasing the labor-related share, to account for the geographic wage variation inherent in all non-clinical professional services costs.

Response: We appreciate the commenters' support to use the Medicare cost report data to determine the proportion of professional fees that are purchased in the local labor market.

However, we disagree that the proportion of professional fees services costs purchased by hospitals outside the local area labor market should be included in the labor-related share. The labor-related share of the IPPS standardized amount is adjusted to account for geographic differences in area wage levels by applying the applicable IPPS wage index. The purpose of the labor-related share is to reflect the proportion of the national IPPS standardized amount that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market.

As acknowledged by the commenter and confirmed by the Medicare cost report data for IPPS hospitals, professional services can be purchased from local firms as well as national and regional professional services firms. It is not necessarily the case, as asserted by the commenter, that these national and regional firms have fees that match those in the local labor market even though providers have the option to utilize those firms. That is, fees for services purchased from firms outside the local labor market may differ from those that would be purchased in the local labor market for any number of reasons (including but not limited to, the skill level of the contracted personnel, higher capital costs, etc.). We believe it is reasonable to conclude that the 59 percent of those Professional Fees costs purchased directly within the local labor market are directly related to local labor market conditions and, thus, should be included in the labor-related share. The remaining approximately 41 percent of Professional Fees costs, which are purchased outside the local labor market, reflect different and additional factors outside the local labor market and, thus, should be excluded from the labor-related share. In addition, we note the compensation costs of professional services provided by hospital employees (which would reflect the local labor market) are included in the labor-related share as they are included in the Wages and Salaries and Employee Benefits cost weights. Therefore, for the reasons discussed, we believe our proposed methodology of continuing to allocate only a portion of Professional Fees to the Professional Fees: Labor-Related cost category is appropriate.

After consideration of public comments, we are finalizing the rebasing of the 2023-based IPPS market basket without modification and the derivation of a labor-related share of 66.0 percent based on the final 2023-based IPPS market basket. Table IV–07 presents a comparison of the proposed and final 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 final 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 2023-BASED LABOR-RELATED SHARE

	2018-Based IPPS Market Basket Cost Weights	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 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 proposed and are finalizing a labor-related share of 66.0 percent based on the 2023-based IPPS market basket. 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 will 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 final rule, we proposed and are finalizing 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 proposed to use the percentage increase in the 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 2023-based IPPS operating market basket.

We received no comments on this proposal and therefore are finalizing this proposal without modification.

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 proposed to rebase and revise the CIPI to a 2023 base year to reflect a more current structure of capital costs for IPPS hospitals. This 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 also proposed 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 final rule. As with the 2018-based index, we proposed to develop two sets of weights to derive the 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 proposed 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 proposed that Depreciation costs are equal to the sum of Worksheet A–7, Part III, column 9, lines 1 and 2. We proposed that Interest costs are equal to the sum of Worksheet A–7, Part III, column 11, lines 1 and 2. We proposed that Lease costs are equal to the sum of Worksheet A–7, Part III, column 10, lines 1 and 2. We proposed that Other costs are equal to the sum of Worksheet A–7, Part III, columns 12 through 14, lines 1 and 2. We proposed that Total Capital costs are equal to the sum of Worksheet A–7, Part III, column 15, lines 1 and 2. We proposed 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 proposed to apply a set of simultaneous trims based on these derived cost weights to remove outliers. Specifically, we proposed 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 proposed 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 proposed to allocate lease costs across each of the remaining capital cost categories as was done in the 2018-based CIPI. We proposed 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 proposed 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 proposed to add this 1.2 percent to the 6.0 percent Other cost category weight. We then proposed 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.

We did not receive any comments on the proposed methodology to derive the cost weights of the 2023-based CIPI and therefore are finalizing this methodology without modification. The resulting cost weights of the allocation of lease expenses are shown in the right column of Table IV–08.

TABLE IV-08.— ALLOCATION OF LEASE EXPENSES FOR THE 2023-BASED CIPI

Cost Categories	Cost Shares Obtained from Medicare Cost Reports (Percent of Total Capital Costs)	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 proposed to further divide the Depreciation and Interest cost categories. We proposed to separate the Depreciation cost category into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We also proposed 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 proposed 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.

We did not receive any comments on the proposed methodology to disaggregate the Depreciation and Interest cost weights of the 2023-based CIPI and therefore are finalizing this methodology without modification.

Table IV–09 provides a comparison of the 2018-based CIPI cost weights and the proposed and final 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 proposed to use the same price proxies as were used in the 2018-based CIPI, which are listed in Table IV–09. We also proposed 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 final rule.

For the Depreciation—Building and Fixed Equipment cost category, we proposed 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 proposed 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 will be utilized by hospitals including but not limited to communication equipment, computers, and medical equipment. For the Nonprofit Interest cost category, we proposed 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 proposed 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 proposed 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.

We did not receive any comments on our proposed price proxies for the 2023-based CIPI and therefore are finalizing without modification.

TABLE IV-09.—2023-BASED CIPI COST WEIGHTS AND PRICE PROXIES COMPARED TO 2018-BASED CIPI COST WEIGHTS

Cost Categories	2018 Cost Weights	2023 Cost Weights	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 3 decimal places. For presentational purposes, we are displaying 1 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 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 proposed to use an alternative data source for deriving the capital purchases needed to calculate the vintage weights. Specifically, we proposed 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 proposed 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 proposed 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. We provide the proposed steps for calculating capital acquisitions (that is, capital purchases) used to derive the vintage weights for the 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 final rule. For the interest vintage weights, we proposed 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 proposed 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 proposed 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 proposed 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 2023-based CIPI and the 2018-based CIPI are presented in Table IV–10. While we proposed 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 2023-based vintage weights instead of the 2018-based vintage weights has a minimal impact on the overall CIPI update (averaging less than 0.1 percentage point over FY 2021 through FY 2026).

We did not receive any comments on our proposed vintage weights and therefore are finalizing without modification.

TABLE IV-10.--2023-BASED CIPI AND 2018-BASED CIPI VINTAGE WEIGHTS

Year[1]	Building and Fixed Equipment		Movable Equipment		Interest	
	2018-Based 27 years	2023-Based 28 years	2018-Based 12 years	2023-Based 12 years	2018-Based 27 years	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 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 will be applied to the 2026q3 fixed price proxy level, year 27 vintage weight will 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 final rule compares both the historical and forecasted percent changes in the 2018-based CIPI and the 2023-based CIPI. Over the most recent historical period, the 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 2023-BASED CAPITAL INPUT PRICE INDEX, PERCENT CHANGE, FY 2021 THROUGH FY 2028

Fiscal Year	CIPI, 2018-Based	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	2.8	2.8
FY 2026	2.9	2.8
FY 2027	2.8	2.7
FY 2028	2.7	2.6
Average FYs 2025-2028	2.8	2.7

Source: IHS Global, Inc., 2nd quarter 2025 forecast.

IHS Global, Inc. forecasts a 2.8 percent increase in the 2023-based CIPI for FY 2026, as shown in Table IV–11. This is 0.2 percentage point higher than in the proposed rule due to higher projected price inflation for machinery and fixed investment as well as higher expected interest rates. 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 2023-based CIPI are included in Table IV–12.

TABLE IV-12.— 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	2.8	3.3	-0.2
FY 2026	2.8	3.4	-0.2
FY 2027	2.7	3.2	-0.2
FY 2028	2.6	3.1	-0.4

Source: IHS Global, Inc., 2nd quarter 2025 forecast.

The FY 2026 percentage increase based on the 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, primarily due to rebasing the CIPI to reflect 2023 costs.

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 [150] 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 later in this section, under which the DSH payment adjustment is based a complex statutory formula which includes the hospital's geographic designation, the number of

[150] See section 1886(d)(1)(B) of the Act for the definition of a ''subsection (d) hospital''.

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.
"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.[151] 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

[151] *https://www.medpac.gov/document/march-2007-report-to-the-congress-medicare-payment-policy/.*

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 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 the IPPS/LTCH PPS proposed rule (90 FR 18254), 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 noted that FY 2021 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing the proposed rule.[152] We stated that if more recent data on DSH eligibility became available before the final rule, we would use such data in the final rule. The FY 2022 SSI ratios are the most recent data available at the time of developing this FY 2026 IPPS/LTCH PPS final rule, and so we have used this data to estimate DSH status for all hospitals.

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

[152] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

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 (FY 2012 IPPS/LTCH PPS final rule 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 final 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 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).[153] 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 the proposed rule, we stated we believed 16 hospitals may participate in the demonstration program at the start of FY 2026. We noted 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. At the time of developing this FY 2026 final rule, we believe 30 hospitals may participate in the demonstration program during FY 2026.

We received comments that are outside the scope of the proposed rule. For example, we received comments related to the eligibility of SCHs paid under hospital-specific rate and MDHs to receive DSH payments, our policy related to patient days associated with Section 1115 demonstrations, and determination of patient SSI eligibility. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing these comments in this 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://*

[153] 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.

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.

In the FY 2026 IPPS/LTCH PPS proposed rule, we did not propose any changes to the methodology for determining the amount of or hospital eligibility for supplemental payments. For FY 2026, 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.

Comment: A commenter reiterated their prior recommendation that was submitted in response to the proposal to establish these supplemental payments in the FY 2023 IPPS/LTCH PPS proposed rule. The commenter recommended that CMS calculate the supplemental payment for Puerto Rico hospitals using a base year amount determined using a Medicare SSI days proxy of at least 42 percent, consistent with the local poverty level, instead of the current value of 14 percent which incorporates the proxy that was applied from FY 2017 through FY 2022 of 14 percent of the hospital's Medicaid days and that was based on national data on the relationship between Medicare SSI days and Medicaid days.

Another commenter reiterated similar comments submitted in response to the FY 2025 IPPS/LTCH PPS proposed rule, thanking CMS for the supplemental payments but requesting that CMS evaluate alternatives to better support hospitals in Puerto Rico if uninsured days increased. This commenter suggested reverting to the previous method of using a proxy to determine uninsured days for hospitals in Puerto Rico, citing ongoing challenges with collecting reliable Worksheet S–10 data for hospitals in Puerto Rico.

Response: In the proposed rule, we did not propose any changes to our methodology for calculating or determining hospital eligibility for supplemental payments. Therefore, we consider these comments to be outside the scope of the proposed rule. However, we refer readers to our responses to substantially similar comments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69314, FY 2024 IPPS/LTCH PPS final rule (88 FR 58992–58993) and FY 2023 IPPS/LTCH PPS final rule (87 FR 49047–49048) for fulsome discussion on these issues.

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. 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 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18255 through 18257), we proposed to continue the policy that has applied since the FY 2014 final rule (78 FR 50627 through 50631), to determine 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.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18255 through 18257), 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18255 through 18257), 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 the 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, as corrected, was approximately $15.791 billion. (90 FR 18256 and 90 FR 23867). 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, as corrected, was approximately $3.95 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2026). (90 FR 18256 and 90 FR 23867.) Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18255 through 18257), as corrected, we proposed that Factor 1 for FY 2026 would be $11.843 billion, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2026 ($15.791 billion minus $3.95 billion). (90 FR 23867.) We noted that consistent with our approach in previous rulemakings, OACT intended 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.

In the FY2026 IPPS/LTCH PPS proposed rule, we noted 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. Consistent with historical practice, we stated in the proposed rule that we expected the Midsession Review will have updated economic assumptions and actuarial analysis, which would 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 referred readers to the ''2025 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/2025*.[1] 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 the FY 2026 IPPS/LTCH proposed rule (90 FR 18255 through 18257), we included information regarding the data sources, methods, and assumptions employed by OACT's actuaries in determining our estimate of Factor 1. In summary, we indicated the historical HCRIS data update OACT used to estimate Medicare DSH payments; we explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided 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 the associated rationale and assumptions. The discussion also included descriptions of the ''Other'' and ''Discharges'' assumptions and provided additional information regarding how we address Medicaid expansion.

We invited public comments on our proposed Factor 1 for FY 2026.

Comment: A few commenters thanked CMS for the increase in the proposed Factor 1 amount for FY 2026. Some commenters requested clarification on a discrepancy between the Factor 1 estimate cited in the proposed rule's preamble and the figure provided in the supplemental file.

Response: We thank the commenters for their support. Regarding the discrepancy in Factor 1 estimates, we refer readers to the June 5, 2025 correction to the proposed rule (*CMS–1833–CN*) (90 FR 23867).

Comment: As in previous years, some commenters expressed concerns with and requested greater transparency in the methodology used by CMS and OACT to calculate Factor 1. A few commenters emphasized their inability to accurately replicate CMS' calculations without clarity on how inputs, such as the effects of the COVID–19 public health emergency (PHE) on Medicare discharges, case mix, Medicaid enrollment and subsequent disenrollment through redeterminations, impact Factor 1 estimates. Some of these commenters requested that CMS provide details of its Factor 1 calculation in advance of the publication of the IPPS/LTCH PPS final rule and in the IPPS/LTCH PPS proposed rule each year going forward, so that sufficient data is available to replicate CMS' DSH payment calculations and enable commenters to provide more informed comments in future years. Another commenter requested that CMS provide detailed explanations for how the agency calculates Factor 1 to ensure safety net providers are not being disproportionately impacted.

A few commenters asserted that the lack of opportunity afforded to hospitals to review the data used to estimate DSH

payment calculations in rulemaking is in violation of the Administrative Procedure Act. These commenters expressed concerns about the lack of transparency in how Factor 1 is calculated, arguing that hospitals cannot meaningfully comment on the Factor 1 calculation methodology given the lack of details provided by CMS in each IPPS/LTCH PPS proposed rule. In particular, these commenters stated that the FY 2026 IPPS/LTCH proposed rule provided neither sufficient details nor a complete explanation of the treatment of Medicaid expansions in the calculation for Factor 1.

Additionally, several commenters stated that CMS failed to provide sufficient details on how the ''Other'' factor, including both the overall calculation and individual inputs used to determine the estimate, is calculated. These commenters noted that although CMS indicates Medicaid enrollment is included in the ''Other'' factor, the agency does not explain its specific impact on the overall estimate. One commenter emphasized the importance of interested parties understanding how changes in Medicaid enrollment affect Medicare DSH payments, particularly considering recent, significant shifts in Medicaid enrollment. Other commenters specifically questioned whether the ''Other'' factor accurately reflects the impact of the COVID–19 PHE. Some of these commenters requested that CMS publish a detailed methodology of its ''Other'' calculation specifying how all the components contribute to changes in its estimate from year to year. A couple commenters requested that CMS clarify why the ''Other'' factor frequently varies in successive rulemaking cycles. Some of these commenters requested that this information be provided in advance of the final rule publication and in the IPPS/LTCH PPS proposed rule each year going forward to ensure the data is available to replicate CMS' DSH calculation, allowing for sufficient ability to comment in future years.

Response: We thank the commenters for their input. We disagree with commenters' assertions regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18255–18257) and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2026 IPPS/LTCH PPS proposed rule (*90 FR 18002*) included a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate. Accordingly, we believe commenters were able to meaningfully comment on our proposed estimate of Factor 1.

To provide additional context, and as we have explained in prior rulemakings (*see, for example, 89 FR 68986*), we note that Factor 1 is not estimated in isolation from other projections made by OACT. The Factor 1 estimates for the proposed rules are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law, and the Factor 1 estimates for the final rule are the latest estimates from OACT at the time of development of this final rule. We recognize that our reliance on the economic assumptions and actuarial analyses used to develop the President's Budget in estimating Factor 1 has an impact on hospitals, health systems, and other impacted parties that wish to replicate the Factor 1 calculation by, for example, modeling the relevant Medicare Part A portion of the President's Budget. Yet, we believe commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available under ''Downloads'' on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html*. 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 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, given that 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.

Additionally, in the FY 2026 IPPS/LTCH PPS proposed rule and described in more detail later in this section, we included information regarding the data sources, methods, and assumptions employed by the actuaries to determine the OACT's estimate of Factor 1. We explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all update factors that were applied to historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other,'' ''Case-Mix,'' and ''Discharges'' assumptions, as well as additional information regarding the estimated impact of the COVID–19 PHE.

Regarding the commenter who expressed concern that our proposed calculation of Factor 1 would disproportionately impact safety net providers, we continue to believe that estimating Factor 1 based on the economic data and assumptions detailed in this final rule and the FY 2026 IPPS/LTCH PPS proposed rule is appropriate and consistent with the requirements of section 1886(r)(2)(A) of the Act.

Comment: Some commenters requested that CMS provide additional detail on the calculations and assumptions related to the ''Discharge'' component used in the Factor 1 formula so they can evaluate the impact of Medicare Advantage (MA) growth on Medicare Fee for Service (FFS) inpatient hospital payments. These commenters noted that the continued expansion of MA has raised concerns—particularly around prior authorization requirements imposed by plans, which often create burdens for both patients and providers. The same commenters noted that these issues have prompted broader questions about the sustainability of MA growth and its implications for inpatient hospital payments, especially for hospitals serving a disproportionate share of low-income beneficiaries. The same commenters welcomed the opportunity to work with CMS in examining the impacts of MA enrollment on FFS inpatient hospital payments. Other commenters urged CMS to use more recent data and update its estimates of Medicare DSH payment amounts to reflect changes in the discharge volume more accurately.

Finally, a commenter, citing the Medicare Payment and Advisory Commission's (MedPAC) draft recommendation for 2026 and its March 2025 report to Congress, urged CMS to increase the market basket updates for

2024 through 2026 used in the FY 2026 Factor 1 ''Update'' component by at least 1 percentage point. The same commenter also requested that the market basket update be increased by at least 1.5 percentage points per MedPAC's March 2024 report to Congress. Another commenter argued that the proposed 0.8 percent productivity adjustment used to offset the projected 3.2 percent market basket increase in the ''Update'' component of Factor 1 was inappropriately high, given the significant economic volatility caused by recent cost period outliers.

Response: We thank the commenters for their input. Regarding commenters' requests for additional detail on the calculations and assumptions underlying the ''Discharges'' factor, we refer the commenters to the discussion elsewhere in this section of this final rule and the relevant discussion in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18002), which detail the calculations and assumptions we used to calculate the FY 2026 ''Discharges'' factor. We also note that in updating our estimate of Factor 1 for this final rule, we considered, as appropriate, the same set of factors that we used in the FY 2025 IPPS/LTCH PPS proposed rule and in prior rulemakings (*see example,* 89 FR 35934 35934 through 36649). As we stated we would do in the FY 2026 IPPS/LTCH PPS proposed rule, we then updated our estimates for the FY 2026 ''Discharges'' component, and other Factor 1 components, to incorporate the latest available data based on more recent economic assumptions and actuarial analyses as available to us.

Regarding the comments on the impacts of MA enrollment on the Medicare FFS discharge volume, we refer commenters to the actuarial projections and assumptions regarding future trends in Medicare FFS and MA program enrollment, utilization, and costs of health care services covered by Medicare, as well as other factors affecting Medicare FFS and MA program expenditures, contained in the ''2025 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available under ''Downloads'' on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html*. We considered these projections, assumptions, and other factors when developing our estimate of the ''Discharges'' factor for FY 2026. We also note that in this final rule, consistent with prior years (*see, for example,* 89 FR 68986), our estimate of the ''Discharges'' component for FY 2026 incorporates only claims from the Medicare FFS program rather than claims from the MA program. Accordingly, we believe that the FY 2026 ''Discharges'' factor in this final rule accurately reflects trends in Medicare FFS discharges.

Regarding the commenter who requested that CMS increase the FY 2026 Factor 1 ''Update'' component consistent with the MedPAC recommended increases to the IPPS market basket used to estimate DSH payments for FY 2024, FY 2025, and FY 2026, we note that consistent with the inpatient hospital update discussion in section VI.B of the preamble of this final rule, OACT is using the final inpatient hospital market basket update and productivity adjustment for FY 2026, based on the more recent data available for this final rule, for the final FY 2026 ''Update'' component in the Factor 1 calculation. We refer readers to the discussion of the finalized inpatient hospital update for FY 2026 in section VI.B of the preamble of this final rule. Regarding the commenter expressing concern that the productivity adjustment used to offset the projected market basket was inappropriately high, we also refer to the discussion in section VI.B of the preamble of this final rule.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2026. We discuss the resulting Factor 1 amount for FY 2026 in this final rule. Consistent with prior rulemakings, for this final rule, OACT used the most recently submitted Medicare cost report data from the March 31, 2025, update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File and applied update factors and assumptions for projected changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year.

The June 2025 OACT estimate for Medicare DSH payments for FY 2026, without regard to the application of section 1886(r)(1) of the Act, is approximately $16.550 billion. This estimate excluded Maryland hospitals, which participate in the Maryland Total Cost of Care Model and are not paid under the IPPS, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on this June 2025 estimate, the estimate of empirically justified Medicare DSH payments for FY 2026, with the application of section 1886(r)(1) of the Act, is approximately $4.14 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, the final Factor 1 for FY 2026 is $12,412,500,000, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2026 ($16,550,000,000 minus $4,137,500,000).

OACT's estimates for FY 2026 for this final rule began with a baseline of $13.022 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	1.0577	1.0859	14.140
2024	1.031	0.997	0.997	1.0310	1.0570	14.946
2025	1.029	1.020	0.9997	1.0029	1.0527	15.734
2026**	1.026	1.020	1.0023	1.0027	1.0519	16.550

*Rounded.

** The FY 2026 figures reflect the inpatient hospital market basket percentage increase and productivity adjustment finalized in this rule and are based on the 2nd quarter 2025 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this final 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.[154]

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	3.3	0.7	0.0	2.6

Note: All figures in this table are the final inpatient hospital updates for the applicable fiscal year. The FY 2026 figures reflect the inpatient hospital market basket percentage increase and productivity adjustment finalized in this rule and are based on the 2nd quarter 2025 IGI forecast, the most recent forecast available at the time of development of this final rule. We refer to section VI.B. of the preamble of this final rule for a complete discussion of the inpatient hospital market basket update for FY 2026.

2. Calculation of 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.

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 2024 through 2033 and were published on June 25, 2025. Those projections used the latest NHEA historical data that were available at the time of their construction (that is, historical data through 2023). 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. Factor 2 for FY 2026

Using these data sources and the previously described methodologies, at the time of developing the FY 2026 IPPS/LTCH proposed rule, OACT had 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 (90 FR 18258). 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

[154] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf.*

of Uninsured prepared for the 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.[155]

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 have used 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 the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to continue to apply the weighted average approach used in past fiscal years to estimate this final 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. In the proposed rule (90 FR 18258), we noted 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.

In the proposed rule, we outlined the calculation of the proposed Factor 2 for FY 2026 as follows:

- Percent of individuals without insurance for CY 2013: 14 percent.
- Percent of individuals without insurance for CY 2025: 7.7 percent.
- Percent of individuals without insurance for CY 2026: 8.7 percent.
- Percent of individuals without insurance for FY 2026: (0.25 times 0.077) + (0.75 times 0.087) = 8.5 percent.
- 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 proposed that Factor 2 for FY 2026 would be 60.71 percent.

The proposed FY 2026 uncompensated care amount was equivalent to proposed Factor 1 multiplied by proposed Factor 2, which was $ 7,190,037,075.

We invited public comments on our proposed Factor 2 for FY 2026.

Comment: Several commenters expressed their support for CMS' proposed increase in Factor 2 and Medicare DSH uncompensated care payments. Most commenters that discussed Factor 2 expressed their concern that CMS has an underestimate of the uninsured rate for FY 2026. Commenters noted that the proposed Factor 2 amount does not account for several finalized and proposed policy changes that could dramatically increase the uninsured rates in FY 2026. These commenters referenced the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits, the unwinding of the Medicaid continuous coverage protections, pending or proposed federal policy changes that may restrict Medicaid and marketplace insurance access, and reconciliation bills and tax changes (that is, the One Big Beautiful Bill Act) that could increase the uninsured population in FY 2026.

Many commenters also referenced data sources and analyses estimating the impact of proposed federal legislation on the FY 2026 uninsured rate. Several commenters cited the Congressional Budget Office's (CBO) projections, which estimated that the number of uninsured individuals will increase by 2.2 million in 2026, 3.7 million in 2027, and 3.8 million on average each year from 2026 to 2034 due to the expiration of the enhanced premium tax credits. Other commenters cited the CBO's projection that 16 million individuals will lose their health insurance by 2034, and of these, almost 11 million will become uninsured due to the One Big Beautiful Bill Act (as referred to by commenters, which became Pub. L. 119–21), with the other 5 million losing their insurance due to the expired enhanced premium tax credits. A few commenters referenced a memorandum issued by the White House Council of Economic Advisers, which projected an increase of 9.2 million in the uninsured population if the proposed reconciliation budget bill does not pass by the end of Summer 2025. A commenter stated that 35 percent of enrollees in Louisiana were disenrolled from Medicaid between 2023 and 2024 according to a Kaiser Family Foundation analysis. Accordingly, these commenters requested that CMS increase Factor 2 to reflect the anticipated increase in the FY 2026 uninsured population. A commenter requested that CMS use administrative discretion to adjust Factor 2 upward in the final rule, stating that the current NHEA projections were certified before the introduction of recent legislative and regulatory proposals that could significantly reshape the insurance coverage landscape. Another commenter requested that CMS commit to recalculate the total DSH uncompensated payments for FY 2026 once the fate of the reconciliation bill is known.

Citing CMS' statement in the proposed rule that the agency could consider more recent data that may become available for the calculation of Factor 2 in FY 2026, many commenters urged CMS to use more recent and accurate data sources to account for the anticipated increase in the uninsured rate. Some of these commenters urged CMS to consider utilizing alternative data sources and calculations, such as real-world data from interested parties and researchers, to ensure that the Factor 2 estimate appropriately reflects the current coverage landscape and accurately estimates uninsured projections. A few commenters stated that the current Factor 2 methodology may have been appropriate during periods of stable insurance coverage but may no longer be adequate given recent and anticipated policy-driven shifts in the uninsured rate. As such, these commenters urged CMS to re-evaluate the current data sources and methodologies used to estimate Factor 2. Given that OACT updates its projected enrollment and spending trends for the coming 10-year period, including the estimated uninsured rate for the upcoming fiscal year, using NHEA data annually between the proposed and final IPPS/LTCH rules, a few commenters requested that CMS update the proposed rule's estimate of the uninsurance rate for the upcoming fiscal year earlier in the rulemaking cycle issue an earlier update to enhance the reliability of the proposed rule in projecting changes to uncompensated care payments for upcoming fiscal years.

Response: We thank the commenters for their input and diligence regarding the estimate of Factor 2 included in the proposed rule. In response to comments concerning the NHEA data source used for calculating Factor 2 for FY 2026, 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 meet all of our considerations for ensuring that the data source meets the statutory requirement that the estimate

[155] *https://www.cms.gov/files/document/certification-rates-uninsured-2026-proposed-rule.pdf.*

be based on data from the Census Bureau or other sources the Secretary determines appropriate. We continue to believe that the NHEA will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle.

In the FY 2026 IPPS/LTCH PPS proposed rule, we explained that we used the most recent available estimates from the NHEA at that time (that were released in June 2024), and we refer readers to the relevant discussion in the proposed rule and OACT's memorandum on ''*Certification of Rates of Uninsured*'' prepared for the proposed rule for further details on the methodology and assumptions used in the proposed rule's calculation of the projected uninsured rate. In brief, we indicated that our projection of the rates of uninsurance for CY 2025 and CY 2026 were from the latest NHEA historical data available and accounted for expected changes in enrollment across all categories of insurance coverage. We note, in particular, that OACT's estimates in the proposed rule considered the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits and the latest Medicaid projections publicly available at that time.

In response to commenters who requested that we update the Factor 2 estimates in the FY 2026 IPPS/LTCH PPS proposed rule to account for any anticipated changes in the uninsured rate using more recent or alternative data sources, in the proposed rule, we stated we may 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. In this final rule, we are using the most recent NHEA estimates for the rate of uninsurance, which became available on June 25, 2025 and account for all updates to the CY 2025 and CY 2026 uninsured rate, and reflect current law and administrative actions as of March 25, 2025, including the legislative impacts of the expiration of the American Rescue Plan's Marketplace enhanced premium tax credits. At this stage of the FY 2026 IPPS/LTCH PPS final rule development, there is not an available estimate of the impact of Public Law 119–21 on the uninsured rate, and there is a wide range of uncertainty associated with the demographic, economic and programmatic outcomes. Consistent with prior final IPPS/LTCH PPS rulemakings (*see, for example,* 89 FR 68986), we are using the updated NHEA data for the final Factor 2 calculation because we believe that it is the most appropriate measure of changes in the rate of uninsurance.

Regarding the comments requesting that CMS update the Factor 2 methodology and data sources and increase Factor 2 we continue to believe that estimating Factor 2 based on the best available data is appropriate and consistent with the requirements of Section 1886(r)(2)(B)(ii) of the Act.

Regarding the comments requesting that CMS issue an earlier update of the uninsured rate for the upcoming FY during each annual rulemaking cycle, we note that we use the most recent NHEA projections available at the time of developing the proposed and final rules.

Comment: Several commenters urged CMS to be transparent in the calculation of Factor 2 and how it accounts for the current coverage landscape, while others urged CMS to be transparent regarding the data sources used for calculating Factor 2 and the assumptions behind the uninsured rate. One commenter asserted that the proposed rule did not provide sufficient details nor an explanation of the treatment of Medicaid expansions in the calculation for Factor 2. A few commenters requested that CMS publish a detailed methodology on the calculation of Factor 2 and how the NHEA projections are incorporated into the estimate.

Response: In response to the comments concerning transparency, we note that OACT's updated memorandum ''*Certification of Rates of Uninsured*'' contains additional background describing the methods used to derive the FY 2026 rate of uninsured for this final rule. Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. As explained elsewhere in this section of this final rule, the NHEA data and methodology that were used to estimate Factor 2 for this final rule are transparent and best meet all our considerations for ensuring reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle, and we have concluded it is appropriate to update the projection of the FY 2026 rate of uninsurance using the most recent NHEA data. For additional information on the projection of the uninsured rate, see the projection's methodology documentation. (Available on the CMS website at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/projectionsmethodology.pdf*).

After consideration of the public comments we received, we are updating the calculation of Factor 2 for FY 2026 to incorporate the most recent NHEA data. The final estimates of the percentage of uninsured individuals have been certified by the Chief Actuary of CMS.

The calculation of the final Factor 2 for FY 2026 using a weighted average of OACT's updated projections for CY 2025 and CY 2026 is as follows:

- Percent of individuals without insurance for CY 2013: 14.0 percent
- Percent of individuals without insurance for CY 2025: 7.9 percent
- Percent of individuals without insurance for CY 2026: 9.0 percent
- Percent of individuals without insurance for FY 2026: (0.25 times 7.9) + (0.75 times 9.0) = 8.7 percent
- Factor 2: 1-|((0.087–0.14)/0.14)| = 1–0.3786 = 0.6214 (62.14 percent)

Therefore, the final Factor 2 for FY 2026 is 62.14 percent. The final FY 2026 uncompensated care amount is $12,412,500,000 * 0.6214 = $ 7,713,127,500.

3. Calculation of 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 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.[156]

(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

[156] 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.

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 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.[157]

(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 final 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 final 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.

We received comments on the newly merged hospital policy.

Comment: A few commenters expressed support for the new hospital and newly merged hospital policies currently in place.

Response: We appreciate the continued support of our policies for new and newly merged hospitals.

(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,

[157] 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.

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 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.[158]

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 final 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 final rule. For purposes of the FY 2026 IPPS/LTCH PPS proposed rule, we used reports from the December 2024 HCRIS extract to calculate Factor 3. In the proposed rule, we noted that we intended 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 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

[158] 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.

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.[159] 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 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 final rule.

We received comments regarding the Factor 3 calculation, including Worksheet S–10 cost report audits and uncompensated care cost report instructions.

Comment: Several commenters expressed their support for CMS' proposal to calculate Factor 3 for FY 2026 based on a three-year average of audited FY 2020, FY 2021, and FY 2022 Worksheet S–10 data. Supporters of this proposal specified that the use of a multi-year average of Worksheet S–10 data significantly reduces year-to-year volatility in uncompensated care payments.

Notably, no commenters expressed opposition to using a three-year average of Worksheet S–10 data to calculate uncompensated care payments.

Response: We are grateful to those commenters who expressed their support for our policy of using a three-year average of audited FY 2020, FY 2021, and FY 2022 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2026. As explained in the FY 2026 IPPS/LTCH PPS proposed rule (*90 FR 18002*), we believe that using a multi-year average of Worksheet S–10 data will provide assurance that hospitals' uncompensated care payments remain stable and predictable, while mitigating unpredictable swings and anomalies in a hospital's uncompensated care costs.

Comment: A commenter urged CMS to monitor trends in uncompensated care as reported on Worksheet S–10 during the COVID–19 Public Health Emergency (PHE). This commenter encouraged CMS to assess how disruptions in care during the COVID–19 PHE affected Factor 3 calculations and consider steps to dampen the effect of any large reductions in uncompensated care costs attributable to the PHE and ensure that the inclusion of FY 2020–2022 data does not reduce Factor 3 for essential hospitals.

Response: Regarding requests for CMS to monitor and account for the impact of the COVID–19 PHE on Worksheet S–10 cost report data, we will continue to monitor the impact of the PHE and will consider this issue further in future rulemaking, as appropriate. We refer readers to our responses to similar comments in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69325–39326), and we note that we will continue to use the three-year average of the most recently audited cost report data for FY 2026 and subsequent years, consistent with the policy finalized in the FY 2023 IPPS/LTCH PPS final rule (*87 FR 48780*) and § 412.106(g)(1)(iii)(C)(11).

Comment: A commenter expressed their support for the continued distribution of the uncompensated care payments based on each DSH hospital's share of total uncompensated care.

Response: We appreciate the support for our policies on the distribution of uncompensated care payments.

Comment: We received comments that were outside the scope of previously discussed methodological concepts concerning the blending of historical Worksheet S–10 data to calculate Factor 3. A commenter recommended that CMS distribute current DSH and uncompensated care payments using the Medicare Safety-Net Index (MSNI) framework outlined by the Medicare Payment Advisory Commission (MedPAC) in its 2024 Report to Congress. Another commenter urged CMS to explore additional policy levers to increase DSH and/or uncompensated care payments, such as temporarily directing supplemental funds—beyond empirically justified DSH payments and/or uncompensated care payments—to hospitals that serve the highest proportion of low-income patients.

Response: Regarding the commenters' suggestions unrelated to the previously discussed methodological concepts for the blending of historical Worksheet S–10 data to calculate Factor 3, we consider these public comments to be outside the scope of the proposed rule and are not addressing them in this final rule. However, we appreciate the commenters' input and note that we may consider these suggestions in future rulemaking, as appropriate.

Comment: Commenters reiterated comments from prior years suggesting modifications to the Worksheet S–10 audit process. Specifically, a commenter requested that CMS publicly disseminate comprehensive audit policy and protocols that must be employed by all auditors and MACs and disclose these through notice and comment rulemaking. The same commenter requested that CMS implement a workable appeal or review process to correct errors and inconsistent audit disallowances in a timely manner. Another commenter requested that CMS provide clear guidelines on its audit protocols and ensure Worksheet S–10 reviews impose minimal burden and are uniformly applied across all hospitals. The commenter urged CMS to disclose the criteria it uses to identify hospitals for audits and ensure audits are conducted consistently and equitably. Lastly, a commenter encouraged CMS to continuously take steps to improve Worksheet S–10 data auditing accuracy.

Response: We thank commenters for their feedback on the audits of the Worksheet S–10 data and their recommendations for future audits, which we will take into consideration for future rulemaking. We note that as we have stated in previous rulemakings in response to comments regarding audit protocols (*see, for example,* 88 FR 58640), audit protocols are provided to MACs in advance of the audit to ensure consistency and timeliness in the audit process.

Regarding the request to make public the audit policies and protocols, as we previously explained most recently in the FY 2024 IPPS/LTCH PPS final rule (*88 FR 58640*), we do not make our protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only. In addition, there is no requirement under either the Administrative Procedure Act

[159] 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.

or the Medicare statute that CMS adopt audit policies or protocols through notice and comment rulemaking. Finally, as noted in the FY 2024 IPPS/LTCH PPS final rule (*88 FR 58640*), to most efficiently and appropriately utilize our limited audit resources, we do not plan to introduce an audit appeal process at this time.

Comment: Commenters thanked CMS for recent revisions to the Worksheet S–10 audit protocols but expressed concern about recent changes that require more detailed information. A commenter expressed concerns regarding cost report exhibits and the Worksheet S–10 audits, in particular the commenter stated that they should not have to put unnecessary effort into exhibits if the MAC asks for different information during the Worksheet S–10 audits. Another commenter requested clarification on how the exhibits will be utilized. The commenter requested that CMS consider making some fields as optional rather than mandatory to reduce administrative burden.

Response: Regarding commenters' concerns about cost report instructions, we note that to ensure the accuracy and integrity of the cost reports, all hospitals are required to maintain documentation for the Worksheet S–10, such as exhibits and Exhibits 3B and 3C (PRM 15–2, 4012.2) in particular. Regarding commenters' concerns about exhibits, we refer commenters to the ''Justification'' section of the Paperwork Reduction Act (PRA) revision request and approval of the existing information collection requirement (ICR) for cost reports (*OMB control number 0938–0050 with an expiration date September 30, 2025*).

Comment: Regarding Worksheet S–10 instructions and guidance, a commenter requested that CMS clarify inconsistent Worksheet S–10 instructions on line 29 so that non-Medicare bad debt is not multiplied by the CCR. The commenter stated that while CMS' revised cost report instructions indicate that non-reimbursed Medicare bad debt is not multiplied by the CCR, CMS' September 2017 transmittal [160] states that non-Medicare bad debt should be multiplied by the CCR.

Response: We appreciate the commenter's concern regarding the need for clarification of the Worksheet S–10 instructions and refer the commenter to our response to a substantially similar comment in the FY 2025 IPPS/LTCH PPS final rule (*89 FR 69327*).

[160] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2017downloads/r11p240.pdf.*

Comment: Some commenters reiterated concerns previously raised in response to the FY 2025 IPPS/LTCH PPS proposed rule (*89 FR 35934*), proposing technical revisions to how CMS defines and calculates uncompensated care costs on Worksheet S–10. They recommended that CMS include all patient care costs, such as costs related to training medical residents, supporting physician and professional services, and paying provider taxes associated with Medicaid revenue, when converting costs to charges. These commenters suggested specific revisions to Worksheet S–10 to incorporate all patient care costs, such as utilizing the total of worksheet A, column 3, lines 1 through 117 (reduced by the amount on worksheet A–8, line 10) as the cost component and worksheet C, column 8, line 200, as the charge component. Additionally, some of these commenters requested that CMS include Graduate Medical Education (GME) costs when calculating a hospital's CCR.

The same commenters further urged CMS to treat the unreimbursed portion of state or local indigent care programs as charity care and revise Worksheet S–10 such that data on Medicaid shortfalls resembles actual shortfalls incurred by hospitals. Specifically, they requested that hospitals be allowed to reduce their Medicaid revenue reported on Worksheet S–10 by the amount of any contributions to the nonfederal share of Medicaid funding, whether through provider taxes, intergovernmental transfers (IGTs), or certified public expenditures (CPEs).

Response: We appreciate commenters' suggestions for revisions and/or modifications to Worksheet S–10. We will consider the modifications as necessary to further improve and refine the information that is reported on Worksheet S–10 to support the collection of information regarding uncompensated care costs.

Regarding the request to include costs for teaching and providing physician and other professional services, including GME costs, when calculating the CCR, as stated in past final rules (*see, for example, 85 FR 58826, 86 FR 44774,* and *89 FR 68986*), we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include any additional costs in the numerator of the CCR calculation. We refer readers to those prior rules for further discussion on this issue.

With regard to the comments requesting that payment shortfalls from Medicaid and state and local indigent care programs be included in uncompensated care cost calculations, we have consistently explained in past final rules (*85 FR 58826, 86 FR 44774,* and *89 FR 68986*) in response to similar comments that we believe there are compelling arguments for excluding such shortfalls from the definition of uncompensated care. We refer readers to those prior rules for further discussion on this issue.

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 final 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 final 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 the FY 2026 IPPS/LTCH proposed rule and this final 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.

We received comments on the trim methodology.

Comment: A commenter expressed their support for CMS' CCR trim and UCC methodologies to address unusual and atypical data.

Response: We appreciate the support for our policies on the CCR trim

methodology and the UCC trim methodology.

For purposes of this 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 this 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, in the proposed rule, we noted 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 also noted in the proposed rule that the March HCRIS data extract would be available during the comment period for the proposed rule if providers wanted 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.

We received comments on the proposed per discharge payment amount used to make interim uncompensated care payments.

Comment: A commenter raised their concern that CMS has understated the per-discharge amount of interim uncompensated care payments in the FY 2026 proposed rule, given the overestimation of discharges from past data years. This commenter also expressed opposition to using a three-year average for determining the discharge volume and requested that CMS project a reasonable estimation of discharges.

Response: We thank the commenter for their feedback. As discussed in the FY 2025 IPPS/LTCH PPS final rule (*89 FR 68986*), we believe using an average of the most recent three-years of available historical discharge data will appropriately reflect year-to-year variations in discharge volumes in FY 2026 and subsequent fiscal years, and this approach is consistent with 42 CFR 412.106(i)(1). We refer the commenter to that final rule for additional discussion on this subject. We also refer the commenter to our response in that rulemaking (89 FR 69329) to similar comments stating that CMS overestimated discharge volume in recent years. Consistent with 42 CFR 412.106(i)(1), we are finalizing our proposal as is and will calculate the per-discharge amount of uncompensated care payments based on a three-year average of discharge data.

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.

We received comments related to the uncompensated care payment reconciliation process.

Comment: Some commenters reiterated their recommendation that

CMS use the traditional payment reconciliation process to calculate final payments for uncompensated care costs pursuant to section 1886(r)(2) of the Act. These commenters did not object to CMS using prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the federal fiscal year. The commenters also stated that CMS' current IPPS/LTCH PPS rulemaking process is flawed because CMS may use data and calculations in final rules that were not included in the relevant proposed rules without providing advance notice to hospitals. The commenters claim that this limits the hospitals' ability to provide informed comments. These same commenters stated that CMS fails to provide meaningful explanations of its uncompensated care payment calculations and is in violation of the Administrative Procedure Act. These commenters recommended that CMS satisfy its legal obligation by providing hospitals with the opportunity to review and comment on the more recent data used to calculate Factors 1, 2, and 3 in each final rulemaking before the agency publishes the final rule.

Response: Consistent with the position that we have taken in past rulemaking, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (*83 FR 41144; 84 FR 42044; 85 FR 58432; 86 FR 44774; 87 FR 48780; 88 FR 58640;* and *89 FR 68986*). We continue to believe that, in affording the Secretary the discretion of estimating the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system.

As a result, we do not agree with the commenter's suggestion that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of prospectivity in a payment system. Furthermore, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule, or a description of the subjects and issues involved. In this case, the FY 2026 IPPS/LTCH PPS proposed rule (*90 FR 18002*) included a detailed discussion of our proposed methodology for calculating Factors 1–3 and the data that would be used. We made public the best data available at the time of the proposed rule to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments, and we have considered those comments in determining our final policies for FY 2026.

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 final 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 7 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 had 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 the 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.[161] In the proposed rule, we stated that 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 indicated that we would 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. We also stated that 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 noted 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 Decisions and Changes to the IPPS for Operating Costs

A. 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

[161] 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.

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 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. Changes for FY 2026

As discussed in the proposed rule and section II.C. of the preamble of this final 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 proposed 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 stated in the proposed rule that 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 noted that for all other proposed changes, the relative volume of cases shifting to or from current MS–DRGs did 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).

In the proposed rule, we noted 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 (90 FR 18264). We therefore proposed to add new MS–DRGs 403 and 404 to the list of MS–DRGs that are subject to the postacute care transfer policy.

We also noted that MS–DRGs 463, 464 and 465 are currently subject to the postacute care transfer policy. As a result of our review, these revised MS–DRGs would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy.

As discussed in section II.C. of the preamble of this final rule, we are finalizing these proposed changes to the MS–DRGs, with exception of the proposal 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) for FY 2026. We have therefore removed MS–DRGs 403 and 404 from further analysis. We are also removing 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) from further analysis for purposes of this final rule as we included them in our initial review due to our determination that more than 5 percent of the current cases would shift from these MS–DRGs to proposed new MS–DRGs 403 and 404 (which are not being finalized).

Using the March 2025 update of the FY 2024 MedPAR file, we have developed the following table which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this final rule with respect to each of these finalized new or revised MS–DRGs.

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LIST OF NEW OR REVISED MS-DRGS SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2026

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 Short-Stay Postacute Care Transfers to all Cases (55th percentile: 9.5453%)	FY 2025 Postacute Transfer Policy Status	Postacute Care Transfer Policy Status
209	Complex Aortic Arch Procedures	335	187*	26	7.3%*	New	No
213	Endovascular Abdominal Aorta with Iliac Branch Procedures	1,168	186*	0	0%*	New	No
318	Percutaneous Coronary Atherectomy without Intraluminal Device	904	163*	7	0.8%*	New	No
359	Percutaneous Coronary Atherectomy with Intraluminal Device with MCC	30,443	8,487	798	2.6%*	New	No
360	Percutaneous Coronary Atherectomy with Intraluminal Device without MCC	46,131	4,209	0	0%*	New	No
321	Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ arteries/intraluminal devices	3,034	873*	66	2.2%*	No	No
322	Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC	3,953	398*	36	0.9%*	No	No

* 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.

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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 (90 FR 18265).

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 met 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 proposed that MS–DRGs 403, 404, 463, 464, and 465 would be subject to the MS–DRG special payment methodology, effective for FY 2026. As new MS–DRGs 403 and 404 are not being finalized, MS–DRGs 403 and 404 have been removed from further analysis. As discussed previously, MS–DRGs 463, 464, and 465 were also removed from further analysis for purposes of this final rule as their inclusion in our review of postacute care transfer policy status was due to an expected shift in cases to the proposed new MS–DRGS 403 and 404, which are not being finalized. As a result, there are no remaining MS–DRGs to evaluate for special payment policy for FY 2026.

Comment: We received a comment requesting CMS to not apply the post-acute transfer policy to proposed new MS–DRGs 403 and 404 for FY 2026 in order to avoid disincentivizing proper care for patients with complex joint infections.

Response: As discussed previously, the proposed new MS–DRGs 403 and 404 are not being finalized for FY 2026.

Based on the finalized changes to the MS–DRGs for FY 2026 and the updated analysis, we are not finalizing to add MS–DRGs to the postacute care transfer or the special payment policies for FY 2026. We note that MS–DRGs 463, 464 and 465 will continue to be subject to the postacute care transfer policy.

The postacute care transfer and special payment policy status of all MS–DRGs is reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available on the CMS website.

B. Changes in the Inpatient Hospital Update for FY 2026 (§ 412.64(d))

1. 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 stated in the proposed rule that 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 stated that 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 the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to rebase and revise the IPPS market basket to a 2023 base year, effective beginning in FY 2026.

We proposed 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 was estimated to be 3.2 percent. We also proposed that if more recent data subsequently became 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 this final rule. We received public comments regarding the rebasing and revising of the IPPS operating market basket and refer readers to section IV.B. of the preamble of this final rule for a complete discussion on the rebasing and revising of the market basket. As stated in section IV.B. of the preamble of this final rule, we are finalizing our proposals without modification and, therefore, are using the finalized rebased and revised 2023-based IPPS market basket rate-of increase for FY 2026 based on more recent data available.

Comment: Several commenters appreciated the proposed net increase in operating payment rates for hospitals. Several commenters stated that CMS's reliance on the current market basket and productivity assumptions fails to capture the financial pressure facing DRG-based hospitals, particularly those providing high-acuity complex, resource-intensive care including the safety-net and rural hospitals which commenters stated often face higher fixed costs, narrower operating margins, and increased demand for services. They stated that the proposed 2.4 percent increase is simply too low and fails to account for the enduring impacts of high price inflation and cost increases. Commenters expressed specific concerns regarding compensation costs (highlighting increased contract labor utilization, employee burnout and a tight labor market (which the commenter stated would persist well into the future)), administrative costs (including what they described as unnecessary administrative costs for prior authorizations, claims appeals and denials from large commercial health insurers, including Medicare Advantage and Medicaid managed care plans), and pharmaceuticals costs. Commenters stated that the AHA found that in 2024 alone, hospital expenses grew by 5.1 percent of which a large portion was labor expenses, and that prices for nearly 2,000 drugs increased an average of 15.2 percent from 2017 through 2023, notably faster than the rate of general inflation. The commenters also referred to other economic headwinds creating uncertainty such as tariffs, which commenters stated would impact the prices of pharmaceuticals, medical equipment/supplies prices, and construction materials. They stated that their concerns are further compounded by the likelihood of additional funding reductions resulting from reconciliation legislation (affecting health insurance

coverage and Medicaid funding) currently under consideration in Congress.

In addition, several commenters stated that CMS did not consider the Medicare Payment Advisory Commission (MedPAC)'s recommendation to Congress to add 1 percent to the annual market basket which the commission stated is merited given that even ''relatively efficient'' hospitals have negative Medicare margins. In its March 2025 report, commenters noted that MedPAC reported Medicare fee-for-service margins of −13 percent in 2023 (and −14 percent for nonprofit hospitals), virtually unchanged from the record-low −13.1 percent margins in 2022.

Several commenters stated that Medicare reimbursement continues to lag behind inflation. A commenter stated that Medicare underpayments reached $100 billion in 2023 (covering just 83 cents per dollar) according to AHA analysis of AHA Annual Survey data (*https://www.aha.org/costsofcaring*). A commenter stated that according to the Kaiser Family Foundation, Medicare payments have not accommodated market increases for at least the last 10 years.

Several commenters urged CMS to focus on appropriately accounting for recent and future trends in inflationary pressures and cost increases in the hospital payment update, which they stated is essential to ensure that Medicare payments for acute care services more accurately reflect the cost of providing hospital care.

Several commenters stated CMS calculates the market basket based on forecasts rather than actual labor and supply cost increases, thus failing to incorporate the challenging circumstances brought on by unprecedented labor, supply, and drug cost increases. They recommended CMS look to alternative data sources that better reflect true labor and input cost increases in a timelier manner. At a minimum, they requested CMS provide additional publicly available data on the assumptions and inputs that go into developing a market basket update.

Commenters also stated that due to the timing of the projections that the CMS Office of the Actuary used for the proposed rule, which were made in December 2024, the effects of tariffs on hospital costs are not accounted for in the IPPS market basket projection. They stated CMS must ensure that its final market basket update for FY 2026 appropriately includes the cost increases attributable to tariffs.

Many commenters requested CMS use its exceptions and adjustments authority to increase the market basket increase from the proposed rate of 2.4 percent.

In addition, a commenter stated that given the continued rise in input costs and the inadequate market basket updates derived from use of the ECI, CMS may consider using the weighted average growth rate in allowable Medicare costs per risk-adjusted discharge for IPPS hospitals to calculate the final or future market basket update for IPPS hospitals.

Several commenters requested CMS increase the FY 2026 market basket update to reflect historic inflationary increases more accurately with a commenter stating it should be no less than the FY 2024 final rule market basket rate of 3.6 percent. However, a commenter stated that when historical data is no longer a good predictor of future changes, the market basket becomes inadequate citing the high inflation, as measured by the consumer price index, of 9.1 percent in June 2022. They urged CMS to use a factor to update the historical data to ensure that rates align with the real-time costs that health systems are experiencing and, therefore requested that CMS include an additional increase to the 2023 historical data to help offset the significant increased costs that providers are currently experiencing.

Commenters recommended CMS consider how it can use its regulatory authority to boost payments to rural hospitals. They believe the market basket update of 2.4 percent is inadequate given inflation, workforce shortages, and labor and supply chain cost pressures that rural hospitals continue to face. They stated nearly 50 percent of rural hospitals are operating with negative margins and the median operating margin for rural hospitals is 1 percent.

Several commenters recommended CMS work with Congress to address economic pressures and reform the Medicare reimbursement formula to better reflect the actual cost of delivering quality care to an ageing population. A commenter urged CMS to evaluate whether the proposed update sufficiently supports operational stability across hospitals with high social risk indicators or atypical cost structures. If disparities emerge, the commenter stated that future rulemaking should explore targeted adjustments to preserve service availability and financial solvency.

Response: Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall update IPPS payments based on a market basket percentage increase estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year. As described in section IV. of the preamble of this final rule, we believe that the proposed 2023-based IPPS market basket (including the ECI) is consistent with the statute as it is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, while maintaining a mix of goods and services purchased by hospitals consistent with a base period. Therefore, the market basket is designed to measure price inflation for IPPS hospitals and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. Likewise, the commenter's suggestion that a weighted average growth rate in allowable Medicare costs per risk-adjusted discharge for IPPS hospitals be used to calculate the final or future market basket update for IPPS hospitals would not be consistent with the IPPS hospital market basket as described in section 1886(b)(3)(B)(iii) of the Act which reflects changes in wages and prices.

CMS understands that the market basket updates may differ from other overall inflation indexes such as the topline CPI; however, we would reiterate that these topline indexes are not comparable since they measure different mixes of products, services, or wages than the legislatively defined CMS IPPS hospital market basket. Additionally, the market basket updates appropriately differ from other payment updates that would reflect anticipated volume and intensity of services.

CMS welcomes feedback on alternative data sources for the market basket price proxies that measure price inflation. For the FY 2026 IPPS/LTCH PPS proposed rule, we proposed to rebase and revise the market basket to reflect a 2023 base year and provided a detailed methodology for calculating the cost weights as well as proposed specific price proxies for each of the cost weights. We note that we did not receive any alternative data sources for measuring the prices of the cost weights in the market basket.

We appreciate the commenters' request for CMS to provide additional

publicly available data on the assumptions and inputs that go into developing a market basket update. As noted, the detailed market basket cost weights (including the methodology) and price proxies used in the market baskets were set forth in the proposed rule and in section IV. of the preamble of this final rule. Additionally, shortly after the publication of the proposed rule, we made available on the CMS website (*https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data*) the detailed historical growth rates for the market baskets as well as price forecasts for the aggregated cost weights (such as compensation, utilities). As stated previously, the detailed price proxies used in the market basket are forecasted by IGI (a nationally recognized economic and financial forecasting firm). We also note that general inquiries on the forecasting methodology can be emailed to *dnhs@cms.hhs.gov*, as is also noted in the market basket spreadsheets on the CMS website.

We would highlight that the market basket percentage increase is a forecast of the price pressures that hospitals are expected to face in FY 2026 based on IGI's consideration of industry-specific and overall economic conditions, which is notably uncertain in FY 2026. More specifically for the ECI for hospital workers, IGI considers overall labor market conditions (including the impact of wage pressures on skill mix) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

As stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18266) we proposed a FY 2026 applicable percentage increase of 2.4 percent, reflecting the proposed 2023-based IPPS market basket rate-of-increase of 3.2 percent and productivity adjustment of 0.8 percentage point, consistent with current law. We also proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2026 IPPS market basket update for the final rule. We appreciate the commenter's concern regarding inflationary pressure and the request to use more recent data to determine the FY 2026 IPPS market basket update. For this final rule (as proposed), we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy (including the impact of economic uncertainty). As discussed in section IV.A. of the preamble of this final rule, based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2025), we estimate that the FY 2026 market basket increase used to determine the applicable percentage increase for the IPPS is 3.3 percent. As discussed later in this section, based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2026 is 0.7 percentage point. Therefore, the applicable percentage increase applied to the standardized amount for hospitals that are considered to be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act and submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act is 2.6 percent, which is 0.2 percentage point higher than the proposed rule.

For these reasons, we believe that the 2023-based IPPS market basket appropriately reflects IPPS cost structures (we note, as described in section IV. of the preamble of this final rule, effective beginning FY 2026, we are finalizing to rebase and revise the IPPS market basket to reflect a 2023 base year), and we believe the price proxies used (such as those from BLS that reflect wage and benefit price growth) are an appropriate representation of price changes for the inputs used by hospitals in providing services. Given that we believe the rebased and revised 2023-based IPPS market basket reflects an index of appropriately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in such inpatient hospital services and the percentage change of the rebased and revised 2023-based IPPS market basket is based on IGI's more recent forecast reflecting the prospective price pressures for FY 2026, we do not believe it would be appropriate to use our exceptions and adjustment authority to create a separate payment that would have the effect of modifying the current law update.

Comment: Many commenters urged CMS to use its special exceptions and adjustments authority under Section 1886(d)(5)(I)(i) of the Act to implement a retrospective adjustment for FY 2026 to account for the difference between the market basket update that was implemented, and the actual market basket increase in prior years. Commenters stated an adjustment would reset hospital losses over the last four years and realign IPPS payments with hospitals' costs. They stated MedPAC's March 2025 report to Congress found that fee-for-service (FFS) Medicare payments in 2023 continued the trend below hospitals' actual costs with a hospital FFS Medicare margin of − 13 percent in 2023 (− 14 percent for nonprofit hospitals) and median FFS Medicare margin of − 2 percent even for efficient providers. They stated hospitals cannot continue to take on losses on their Medicare business and also be expected to keep up with rising costs and inflation that has affected the entire economy. Commenters also stated that the missed forecasts have a significant and permanent impact on hospitals as they are permanently established in the standard payment rate for IPPS and absent action from CMS will continue to compound. Many commenters noted that MedPAC recommended for 2026 to update the 2025 Medicare base payment rates for general acute care hospitals by the amount specified in current law plus 1 percent.

Commenters recommended that CMS implement various one-time adjustments to account for underpayments in 1 or more years between FY 2021 and FY 2024 as well as for forecasted underpayments for FY 2025. The commenters stated the underestimation is, in large part, because the market basket is a time-lagged estimate that cannot fully account for unexpected changes that occur, such as historic inflation and increased labor and supply costs. They stated this is exactly what occurred at the end of the CY 2021 into CY 2022, which resulted in a large forecast error in the FY 2022 market basket update.

Commenters also noted that CMS makes forecast error adjustments under the SNF PPS and the capital IPPS update. In both payment systems, CMS applies the forecast error adjustment based on previously established policy if the difference between the update and the actual rate of inflation, using after-the-fact data, differs by more than a threshold amount (0.5 percentage point for the SNF update and 0.25 percentage point for the capital IPPS update). They noted the forecast errors for FY 2021 through FY 2023 for IPPS exceeded the 0.5 percentage point threshold that is used for the SNF forecast error adjustment policy. A commenter recommended CMS establish a forecast error threshold of 1.5 percentage points and retroactively adjust payments for that year. Commenters stated that while CMS has not developed an analogous

policy for the IPPS operating update, they believe such a forecast error adjustment to the FY 2026 IPPS operating update could be adopted under CMS' rulemaking authority. A commenter requested that CMS apply a positive adjustment of 4.6 percentage points to the IPPS update taking into account the combined forecast error for the years FY 2021 through FY 2024. The commenter stated that if CMS were to adopt this recommendation, the update would be the market basket update of 3.2 percent plus 4.6 percentage points for forecast error correction less 0.8 percentage point for productivity or a net 7.0 percent.

Response: While the projected IPPS hospital market basket updates have been under forecast (actual increases less forecasted increases were positive) for this most recent period, over longer periods the forecasts have generally averaged close to the historical measures (for instance, from FY 2014 through FY 2023 the cumulative forecast error was 0.0 percentage point). CMS will continue to monitor the methods associated with the market basket forecasts to ensure there are not underlying systematic issues in the forecasting approach.

We note that the under forecast of the IPPS market basket increase in the recent time period was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE. However, an analysis of the forecast error of the IPPS market basket over a longer period of time shows the forecast error has been both positive and negative. Only considering the forecast error for years when the final hospital market basket update was lower than the actual market basket update does not consider the full experience and impact of forecast error, in particular the numerous years that providers benefited from the forecast error. Relatedly, as we discussed in the FY 2024 IPPS/LTCH PPS final rule in response to similar comments (88 FR 59034), the capital IPPS and SNF PPS forecast error adjustments were adopted very early in both payment systems and, unlike what commenters are requesting here for the IPPS, forecast errors over many years have been consistently addressed within each of the Capital IPPS and SNF PPS.

For these reasons, we continue to believe it is not appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years. After consideration of the comments received and consistent with our proposal, we are finalizing to use more recent data to determine the FY 2026 market basket update for the final rule. Specifically, based on more recent data available, we determined final applicable percentage increases to the standardized amount for FY 2026, as specified in the table that appears later in this section.

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 proposed a productivity adjustment of 0.8 percent. Similar to the market basket rate-of-increase, for the proposed rule, the estimate of the proposed FY 2026 productivity adjustment was based on IGI's fourth quarter 2024 forecast. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2026 productivity adjustment for the final rule. Based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2026 is 0.7 percentage point.

Comment: Commenters expressed concerns about the application of the productivity adjustment stating it is flawed because it is based on a measure for the private nonfarm business sector. Several commenters stated that the use of private nonfarm business total factor productivity effectively assumes the hospital field can mirror productivity gains achieved by private nonfarm businesses. Other commenters stated that private-sector productivity trends do not reflect the complex operational realities of hospital care, particularly during a time of sustained labor shortages and wage inflation. Several commenters also claimed that it is well proven by the economic literature that the hospital and health care field cannot achieve the same productivity gains as the total economy. For example, the commenters stated that by focusing only on private businesses, this measure excludes nonprofit and government businesses, which account for more than 60 percent of hospitals and health systems. Thus, the commenter stated that this measure is not an appropriate or reliable predictor of productivity for the hospital field. The commenters stated that an Office of the Actuary memo indicated that hospitals are unable to achieve the same productivity gains as the general economy over the long run. Specifically, some commenters requested CMS consider its own findings that hospitals historically have not achieved the same level of productivity as the general economy referencing the June 2, 2022 memorandum where CMS's Office of the Actuary stated hospital TFP ranged from 0.2 percent to 0.5 percent compared to the average growth of private nonfarm business TFP of 0.8 percent. Commenters also referred to the BLS publication on a TFP measure for the combined Hospitals and Nursing and Residential Care Facilities industry, which indicated average TFP growth from 1990–2019 of -0.5 percent, even

lower than either of OACT's estimates. A commenter stated that the productivity adjustment penalizes hospitals for their cost-saving efforts and further compounds their fears of adequate funding. Therefore, commenters stated that using the private nonfarm business sector TFP to adjust the market basket inappropriately exacerbates Medicare's chronic underpayments to hospitals.

Other commenters expressed concern regarding the increase in the productivity adjustment for FY 2026 relative to prior years. Commenters requested CMS explain the magnitude of the proposed productivity adjustment stating it is the largest CMS has used since FY 2019 and is the second largest in the 15 years for which CMS has published data. A commenter stated CMS should evaluate how the rolling average experienced such a significant increase when compared with the productivity adjustments ranging from 0.2 to 0.5 percentage point in the last three years. Several commenters stated that it is puzzling how an indicator based on a 10-year moving average could yield such an increase in the productivity cut from FY 2025 to FY 2026 and stated that they were unable to fully analyze the projections due to a lack of transparency from CMS. A few commenters requested that CMS explain the large increase to the productivity offset relative to its historical average application in the final rule. Some commenters stated that the application of variables as wide as this ten-year range is no longer appropriate due to the unprecedented cost of goods and services during the COVID–19 pandemic and claimed that prices have never leveled back down to pre-pandemic rates. Another commenter requested that CMS reevaluate the calculation of the productivity adjustment, paying particular attention to what it described as the inconsistency in cost during FYs beginning in FY 2020.

Given their concerns about the productivity adjustment, commenters requested CMS use its discretion under section 1886(d)(5)(I)(i) of the Act to reduce or eliminate the productivity adjustment of 0.8 percentage point for FY 2026.

A commenter requested a FY 2026 productivity adjustment of 0.2 percentage point while another commenter urged CMS to consider an alternative or blended productivity adjustment such as a hospital-specific productivity measure.

Response: Section 1886(b)(3)(B)(xi) of the Act requires the application of the productivity adjustment. As required by statute, the FY 2026 productivity adjustment is derived based on the 10-year moving average growth in economy-wide private nonfarm business total factor productivity for the period ending FY 2026.

As previously discussed, the general method for calculating the productivity adjustment is made 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*. The most recent BLS historical TFP data is available at *http://www.bls.gov/productivity/*, which allows interested parties to obtain historical TFP annual index levels for 1987 through 2024. We also provided the IGI projection model (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf*), which is used to derive annual TFP growth rates for 2025 and 2026. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2026 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2026 relative to the 40-quarter moving average projected level for the period ending September 30, 2025. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor 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).

At the time of this final rule, the FY 2026 productivity adjustment reflects BLS historical TFP data through 2024 (released on March 21, 2025) and IGI's forecasted TFP growth for 2025 and 2026. The average annual growth rate of historical TFP published by BLS for 2017 through 2024 is currently 0.9 percent and IGI is projecting average TFP growth of about 0.0 percent for 2025 and 2026 based on IGI's second-quarter 2025 forecast. Combining the historical and projected TFP data over the entire 10-year time period results in a compound annual growth rate of TFP of 0.7 percent for 2026. The productivity adjustment (based on the 10-year period ending with FY 2026) for the FY 2026 IPPS/LTCH PPS final rule is 0.1 percentage point lower than for the FY 2026 IPPS/LTCH PPS proposed rule and primarily reflects the incorporation of a revised outlook from IGI that has lower projected economic growth over 2025 and 2026. The 0.7 percentage point productivity adjustment in this FY 2026 final rule is larger than the productivity adjustment in prior final rules for FY 2023 and FY 2024 mainly due to the incorporation of updated BLS historical data.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing as proposed to use more recent data to determine the FY 2026 productivity adjustment for the final rule.

In summary, based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2025), we estimate that the FY 2026 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent. Based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2025 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2026 is 0.7 percentage point. Based on these more recent data, for this final rule, we have determined four applicable percentage increases to the standardized amount for FY 2026, as specified in the following table:

TABLE VI.B-01: 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
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.475	0.0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.125**	**1.775**	**-0.7**

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, reduced by 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 final 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 final 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 finalized 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 proposed 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 proposed that if more recent data subsequently became 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.

We did not receive any public comments on our proposed updates to hospital-specific rates applicable to SCHs and MDHs. The general comments we received on the proposed FY 2026 update (including the proposed market basket update and productivity adjustment) are discussed earlier in this section. For FY 2026, we are finalizing the proposal to determine the update to the hospital specific rates for SCHs and MDHs in this final rule using the more recent available data, as previously discussed.

For this final rule, based on more recent available data, we are finalizing the following updates to the hospital specific rates applicable to SCHs and MDHs: An update of 2.6 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 1.775 percent for a hospital that fails to submit quality data and is a meaningful EHR user; an update of 0.125 percent for a hospital that submits quality data and is not a meaningful EHR user; and an update of -0.7 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. 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 33 ⅓ 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 66 ⅔ 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.

In the FY 2026 IPPS/LTCH PPS proposed rule, 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 accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we proposed a market basket update of 3.2 percent reduced by a productivity adjustment of 0.8 percentage point. 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 proposed 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 proposed 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 reduced by 0.8 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became 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. We did not receive any public comments on our proposed updates to the standardized amount for FY 2026 for Puerto Rico hospitals. The general comments we received on the proposed FY 2026 update (including the proposed market basket update and productivity adjustment) are discussed in greater detail earlier in this section. For FY 2026, we are finalizing the proposal to determine the update to the standardized amount for FY 2026 for Puerto Rico hospitals in this final rule using the more recent available data, as previously discussed.

As previously discussed in section VI.B. of the preamble of this final rule, based on more recent data available for this final rule (that is, IGI's second quarter 2025 forecast of the 2023-based IPPS market basket rate-of-increase with historical data through the first quarter of 2025), we estimate that the FY 2026 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent and a productivity adjustment of 0.7 percent. 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, in accordance with section 1886(b)(3)(B) of the Act, we determined 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, an applicable percentage increase to the operating standardized amount of 2.6 percent (that is, the FY 2026 estimate of the market basket rate-of-increase of 3.3 percent reduced by 0.7 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 0.125 percent (that is, the FY 2026 estimate of the market basket rate-of-increase of 3.3 percent, less an adjustment of 2.475 percentage point (the market basket rate-of-increase of 3.3 percent × 0.75 for failure to be a meaningful EHR user), and reduced by an adjustment of 0.7 percentage point for the productivity adjustment).

TABLE VI.B-02: 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
Market Basket Rate-of-Increase	3.3	3.3
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.7	-0.7
Applicable Percentage Increase Applied to Standardized Amount	**2.6**	**0.125**

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 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 national median CMI value for FY 2026 is based on the CMI values of all urban hospitals nationwide, and the 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 values are based on discharges occurring during FY 2024 (October 1, 2023, through September 30, 2024), and include bills posted to CMS' records through March 2025. We believe that this is the best available data for use in calculating the national and regional median CMI values and is consistent with our use of the FY 2024 MedPAR claims data for FY 2026 ratesetting.

In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed 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. (We refer readers to the table set forth in the FY 2026 IPPS/LTCH PPS proposed rule at 90 FR 18269). In the proposed rule we stated that we intended to update the proposed CMI values in the FY 2026 IPPS/LTCH PPS final rule to reflect the updated FY 2024 MedPAR file, which contains data from additional bills received through March 2025.

Comment: Commenters supported our proposal to use FY 2024 data to calculate the national and regional median CMI values for FY 2026.

Response: We appreciate the commenters' support.

Therefore, based on the best available data (FY 2024 bills received through March 2025), 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:

- 1.7801 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

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

Region	Case-mix index value
1. New England (CT, ME, MA, NH, RI, VT)	1.4962
2. Middle Atlantic (PA, NJ, NY)	1.558
3. East North Central (IL, IN, MI, OH, WI)	1.6264
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7413
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6352
6. East South Central (AL, KY, MS, TN)	1.5965

Region	Case-mix index value
7. West South Central (AR, LA, OK, TX)	1.7594
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.807
9. Pacific (AK, CA, HI, OR, WA)	1.78045

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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18269), we proposed 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 final rule was developed. We believe that this is the best available data for use in calculating the median number of discharges by region and is consistent with our finalized data proposal to use cost report data from cost reporting periods beginning during FY 2023 for FY 2026 ratesetting. In the FY 2026 IPPS/LTCH PPS proposed rule, we proposed 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 table set forth in the FY 2026 IPPS/LTCH PPS proposed rule at 90 FR 18269). In the proposed rule, we stated that we intended to update these numbers in the FY 2026 final rule based on the latest available cost report data.

Comment: Commenters supported our proposal to use FY 2023 data to calculate median number of discharges by region for FY 2026.

Response: We appreciate the commenters' support.

Therefore, based on the best available discharge data at this time, that is, for cost reporting periods that began during FY 2023, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Number of discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,535
2. Middle Atlantic (PA, NJ, NY)	9,844
3. East North Central (IL, IN, MI, OH, WI)	7,918
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,414
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,897
6. East South Central (AL, KY, MS, TN)	8,511
7. West South Central (AR, LA, OK, TX)	6,002
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	7,901
9. Pacific (AK, CA, HI, OR, WA)	9,100

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 final 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. 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 final 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] x (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 addressed 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 was addressed in Change Request 14045 (Transmittal 13151), issued May 5, 2025. For additional information, please refer to the transmittal *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CMS/r13151otn.pdf*.

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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18271), we proposed 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 proposed 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 proposed 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18002). We further proposed 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.

In the next section, we discuss the comments we received on the extension of the temporary changes to the low-volume hospital payment definition and payment adjustment methodology. We received no comments on our proposed conforming changes to the regulations to codify this extension and we are finalizing the proposed changes to the regulations text in § 412.101 without modification.

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 proposed 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.

Comment: Many commenters supported the legislative extension of the temporary changes to the definition and payment adjustment for low-volume hospitals through September 30, 2025 and expressed support for additional legislative extensions. Many commenters requested that CMS collaborate with Congress to extend or make permanent the temporary modifications to the low-volume hospital payment policy. Several commenters expressed concerns that hospitals, particularly those in rural areas or that serve primarily Medicare patients, would face financial instability in the absence of an extension of the temporary modifications to the low-volume hospital payment policy. Several commenters asked CMS to clarify how it would handle any legislation that would provide a continuation of the modified low-volume hospital payment policy beyond the end of the fiscal year. Another commenter urged CMS to expeditiously process claims and provide instructions to MACs for any subsequent extensions, especially in instances when extensions are made retroactively. A few commenters requested CMS provide a transition payment to hospitals impacted by the expiration of the temporary modifications to the low-volume hospital payment policy.

Response: We appreciate the commenters sharing their support for legislative action and the commenters' concerns about the expiration of the temporary changes to the low-volume hospital policy and the corresponding financial impact. As previously discussed, section 1886(d)(12) of the Act sets forth the applicable low-volume hospital policy beginning FY 2026. As we have said in the past, we make every effort to implement any extension of the low-volume hospital payment policy as expeditiously as possible. However, we believe it would be premature to opine on exactly how any subsequent extension would be implemented. As

with past extensions, we would continue to work to implement any subsequent extensions as quickly and seamlessly as possible based on the specific legislative requirements of the particular extension.

Comment: Several commenters stated that it is not the intent of Congress for the low-volume hospital payment policy to revert to the historical statutory requirements. Some of these commenters believe that CMS is ignoring the congressional intent of this policy and denying a group of IPPS providers low-volume hospital payments with the reversion to the policy that was originally established for FY 2005. A few commenters also stated that CMS did not explain why limiting the low-volume hospital payment adjustment to hospitals with fewer than 200 discharges is ''most consistent'' with statute. These commenters requested expanding eligibility for the discharge criteria to match the statutory requirement to include IPPS hospitals with 200–799 discharges.

Response: We disagree that it is contrary to the congressional intent for the low-volume hospital policy to revert to the policy established under the original historical statutory requirements. As previously discussed, section 2201 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4), enacted on March 15, 2025, provided an extension of the temporary changes to the qualifying criteria and payment adjustment methodology for certain low-volume hospitals through September 30, 2025 only. Consistent with the discussion in the FY 2005 IPPS final rule (69 FR 49100), despite the statutory definition of a low-volume hospital as a subsection (d) hospital that has less than 800 discharges during the fiscal year for FYs 2026 and subsequent years, the statutory provision mandating this adjustment also requires the Secretary to determine the empirical relationship between the standardized cost-per-case, the total number of discharges, and the amount of incremental costs (if any) associated with the number of discharges. In addition, the statute requires that the applicable percentage increase shall be based upon such relationship in a manner that reflects such incremental costs. We continue to believe that the statutory language thus gives the Secretary the flexibility to set the percentage increase at zero for a given number of discharges if the empirical evidence shows that hospitals experience no higher incremental costs when they reach that number of discharges. In other words, the statute does not require the Secretary to provide an adjustment in the absence of empirical evidence that an adjustment is warranted by higher incremental costs.

As discussed in response to public comments in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53408 through 53409), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50612 through 50613), and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38184 through 38189), to implement the original low-volume hospital payment adjustment provision, and as mandated by statute, we developed an empirically justified adjustment based on the relationship between costs and total discharges of hospitals with less than 800 total (Medicare and non-Medicare) discharges. Specifically, we performed several regression analyses to evaluate the relationship between hospitals' costs per case and discharges, and found that an adjustment for hospitals with less than 200 total discharges is most consistent with the statutory requirement to provide for additional payments to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with lower numbers of discharges (69 FR 49101 through 49102). Based on these analyses, we established a low-volume hospital policy under which qualifying hospitals with less than 200 total discharges receive a payment adjustment of an additional 25 percent. (Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent.) At this time, we are not aware of any analysis or empirical evidence that would support expanding the originally established low-volume hospital adjustment policy and we did not make any proposals regarding the low-volume hospital payment adjustment for FY 2026. For these reasons, we are not making any changes to the low-volume hospital payment adjustment policy in this final rule.

Comment: A few commenters expressed support for the methodology for calculating the low-volume payment adjustment using a single, non-sliding scale adjustment of 25 percent for qualifying hospitals discharges beginning in FY 2026. A commenter requested that CMS publish disaggregated impact analyses to help stakeholders and legislators understand the projected consequences of expiration.

Response: We appreciate commenters' support for the single, non-sliding scale payment adjustment for qualifying hospitals beginning in FY 2026. In response to the comment requesting that CMS publish disaggregated impact analyses to help stakeholders and legislators understand the projected financial effect of expiration, we refer the commenter to the provider data used in creating Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2026, in Appendix A of this final rule, which can be used to estimate individual hospital's payments for FY 2026 and is available on the CMS website for this final rule at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps.*

After consideration of the public comments we received regarding the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals for FY 2026, we are finalizing our proposals without modification.

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 proposed 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 meets 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 proposed 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. We received no comments on our proposed process for requesting and obtaining the low-volume hospital payment adjustment for FY 2026 and therefore are finalizing this proposal without modification.

E. 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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18273), we proposed 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 addressed the extension provided by section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4) in Change Request 14045 (Transmittal 13151), issued May 5, 2025. For additional information, please refer to the transmittal *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/CMS/r13151otn.pdf.*

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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18273), we proposed 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 also proposed 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. We also noted that 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.

Comment: Many commenters expressed support for extending the MDH program or making the MDH program permanent and noted that they would continue supporting congressional efforts to protect the MDH program. A few commenters urged CMS to advocate for action to be taken to ensure that the MDH program is extended. Several state hospital associations expressed their concern that hospitals in their states would experience significant payment decreases as a result of the expiration of the MDH program. One commenter stated that if CMS moves forward with the proposed changes, any transitional payments must be meaningful and implemented over a multi-year period to

prevent harmful disruptions in patient care. Another commenter asked that CMS consider whether any alternative regulatory flexibilities exist to assist these hospitals if the program is not renewed. Some commenters also expressed support for increasing the base rates for these hospitals. Others supported an additional base rate for calculating MDH payments.

Response: While we appreciate the commenters' concerns about the expiration of the MDH program and the financial impact to affected providers if the MDH program is not extended beyond FY 2025, CMS does not have the authority under current law to extend the MDH program beyond the September 30, 2025 statutory expiration date. Similarly, section 1886(b)(3)(D) of the Act specifies the applicable base years or ''target amounts'' for hospitals classified as MDHs. These comments are similar to comments we received previously, prior to the most recent statutory extension of the MDH program for FY 2025. We refer commenters to our discussion in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69353). In response to the comment requesting CMS explore other regulatory support options, should Congress not act, we may consider this for future rulemaking.

Comment: Several commenters expressed support for CMS' policy that allows MDHs to apply for SCH status in advance of the expiration of the MDH program and be paid as such under certain conditions. A commenter requested that CMS provide technical assistance to MDHs seeking to transition to SCH classification. Commenters requested that CMS explicitly clarify how it would handle the MDH program should Congress extend it and requested that CMS expedite restoration of MDH status and expeditiously process claims in the event the program lapses. Commenters also urged CMS to ensure that affected hospitals have access to technical assistance and timely guidance to minimize confusion. Other commenters requested that CMS provide instructions to MACs during program extensions, especially in instances when extensions are made retroactively. A commenter requested that CMS publish disaggregated impact analyses to help stakeholders and legislators understand the projected consequences of expiration.

Response: We appreciate the commenters' support of our policy allowing MDHs to apply for SCH status in advance of the expiration of the MDH program and to be paid as such under certain conditions and allow for a seamless transition from MDH classification to SCH classification. MDHs looking to apply for SCH classification should contact their individual MACs for assistance on the application requirements or for any technical assistance. We appreciate the commenters' sharing their concerns relating to a retroactive restoration of the MDH program. As with past extensions, CMS will evaluate enacted legislation to determine the most appropriate approach to implement changes to the law, including issuing instructions to the MACs to reinstate MDH status to eligible hospitals and to communicate with affected hospitals. As in the past, we will make every effort to implement any extension of the MDH program as expeditiously as possible. In response to the comment requesting that CMS publish disaggregated impact analyses to help stakeholders and legislators understand the projected financial effect of expiration, we refer the commenter to the provider data used in creating Table I—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2026, in Appendix A of this final rule and posted on the web which can be used to estimate individual hospital's payments for FY 2026. The data can be found on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*.

In addition, we note in Table I in Appendix A of this final rule, the lines reflecting the changes for ''Bed Size (Rural)'' with 0–49 beds and 50–99 beds generally reflect the expected impact for hospitals classified as MDH prior to the expiration on October 1, 2025 under current law.

In summary, under current law, beginning October 1, 2025, all hospitals that previously qualified for MDH status will no longer have MDH status. After consideration of the public comments we received, we are adopting as final the proposed conforming changes to the regulations text at §§ 412.90 and 412.108 to reflect the extension of the MDH program through September 30, 2025 in accordance with section 2202 of the Full-Year Continuing Appropriations and Extensions Act, 2025 (Pub. L. 119–4). We are finalizing the proposed changes in paragraphs (a)(1) and (c)(2)(iii) of § 412.108 and paragraph (j) of § 412.90 without modification.

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.

We received some comments related to IME and direct GME payment that were outside the scope of the proposed rule, including comments related to the eligibility of SCHs and MDHs paid under the hospital-specific rate to receive IME payments. Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing these comments in this final rule.

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 later in this section, 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.

In the FY 2026 IPPS/LTCH PPS Proposed Rule (90 FR 18274 through 18277), we stated that 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 were taking the opportunity to restate and clarify our FTE counting policy in rulemaking. We did not propose any changes to the FTE counting policy in the proposed rule.

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).[162] 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

[162] 366 days should be used when the cost reporting period includes February 29.

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.

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 previously, 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 previously.

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 previously, 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 previously 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 previously, 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).

Comment: Commenters expressed support for our proposed clarification of

the policy for determining the DGME and IME FTE resident counts for 12-month and non-12-month cost reporting periods.

Response: We thank the commenters for their support.

As noted previously, we did not propose any changes to our existing FTE counting policies. Accordingly, we are finalizing our proposed clarification with no change to the regulations at 42 CFR 412.105 or §§ 413.75 through 81.

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)) [163] 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 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

[163] 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.

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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18278 through 18280), we proposed the rates for CY 2024. Consistent with the use of HCRIS data for past calendar years, we proposed 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 the 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 ''projected'' Part A direct GME payments and MA direct GME payments for the current calendar year, which in the proposed rule and in this final 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 increased 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 stated in the proposed rule that we intended 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
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

Comment: We received a few comments in support of our proposed calculation of the NAH MA payment rates for CY 2024.

Response: We thank the commenters for their support.

For this final rule, consistent with the use of HCRIS data for past calendar years, for CY 2024, we 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, and MA Inpatient Days. For this final rule, we accessed the HCRIS data from the first quarterly update of 2025. 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 final rule in CY 2024, based on the best available cost report data. Next, consistent with the method we described previously from 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 first quarterly update of CY 2022 HCRIS, adjusted for the CPI–U and for increasing MA enrollment.

For CY 2024, the final national rates and percentages, and their data sources, are set forth in this table.

Final CY 2024 NAH MA Rates	Final CY 2024	SOURCE
NAH Pass-Through	$277,260,868	Cost reports ending in FY 2022 HCRIS
Part A Inpatient Days	75,307,860	Cost reports ending in FY 2022 HCRIS
MA Inpatient Days	16,306,570	Cost reports ending in FY 2022 HCRIS
Part A Direct GME	$3,086,768,889	CY 2022 HCRIS + CPI-U + MA enrollment
MA Direct GME	$2,571,220,535	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	2.33%	Pool/MA direct GME

3. 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 (DC) 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,* 717 F.Supp.3d 33 (D.D.C. 2024)). 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18280 through 18282), we stated that we disagree with the Court's ruling and asserted 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, to further clarify the regulations, we proposed 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 noted 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 did not propose 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 have been cost reporting periods beginning on or after October 1, 2025.

We received many comments in opposition to our proposal to determine the net cost of approved nursing and allied health education programs by deducting tuition and other revenue from direct costs prior to the allocation of indirect costs. Commenters objected that the proposed policy is inconsistent with general cost-finding principles and would result in the NAH cost centers receiving less than their share of institutional overhead. We thank the commenters for their feedback. Due to the number and nature of the comments that we received, and after further consideration of this issue, we have decided not to finalize changes to our existing policy in this final rule. We expect to revisit the treatment of NAH education costs in future rulemaking and we encourage interested parties to submit comments on any proposed policy changes at that time.

H. 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 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).[164]

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

[164] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

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 proposed 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 proposed 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 final 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 final 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 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 proposed 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 also proposed 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 proposed 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 also proposed 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 final rule for further discussion of our proposed and finalized 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 proposed 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 final rule, we proposed 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 final rule for further discussion of our methodology.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for the proposed rule we proposed 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 proposed 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 proposed to update the value of the adjustor based on more recent data for the final rule.

We did not receive any comments specifically relating to the proposed payment adjustment for applicable clinical trial cases, 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 are therefore finalizing our proposal without modification. We are also finalizing our proposed modifications to our regulations at 42 CFR 412.85 and

412.312 to codify this payment adjustment for other cases where the immunotherapy product is not purchased in the usual manner, such as obtained at no cost, without modification. We are also finalizing our proposal to update the value of this adjustor based on more recent data for this final rule. Therefore, using the March 2025 update of the FY 2024 MedPAR data, we are finalizing an adjustor of 0.16 for FY 2026, which will be multiplied by the final FY 2026 relative weight for MS–DRG 018 as part of the calculation of the payment for claims determined to be applicable clinical trial cases, expanded use access immunotherapy claims, 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.

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. Integration of 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18283 through 18286), we proposed 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 proposed 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.[165] It is projected that nearly two-thirds of all Medicare enrollees will be enrolled in MA plans by 2030.[166] 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,[167] [168] others have found no difference or even higher risk-adjusted readmission rates for certain conditions.[169] [170] 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.[171] 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.[172] [173]

We proposed 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

[165] 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*.

[166] 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*.

[167] Jacobs PD, 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*.

[168] Huckfeldt PJ, Escarce JJ, 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*.

[169] Yayac MF, Harrer SL, Janiec DA, 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*.

[170] Henke RM, Karaca Z, Gibson TB, 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*.

[171] Panagiotou OA, 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*.

[172] CMS Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#*.

[173] CMS Quality Net. Available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

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.'' [174] We proposed 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.'' [175] 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.[176] We refer readers to QualityNet for more on the list of ICD–10 codes used in the risk adjustment model, available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/resources*.[177]

(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.[178] 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.[179]

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.[180]

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 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

[174] CMS Measures Inventory Tool. Available at: *https://cmit.cms.gov/cmit/#*.

[175] 2024 Measures Under Consideration List. Available at: *https://mmshub.cms.gov/2024/2024-11/2024-measures-under-consideration-list-now-available*.

[176] Krumholz HM, Coppi AC, 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/*.

[177] In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18284), we referred readers to the CMS Measures Management System, available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports/2024-MUC-List-materials* for the list of ICD–10 codes used. Subsequently, we issued a correction notice, available at 90 FR 23867.

[178] 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.*

[179] Battelle—Partnership for Quality Measurement. (February 2025). PRMR 2024 MUC Recommendations Spreadsheet Final. Available at: *https://p4qm.org/PRMR/Resources.*

[180] Battelle—Partnership for Quality Measurement. (February 2025). PRMR 2024 MUC Recommendations Spreadsheet Final. Available at: *https://p4qm.org/media/3891.*

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 proposed 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 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.[181] 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, hospital-submitted MA claims, and MAO-submitted encounter data. Additional comorbidities prior to the index admission are assessed using Part A and Part B Medicare claims and/or 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 proposed 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 at *https://data.cms.gov/provider-data/*, as codified at § 412.154(f).

We invited public comment on this proposal.

Comment: Many commenters supported the inclusion of MA beneficiaries into the Hospital Readmissions Reduction Program measure set stating that inclusion would result in a fairer, more representative evaluation of hospital performance; improve data accuracy and timeliness; and align with broader initiatives in value-based care. Commenters stated that this inclusion enhances representativeness and fairness by creating a more comprehensive view of the Medicare population since MA beneficiaries comprise a growing share of Medicare beneficiaries. A commenter supported the inclusion because the PRMR Hospital Committee reviewed and supported these changes.

Response: We thank these commenters for their support.

Comment: A few commenters recommended that CMS stratify performance results by payer type, which would allow comparison of performance between MA and FFS populations. A commenter stated that stratification by payer would allow analysis of the effects of MA plan design on readmissions rates. Some elements of MA plan design cited by the commenter were a limited post-acute care network, a limited specialty network, referral restrictions, and denials of post-acute care coverage.

Response: We thank commenters for this recommendation. Consistent with the recommendation from the PRMR Hospital Recommendation Group, we intend to review the applicability of stratifying the measures by MA or FFS data. We note that stratifying the model by FFS and MA did not yield meaningful differences in performance, supporting the decision to model them together with an indicator variable. Finally, keeping FFS and MA patients together for purposes of this measure's calculation will keep the hospitals' total volume higher for more reliable measure scores. We would provide data regarding payer for hospitals to review through annual confidential feedback reports provided as part of participation in the Hospital Readmissions Reduction Program.

Comment: A commenter supported inclusion of index admissions for MA beneficiaries in the measure cohorts but did not support stratifying by Medicare FFS and MA data. This commenter stated that the measures were not developed and have not been tested for reporting at the health plan level.

Response: We understand the commenter's concern about potential stratification of measure results and will consider whether the lack of testing at the health plan level affects the applicability of stratifying the measures by MA or FFS data. We would only make data regarding payer available through the confidential feedback reports for hospitals. Any potential public reporting of stratified measure data would be through future notice-and-comment rulemaking.

Comment: Several commenters expressed concern that MA plans do not follow the same readmission calculation methodologies and reimbursement policies as traditional Medicare. These commenters recommended requiring MA plans to adhere to traditional Medicare payment policies prior to incorporating index admissions for MA beneficiaries into the cohorts for Hospital Readmissions Reduction

[181] 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*.

Program measures. Commenters specifically expressed concern that MA plans bundle multiple admissions into one or refuse to pay for readmissions within defined windows which could result in hospitals being penalized for events related to MA plan policies. Some commenters requested clarification regarding whether admissions for which MA plans denied payments would be excluded as readmissions for the purposes of the Hospital Readmissions Reduction Program.

Response: We acknowledge commenters concerns regarding readmission calculation methodologies and reimbursement policies differences between MA plans and traditional Medicare. However, adding MA beneficiaries into the cohorts of the Hospital Readmissions Reduction Program measure set will provide a more robust and holistic view of quality of care provided to all Medicare beneficiaries despite reimbursement differences. For measure calculation, we identify index admissions and subsequent admissions (that is, readmissions) for patients enrolled in MA plans using MA encounter data and information-only claims for MA inpatient stays. We note that neither of these data sources are dependent on the MA plan's coverage determinations (including bundling or denying coverage) for that admission. Therefore, the measures would continue to encourage hospitals to focus on preventing readmissions, which are often an adverse event for patients and impose a financial burden on the patient and the healthcare system. Because an increasing portion of Medicare beneficiaries are covered by MA plans, including index admissions for these patients in our measure cohorts is an important step in ensuring high-quality, safe care for all Medicare beneficiaries. Including index admissions for Medicare beneficiaries enrolled in MA also increases the cohort size for the Hospital Readmissions Reduction Program measures, which in turn improves the measures' precision for each hospital. Due to the benefits of improving accuracy and reliability of the measures, we do not think it is appropriate to exclude any readmissions for which MA plans may have denied payment for the readmission if the administrative data reflect that a readmission occurred.

Comment: A few commenters recommended the development of separate or modified quality measures designed specifically for MA's capitated payment model.

Response: While separate quality measures designed specifically for MA's capitated payment model could be possible, the Hospital Readmissions Reduction Program is designed to encourage hospitals to improve communication and care coordination to better engage patients and caregivers in discharge plans and, in turn, reduce avoidable readmissions. As previously stated, adding the MA cohort to the Hospital Readmissions Reduction Program measures would provide a more robust and holistic view of quality of care provided to all Medicare beneficiaries. Therefore, we find the addition of the MA cohort to the Hospital Readmissions Reduction Program measures to further the Hospital Readmissions Reduction Program goals.

Comment: A few commenters requested that CMS clarify whether readmissions data regarding MA beneficiaries would be based on shadow claims that hospitals submit to CMS or whether the MA plan would be responsible for reporting readmissions.

Response: For determining readmissions for the Hospital Readmissions Reduction Program, we would evaluate the detailed data regarding enrollee health care encounters that MA plans are already required to submit to CMS as well as the information-only claims that hospitals submit (that is, ''shadow claims''). We would use index admission diagnoses from Medicare FFS Part A claims and MA encounter data as well as data from hospital inpatient information-only claims, outpatient and physician Medicare FFS claims (information-only claims), and MA encounter data from the 12 months prior to the index admission to identify comorbidities for risk adjustments. We would use the MA encounter data, information-only claims, and Medicare Part A claims to identify index admissions and applicable readmissions such that neither hospitals nor MA plans would be required to submit any additional data for this cohort expansion.

Comment: Many commenters expressed concern that MA encounter data are neither as complete nor as reliable as FFS claims, which they stated could affect the fairness and accuracy of Hospital Readmissions Reduction Program performance assessments. Some commenters expressed concern that basing performance calculations on data which could be incomplete or unreliable could cause financial or reputational harm to hospitals. Some commenters noted that MedPAC and the Government Accountability Office (GAO) have found that variations in coding practices, historical discrepancies, and a lack of data validation have impacted the completeness and reliability of MA encounter data. Some commenters also stated that under the current Health Effectiveness Data and Information Set (HEDIS) data submission requirements, MA plans are not obligated to report all hospital readmissions, only those for which they have approved payment, which could potentially undercount readmissions for index admissions for beneficiaries enrolled in MA plans.

Response: We refer readers to the Announcement of Calendar Year (CY) 2022 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies where CMS discussed the efforts undertaken to improve the completeness and validity of encounter data, and transitioned to calculating 100 percent of the risk score using diagnoses from encounter data and FFS (see discussion in Attachment III, Sections G and M of this Announcement). We respectfully disagree that the level of completeness of the MA data presents a significant issue with regard to measure reliability. We have been evaluating the MA data for use in quality measurement since 2017, and we note recent CMS policies have aimed to improve timeliness, completeness, and accuracy of MA data, thereby further enhancing its usability for hospital outcome measures.[182] [183] Hospital-submitted MA claims data are currently already in use for DSH and GME payment calculations and Medicare Advantage Organization (MAO)-submitted encounter data are currently already in use for calculating MA beneficiary risk scores.[184] In calculating both the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measures in the Hospital Inpatient Quality Reporting Program, we specify that for each MA admission, we would use either the hospital-submitted MA claim or the

[182] Centers for Medicare & Medicaid Services. Calendar Year (CY) 2024 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice). Accessed March 5, 2023. Available from: *https://www.cms.gov/files/document/2024-advance-notice.pdf*.

[183] Medicare Payment Advisory Commission. March 2022 report to the Congress: Medicare Payment Policy: The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. May 30, 2022. Available from: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf*.

[184] Medicare monthly enrollment data available at: *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment*

MAO-submitted MA encounter data record, whichever is available. If the MA admission information for a patient is available in both sources, we would use the hospital-submitted MA claim because it is timelier and already associated with the applicable hospital's CMS Certification Number (CCN).

More generally, we have found that incorporating data regarding MA patients into the readmission measures improve reliability, narrow the confidence intervals of measure scores, and lead to more hospitals and beneficiaries being included in the measures. Based on internal analyses of MA data reported to CMS by hospitals and MAOs for the years 2017 through 2021, we determined that it is feasible to use MA admissions in CMS hospital outcome measures. Hospitals and MAOs submit the data on a schedule that allows for their use. National Provider Identifiers (NPIs) from inpatient MA encounter data in CMS' Integrated Data Repository (IDR) can be matched to CMS CCNs currently used to identify hospitals in the CMS outcome measures. A high percentage of MA encounter data were submitted within the three-month time frame needed for reporting hospital measures and has improved over time (90.3% in 2018 compared to 95.2% in 2021 for inpatient encounters for acute care and critical access hospitals). Our internal analysis found a high rate of matching diagnoses between the MAO-submitted MA encounter data and the hospital-submitted MA claims, supporting the use of either data source for a given admission for measure calculation As stated previously, the measures will capture readmissions from information-only hospital claims and/or MA encounter data regardless of whether the plan paid for them or reported (or not reported) them in other information sets, such as HEDIS.

Generally, while HEDIS evaluates the quality of care at the population plan level where MA plans submit HEDIS-required data elements to evaluate quality across the enrolled population, the Hospital Readmissions Reduction Program uses fee-for-service claims, hospital-submitted MA claims or the MAO-submitted MA encounter records to calculate condition or procedure-specific hospital-level readmission rates to hold hospitals directly accountable for excess readmission rates. Essentially, HEDIS focuses on broad plan quality, while the Hospital Readmissions Reduction Program focuses on condition- and procedure-specific hospital outcomes at the facility-level. The fundamental difference is that HEDIS measures evaluate how well MA plans manage their members' overall health and care experience, while the Hospital Readmissions Reduction Program condition- and procedure-specific measures evaluate how well individual hospitals prevent unnecessary readmissions after discharge.

Comment: Many commenters expressed concern about the proposal, stating that MA beneficiaries experience different benefit designs, network restrictions, utilization management requirements, and prior authorization practices than beneficiaries covered under Medicare FFS. Some commenters were also concerned that MA plan policies may affect readmissions, leading to higher readmission rates, due to policies such as restrictive formularies, denials or delays in home care services, or limited specialist access. Commenters stated that this could cause hospitals to be penalized for delays or denials that originate in MA plan policies rather than from substandard hospital care.

Response: We recognize that Medicare Advantage payment policies are not the same as Medicare FFS payment policies, and by design, MAOs are given more flexibility in benefit and provider reimbursement design. However, from a patient's perspective, a readmission is an adverse outcome irrespective of benefit or payment policies. It is important to measure and provide transparency as to readmission rates for all Medicare beneficiaries. Using data from calendar year (CY) 2022 to 2023, internal analyses showed no statistical difference in the average risk-standardized readmission rates (RSRR) across the condition- and procedure-specific measures for the FFS-only and MA-only patients. While we understand that MA enrollees are subject to different benefits design and payment approaches than FFS enrollees, we do not agree that these differences mean that their clinical outcomes are beyond the hospital's control. We continue to encourage hospitals to work closely with insurers, including MA plans, to coordinate the highest quality care for their patients.

Comment: Some commenters requested that CMS communicate any shifts in benchmarks, distributions, or penalty thresholds that result from the inclusion of MA data. A few commenters also requested analysis of the impact of including index admissions for beneficiaries enrolled in MA plans in the measure cohort on hospital reimbursement, including identification of regional and local trends.

Response: We note that there is no baseline or benchmark period under the Hospital Readmissions Reduction Program. We will continue to use excess readmission ratios (ERRs) to assess a hospital's excess readmissions during the applicable period for each of the conditions or procedures included in the program. The ERR is a measure of a hospital's relative performance compared with an average hospital with a patient case mix similar to that hospital's (that is, if patients with the same characteristics had been treated at an average hospital, rather than at that hospital).

Additionally, under the peer grouping methodology as required by section 1886(q)(3)(D) of the Act, we assess hospitals' performance relative to other hospitals with a similar proportion of stays for beneficiaries who are dually eligible for Medicare and full Medicaid benefits during the applicable period. Under the peer grouping methodology, we use the peer group median ERR (that is, the median ERR within a peer group) as the threshold to assess hospital performance on each measure. We will continue to communicate information on peer groups and peer group median ERRs during the Review and Correction period.

Comment: Some commenters expressed concern that inclusion of index admissions for MA beneficiaries in the measure cohort would disproportionately affect hospitals in regions with high MA adoption rates.

Response: Table VI.K–02 of this final rule displays a comparison of hospital performance under the proposed updates to performance under the current methodology. This table analyzes performance across a number of hospital characteristics, including geographic region. The table shows that the number of penalized hospitals increases moderately (up to 7 percentage points) among all regions, with the exception of hospitals in the West South Central and Mountain regions. Additionally, although the penalty as a share of payments, which indicates the estimated financial impact on hospitals, increases for hospitals in the Middle Atlantic, East North Central, West North Central, and Pacific regions, no region is disproportionately impacted by the addition of MA beneficiaries in the measure cohort. With respect to the concern that this update would disproportionately affect hospitals in regions with high MA adoption rates, we note that MA beneficiaries comprise a majority of Medicare enrollees (51.2 percent as of

March 2025 [185]) and that hospitals are responsible for providing high quality care to all their patients, regardless of payer. We continue to encourage hospitals to work closely with insurers, including MA plans, to coordinate the highest quality care for their patients. By adding the MA cohort to the Hospital Readmissions Reduction Program measures we would provide a more robust and holistic view of quality of care provided to all Medicare beneficiaries. We note that our analysis of the mean risk-standardized readmission rates (RSRRs) using calendar years (CYs) 2022 and 2023, the rates are similar between FFS-only and MA-only patients for most conditions and procedures. The largest difference was 0.5 percentage points for performance both on the Hospital 30-Day, All-Cause, RSRR Following CABG Surgery measure and the Hospital 30-Day, All-Cause, RSRR Following HF Hospitalization measure (the results were statistically significant at the 0.05 level).[186]

Comment: A commenter requested clarification on when baseline reports including the MA patient cohort data will be distributed.

Response: We assume the commenter is referring to baseline reports such as are used in the Hospital VBP Program and note that the Hospital Readmissions Reduction Program does not use baseline reports. For the Hospital Readmissions Reduction Program, hospitals will receive annual confidential feedback reports that include details such as a hospital's payment reduction percentage, payment adjustment factors, dual proportion, peer group assignment, measure results, ratio of base operating DRG payments per measure to total payments, national readmission rates, detailed discharge-level data, and risk factor information for the readmission measures, and a flag to indicate whether the index admission data originated from FFS or MA.

Comment: A few commenters requested CMS clarify how risk adjustment methodologies will be adapted to account for differences in MA populations and ensure that hospitals are not unfairly penalized.

Response: The risk adjustment for each readmission measure in the Hospital Readmissions Reduction Program is based on patient comorbidities as identified through an analysis of the admission diagnoses and in-hospital comorbidity data as well as clinical data (currently assessed from Medicare Part A and Part B claims) for the 12 months prior to the index admission. Under this updated measure cohort, we would also include MA encounter data for the index admission and the 12 months prior to the index admission to identify clinical risk factors to risk adjust the measures. Internal analyses showed that stratification of the model by FFS and MA did not yield meaningful differences in risk profiles. And as previously discussed, we saw similar readmission rates between FFS-only and MA-only patients for most conditions and procedures. Therefore, the clinical variables for risk adjustment were identified through an analysis of a combined MA and FFS cohort.[187] This cohort was approximately evenly split between FFS and MA beneficiaries, and the prevalence of clinical risk factors and their associations with readmission outcomes were similar across both groups. The final models also included an indicator for MA versus FFS enrollment to adjust for any potential residual case-mix differences between the two beneficiary groups.

Comment: A commenter expressed concern that the URL provided in the proposed rule for the CMS Measures Management System does not actually display the list of applicable ICD–10 codes used in the risk adjustment model. The commenter requested that CMS clearly identify the location or provide a document containing those ICD–10 codes so that stakeholders may verify the standards underlying risk adjustment.

Response: The commenter is correct that the cited website did not display the list of applicable ICD–10 codes used in the risk adjustment model. We subsequently issued a correction notice to correctly refer readers to the QualityNet website for a crosswalk between ICD–10 codes and condition categories used for risk adjustment (90 FR 23867). This crosswalk is available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/resources*.

Comment: A few commenters stated that adding MA beneficiaries to the Hospital Readmissions Reduction Program would likely increase administrative burden on hospitals. Some commenters stated that the incorporation of MA data would require significant updates to reporting systems, staff training, and potentially new infrastructure, thereby diverting resources from direct patient care.

Response: These measures will continue to be calculated using administrative data already reported to CMS by hospitals and MA plans. Therefore, we do not agree that hospitals would be required to invest in reporting systems, staff training, or new infrastructure. In addition, we note that MA plans have been using hospital readmission measures and hospitals have been preparing for the addition of MA data to several Hospital IQR Program measures, including the Hybrid Hospital-Wide All-Cause Readmission and Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measures (88 FR 59161 through 59168) and the Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications measure (89 FR 69545 through 69552).

Comment: Many commenters recommended a phased implementation approach with a confidential review period during which hospitals could assess the data's accuracy and understand its impact on performance. Some commenters further requested that CMS release detailed, provider-level data and analyses before final adoption of the new methodology. A few commenters urged a phased rollout which initially integrates MA data in quality reporting programs (such as the Hospital IQR Program) rather than in pay-for-performance programs. A few commenters recommended that CMS establish stakeholder workgroups to harmonize definitions and reporting requirements across Medicare populations.

Response: As discussed previously, several Hospital IQR Program measures have integrated MA data similar to our proposal for the Hospital Readmissions Reduction Program measure set. We are also finalizing the integration of MA data for the Hospital-level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty measure in the Hospital IQR and Hospital VBP programs, as discussed in section X.C.3.b and VI.L.2.a., respectively, of the preamble of this final rule. We note that restricting the measure cohort to only include index admissions for patients covered by Medicare FFS does not incentivize hospitals to improve care-coordination for Medicare beneficiaries enrolled in MA plans. Expanding the measure cohort to include index admissions for this patient population will enable us to address this, and encourage high-quality, safe care for all Medicare beneficiaries regardless of

[185] Medicare monthly enrollment data available at: *https://data.coms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports//medicare-monthly-enrollment.*

[186] CMS internal analysis. February 2025.

[187] 2024 Condition- and Procedure-Specific Readmission Measures Supplemental Methodology Report (available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*).

payer. Therefore, we believe it is appropriate to include these index admissions in the measure cohort as early as technically feasible. We will continue to monitor and evaluate the effects of including these data in the cohorts for the Hospital Readmissions Reduction Program measures. We welcome continued input on harmonizing definitions and reporting requirements to ensure that our quality programs serve the largest number of patients possible.

Comment: A few commenters supported CMS's technical update to transition from Hierarchical Condition Categories (HCCs) to International Classification of Diseases (ICD)–10 codes, stating that this would reduce incentives for upcoding and improve comparisons. Another commenter stated that the transition would increase precision and clinical relevance, particularly for high-variability conditions, as well as promote more accurate modeling and benchmarking, potentially allowing for better differentiation between hospitals serving complex and socially vulnerable patient populations.

Response: We thank commenters for their support.

Comment: A commenter expressed concern that removing key clinical risk adjustment covariates from the Excess Readmission Ratio (ERR) calculation would unfairly penalize hospitals that serve complex and vulnerable populations. The commenter recommended retaining the current clinical risk adjustment until Z-codes and comprehensive social risk data are available to avoid unwarranted penalties. A commenter noted that the projected increase in aggregate penalties may signal that the program thresholds are too stringent or not sufficiently adjusted for social risk.

Response: We note that the technical update does not remove risk adjustment for the ERRs, rather the update transitions to the more specific ICD–10–CM codes as opposed to the grouped HCC. This risk adjustment continues to be based on patient-level comorbidities as identified through an analysis of the admission diagnoses and in-hospital comorbidity data as well as clinical data for the 12 months prior to the index admission. The Hospital Readmissions Reduction Program is intended to encourage high-quality, safe care for all Medicare beneficiaries, and beginning in FY 2019, CMS used the peer grouping methodology to evaluate a hospital's performance by assessing hospitals' performance relative to the performance of other hospitals with a similar proportion of stays for beneficiaries who are dually eligible for Medicare and full Medicaid benefits. Our analysis of the estimated impact of adding MA data to the readmission measures, shortening the performance period to two years, the technical updates to the measures, and adding MA data to the aggregate payments for each condition/procedure and all discharges indicated that, while those changes are likely to increase payment reductions, the addition of MA data to the aggregate payments for each condition/procedure and all discharges is the largest driver of payment reduction increases. Refer to section VI.K.3.b.(1) for more detailed information about our analysis.

Comment: Several commenters raised concerns about CMS's technical update to base the risk adjustment model directly on individual ICD–10–CM diagnosis codes instead of on HCC-based variables for the measures in the Hospital Readmissions Reduction Program. Some commenters stated that this is inconsistent with CMS's continued use of HCC models for some payment models. Some commenters expressed concern that the transition to ICD–10–CM diagnosis codes could result in unintended changes in reported outcomes, particularly for smaller, rural, or safety net hospitals. Some commenters urged CMS either to postpone the switch to an ICD–10–based model or to implement a transition period during which both HCC and ICD-10–based risk models are reported to monitor impact. Some commenters requested that CMS conduct clinical validations and implement rigorous testing and consistent application of risk adjustment methodology across all programs to ensure transparency and comparability. A commenter further advised caution and transparency in model development, recommending that CMS clearly document the rationale and process for ICD–10 code selection and grouping.

Response: We note that individual ICD–10 codes are more specific than HCCs. By re-specifying the risk models for each measure with individual ICD–10 codes, we improve the performance of the risk adjustment models for our condition- and procedure-specific measures. We understand that some payment models continue to use HCC models to calculate payments and note that because different programs are focused on achieving different elements of our priorities, it is sometimes appropriate to use different methods of calculating risk. We note that we conduct annual measure re-evaluations to ensure that the risk-standardized complication model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time.[188] Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns.[189] Input is solicited from a workgroup composed of up to 20 clinical and measure experts, inclusive of internal and external consultants and subcontractors. As a part of annual re-evaluations, one of the activities we undertook was reviewing select pre-existing ICD–10 code-based specifications with our workgroup to confirm appropriateness unaffected by the updates, as well as review any potentially clinically relevant codes that ''neighbor'' existing codes used in the measure to identify any warranted specification changes.[190] As a part of our routine monitoring and evaluation, we will watch for any unintended consequences from this updated risk model.

After consideration of the public comments we received, we are finalizing our 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 as proposed.

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

[188] Centers for Medicare & Medicaid Services. 2025 Condition-Specific Readmission Measures Updates and Specifications Reports. Available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

[189] *Ibid.*

[190] *Ibid.*

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 PPS 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 PPS 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 final 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.

While we are not required to solicit comments for technical updates, we received public comment on this proposed update.

Comment: Many commenters supported the technical update to remove COVID–19 exclusions from the Hospital Readmissions Reduction Program measure set as part of the transition from a public health emergency to managing COVID–19 as an endemic risk. A commenter stated that eliminating the exclusion of COVID–19 diagnosed patients from index admissions and readmissions will reflect a more accurate depiction of all Medicare patients, improve data collection, and therefore measure hospitals more accurately and fairly. In addition, a commenter noted that the removal of these exclusions will incentivize hospitals to implement robust infection prevention strategies and ensure that care for all Medicare patients is measured consistently.

Response: We thank commenters for their support.

Comment: Several commenters emphasized the need for careful risk adjustment given the potential long-term clinical effects of COVID–19. Commenters noted that patients with prior COVID–19 exposure may experience persistent complications that could influence post-acute outcomes and readmission rates and recommended that CMS update its risk adjustment models to account for the long-term clinical effects of COVID–19 to avoid penalizing hospitals that care for a higher proportion of post COVID patients. A commenter recommended that CMS continue to closely monitor the data to ensure that the removal of this exclusion accurately reflects hospital performance, and that hospitals are not being penalized due to variation in local disease spread. Another commenter recommended incorporating COVID–19 on the co-condition list for risk adjustment stratification.

Response: We thank commenters for their recommendations. As a part of our routine monitoring and evaluation, we will watch for any unintended consequences from this updated risk model. We note that we conduct annual measure re-evaluations to ensure that the risk-standardized complication model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time.[191]

Comment: A few commenters recommended that CMS provide a phased implementation approach to ensure data integrity and support hospitals in adapting to the COVID–19 exclusion removal. A few commenters recommended that the phased implementation contain one to two reporting cycles of data for internal review, delay public reporting of measures that include COVID–19 as a secondary diagnosis, and exclude these measures from the Hospital Readmissions Reduction Program during the initial reporting periods to avoid financial implications.

Response: We do not believe that delaying technical updates to the measures will help meet the goals the commenters specify—that is, ensuring that accurate and reliable data are scored under the Hospital Readmissions Reduction Program. Rather, including COVID–19 patients provides a broader view of the care that hospitals provide to Medicare beneficiaries. Hospitals will also have the chance to review their measure data during the 30-day review and correction period each year prior to application of payment adjustments and public reporting.

Comment: A commenter did not support the technical update to remove COVID–19 exclusions from the Hospital Readmissions Reduction Program measure set because clinical and operational impacts of COVID–19 continue to affect hospital performance; patients with COVID–19 often present with complex conditions, extended lengths of stay, and increased risk of complications; added cases may lead to skewed performance data, especially for those hospitals that serve a disproportionate share of medically complex or underserved populations; and the health care system is still contending with the long-term effects of COVID–19 on workforce capacity, patient outcomes, and systemic

[191] Centers for Medicare & Medicaid Services. 2025 Condition-Specific Readmission Measures Updates and Specifications Reports. Available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

challenges with access to post-acute care.

Response: We appreciate the commenter's concerns. However, while hospitals and other types of health care facilities may face continuing challenges due to the long-term effects of the COVID–19 pandemic, we do not agree that these challenges represent such a significant threat to health care operations that patients with a principal or secondary COVID–19 diagnosis should be excluded from these measures' cohorts. Based on data from July 2021 to June 2024, internal analyses for the Hospital Readmissions Reduction Program measure set showed a small percentage of patients, ranging in cases from 0.15 percent for THA/TKA and 2.5 percent for PN met the COVID–19 exclusion criteria. Please note that some of these cases could also have been excluded for other reasons besides the COVID–19 exclusion. More importantly, such patients, as with all patients treated by hospitals, should receive the best quality care from their providers, and incorporating them into quality measures represents the best way for us to incentivize high-quality care for all. Rather than unfairly penalizing hospitals, including patients with a principal or secondary diagnosis of COVID–19 will encourage them to provide the best care to a broader patient population.

We appreciate commenters' input on our technical update to remove the COVID–19 exclusion from the readmission measures beginning with the FY 2027 program year.

3. Additional Policies for the Hospital Readmissions Reduction Program

a. Modification of the Applicable Period for the Hospital Readmissions Reduction Program Measures Set

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18286), we proposed 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 in 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, in the FY 2026 IPPS/LTCH PPS proposed rule we proposed to reduce the applicable period from 3 to 2 years (90 FR 18286). 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 proposed 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 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 invited public comment on this proposal.

Comment: Many commenters supported the proposal to reduce the applicable period from three years to two years. Some commenters stated that a shorter window will ensure that hospital performance metrics reflect more current quality improvements and care practices while maintaining acceptable reliability. A few commenters also stated that a two-year applicable period enables hospitals to implement more responsive and sustainable improvements, promoting more effective allocation of resources and ultimately supporting improved health outcomes. Additionally, a few commenters stated that the proposed update to shorten the applicable period, when considered with the inclusion of MA beneficiaries and enhanced risk adjustment based on individual ICD–10 codes, would improve the measures by creating a larger, more representative patient cohort with more recent, accurate, and actionable information.

Response: We thank commenters for their support.

Comment: A few commenters stated that decreasing the applicable period to two years may reduce the reliability of hospital comparisons and increase performance variability. A commenter recommended that CMS monitor the statistical reliability of this change for low-volume hospitals. Another commenter recommended a phased implementation or pilot evaluation of the impact on measurement validity for a 2-year applicable period.

Response: We appreciate commenters' concerns and recommendations. We reiterate that reducing the applicable period to two years will continue to preserve reliability while ensuring that hospital performance metrics reflect more recent quality improvements and care practices. We note that prior to proposing to shorten the applicable period to 2 years, we assessed whether the reliability of the measures could reach a satisfactory level. 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. The measure reliability remains robust despite the change from a 3-year period to a *2*-year period for several key reasons. More low-volume hospitals meet the 25 or more criteria for reporting despite the reduction from 3 to 2 years of data due to the inclusion of MA admissions resulting in nearly doubling of the annual cohort size. The combined effect is a roughly one-third increase in overall hospital volume. Empirical comparisons of the 3-year FFS-only cohort (July 2021–June 2024 FFS data) and the 2-year FFS+MA cohort (CY 2022 and CY 2023) showed that the median hospital volume and number of *hospitals* included for public reporting were similar to or higher in the 2-year FFS+MA cohort, and median reliability scores improved for every measure except THA/TKA (for example, AMI (0.5589 for *2*-year FFS+MA versus 0.4458 for 3-year FFS-only) and HF (0.5832 for 2-year FFS+MA versus 0.4914 for 3-year FFS-only)). Our analysis of THA/TKA procedures under the combined FFS+MA cohort did not demonstrate the anticipated volume increases. This outcome can be attributed to the ongoing migration of these procedures from inpatient to outpatient care settings, reflecting broader trends in healthcare delivery patterns. Given the evolving nature of care delivery for these procedures, we acknowledge uncertainty regarding

future volume trends and care setting distributions. The continued shift toward outpatient settings presents challenges for accurate volume projections and measure implementation. To ensure consistency across our quality measurement framework, the applicable period for TKA/THA measure with a 2-year applicable period ensures consistency and alignment with the program's measure set.

However, we intend to monitor the effects of the applicable period length for hospitals, including for low-volume hospitals, and make any future refinements as needed.

Comment: A commenter did not support the proposal to reduce the applicable period from 3 years to 2 years stating that this change, along with the addition of MA beneficiaries into the Hospital Readmissions Reduction Program measure set and the transition of the risk adjustment model from Hierarchical Condition Categories (HCCs) to individual ICD–10 codes, could increase hospitals' risk of incurring penalties. This commenter expressed concern that these proposals did not include adequate transparency, impact modeling, or data reliability safeguards.

Response: Including MA beneficiaries and enhancing the risk adjustment based on individual ICD–10 codes would generate a broader, more representative patient population with more precise and actionable insights for both the public and providers. Because of the expanded cohort of index admissions, we can obtain the same or better measure precision with a shorter applicable period. We note that we performed impact modeling, as shown in Table VI.K–02. of the proposed rule (90 FR 18287 through 18288) and reprinted below in this final rule. Furthermore, as discussed above in response to concerns in the section that discusses the Modification of the Applicable Period for the Hospital Readmissions Reduction Program Measures Set, all measures displayed better between-hospital variance with the 2-year FFS+MA combined cohort compared to the current measure specifications of 3-year FFS-only cohort, more low-volume hospitals now meet the 25 or more criteria for reporting despite the shorter timeframe, MA inclusion nearly doubles the annual cohort size, resulting in roughly one-third increase in overall hospital volume despite the reduction from 3 to 2 years of data. CMS intends to monitor the effects of this change, particularly for low-volume hospitals, and will make refinements as needed. This represents a significant methodological improvement that maintains statistical reliability while providing more timely quality assessments by incorporating a broader patient population.

After consideration of the public comments we received, we are finalizing our proposal to reduce the applicable period from 3 years to 2 years, as proposed.

b. Identification of 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.[192]

[192] CMS Quality Net. Available at: *https://qualitynet.cms.gov/inpatient/measures/readmission/methodology*.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18286 through 18288), we proposed 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 would 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 resulted from our proposal to include MA beneficiaries in the Hospital Readmissions Reduction Program measure set cohorts.

We noted 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 Estimated Impacts on Aggregate Payments

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18286 through 18288), 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 2-year applicable period, and the proposed updates to the calculations for aggregate payments for each condition/procedure to include MA data. In the proposed rule, we showed the estimated total Medicare savings under the current payment adjustment factor calculations and the proposed payment adjustment factor calculations which would use a 2-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 proposed rule analysis also assessed 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 Table VI.K–02 of the proposed rule (90 FR 18287 through 18288) and reprinted in the table below indicate 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 indicated 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 indicated the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. The fourth and eighth columns in the table estimated 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.

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TABLE VI.K-02: COMPARISON OF PROPOSED UPDATES TO CURRENT METHODOLOGY IN HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

	Current methodology (FY 2025 results: FFS only and 3-year performance period)				Proposed Updates (Adding MA Stays and 2-year performance period)			
Hospital Characteristic	**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
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]								

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]
Safety-net hospitals	544	453	83.27	0.34	556	472	84.89	0.42
Non-safety-net hospitals	2,284	1,889	82.71	0.44	2,312	1,945	84.13	0.47
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.

Note: An error in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18288) resulted in the results for safety-net hospitals and non-safety-net hospitals being inadvertently switched. The data for safety-net and non-safety-net hospitals has been updated in this table.

[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.

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We invited public comment on this proposal.

Comment: A few commenters expressed concerns over the use of hospital submitted information-only claims for MA patients in the MedPAR data to calculate aggregated payments for excess readmissions. These commenters stated that while some hospitals (such as teaching hospitals and safety net hospitals) are required to submit information-only claims for MA inpatient stays, other hospitals may not submit complete information-only claims. These commenters stated that this could introduce bias in the data used to calculate aggregate payments and urged CMS to only use data reported consistently across all hospitals in calculating aggregate payments.

Response: We acknowledge that not all hospitals in the Hospital Readmissions Reduction Program use information-only claims for MA inpatient stays and not all types of hospitals are required to submit complete data on such information-only claims. Further, our analysis on 2023 data showed that approximately 94% of IPPS hospitals submitted information-only claims for MA inpatient stays.[193] Due to this current state, we understand commenters' concern with our proposal to use the information-only claims to calculate aggregate payments for excess readmissions, potentially leading to some types of hospitals being more likely to be subject to increased penalties under the Hospital Readmissions Reduction Program than other hospital types. Due to this concern, we are not finalizing our proposal to include MA data in the calculations of aggregate payments for excess readmissions at this time. We will continue to evaluate the consistency of data reported across hospital types.

Comment: Several commenters expressed concern that CMS has not clearly explained the proposed changes to the calculation of aggregate payments for excess readmissions. These commenters stated that the terminology used in the methodology is unclear and that CMS has not provided sufficient data for hospitals to accurately assess the impact of the proposed changes. A few of these commenters noted that hospitals would need access to MA encounter data to replicate the impact estimates.

Response: We note that we are not finalizing the proposed changes to the calculation of aggregate payments for excess readmissions. However, we did provide sufficient data in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18286 through 18289) to allow hospitals to accurately assess the impact of the proposed changes by providing TABLE VI.K–01 and TABLE VI.K–02, along with relevant resources. In connection with the other program changes we are finalizing in this final rule, we present the newly estimated impacts to payments in TABLE VI.K–03 and TABLE VI.K–04 below along with relevant resources. Please refer to the program's payment reduction methodology on the CMS web page for additional information (*https://qualitynet.cms.gov/inpatient/hrrp/methodology*) and the payment reduction methodology infographic resource document (*https://qualitynet.cms.gov/inpatient/hrrp/resources*). If we revisit this policy in future rulemaking, we will consider ways to clarify our proposal and our intended data sources.

Comment: Several commenters expressed concerns that blending MA and FFS data in DRG calculations may inflate penalty calculations due to differences in patient mix and utilization characteristics rather than hospital performance. Several commenters expressed concern that penalties would be impacted by MA plan coverage determinations rather than the quality of hospital care and recommended basing DRG ratio calculations exclusively on FFS data. Some commenters expressed concern that hospitals serving MA beneficiaries may experience two impacts to payments, one from the MA plans denial of coverage for a readmission and the second from an increased penalty in the Hospital Readmissions Reduction Program. Some commenters expressed concern that inclusion of index admissions for MA beneficiaries in DRG calculations would disproportionately affect hospitals located in regions with high MA adoption rates. A few commenters stated their belief that the inclusion of MA patients in the DRG ratio is inconsistent with the broader design of the program.

Response: We note that MA beneficiaries comprise a growing share of Medicare enrollees and that hospitals are responsible for providing high quality care to all their patients, regardless of payer. Hospitals must work closely with insurers, including MA plans, to ensure high quality care for all their patients. By adding the MA cohort to the Hospital Readmissions Reduction Program measures we would provide a more robust and holistic view of quality of care provided to all Medicare beneficiaries. However, we note that we are not finalizing the proposed changes to the calculation of aggregate payments for excess readmissions.

After consideration of the public comments we received, we are not finalizing our proposal to include MA data in the calculations of aggregate payments for excess readmissions, and instead we will continue to use Medicare FFS claims in the calculations of aggregate payments for excess readmissions and include MA data only in the ERR calculations.

To assess the expected impact on hospital payment adjustments resulting from the changes to the readmission measures and the ''applicable period'' only and excluding the proposed updates to the calculations for aggregate payments, we have updated our estimation of hospitals' payment adjustment factors using the measures updates to include MA data and the 2-year applicable period. Later in this section we show the updated estimated total Medicare savings under the current payment adjustment factor calculations and the newly finalized payment adjustment factor calculations which use a 2-year applicable period and include MA data only in the ERR calculations. Based on our analysis, as shown in TABLE VI.K–03, the updated estimated average change in Medicare savings per hospital from the newly finalized updates is $2,265, with 1,305 hospitals having a greater penalty amount and 1,666 hospitals having the same or lower penalty amount.

[193] CMS internal analysis of CY 2023 IPPS hospital FFS and information-only claims.

TABLE VI.K-03: ESTIMATED TOTAL MEDICARE SAVINGS OF NEWLY FINALIZED ADDITION OF MA COHORT TO HOSPITAL READMISSIONS REDUCTION PROGRAM MEASURE SET

	Current methodology (FY 2025)	Newly Finalized updates	Difference between newly finalized updates and current methodology (FY 2025)	Percentage difference between newly finalized updates and current methodology (FY 2025)
Estimated total Medicare savings	$316,131,336	$322,109,431	$5,978,095	2%
Number of penalized hospitals	2,342	2,410	68	3%

As shown in TABLE VI.K–04, our analysis also assesses the impact of the newly finalized 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 indicate 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 indicate 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 indicate 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 (FY 2025), the penalty as a share of payments for urban hospitals is 0.42 percent, and with the newly finalized updates, the penalty as a share of payments for urban hospitals is 0.41 percent. This means that total penalties for all urban hospitals is 0.42 percent of total payments for urban hospitals under the current methodology (FY 2025) and 0.41 percent with the finalized 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.

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TABLE VI.K-04: COMPARISON OF NEWLY FINALIZED UPDATES TO CURRENT METHODOLOGY (FY 2025) IN HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

	Current methodology (FY 2025 results: FFS only and 3-year performance period)				Newly Finalized Updates (Adding MA Stays to ERRs only and 2-year performance period)			
Hospital Characteristic	**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	2,410	84.03	0.42
By Geographic Location								
Urban hospitals	2,164	1,836	84.84	0.42	2,201	1,896	86.14	0.41
1-99 beds	505	336	66.53	0.39	518	353	68.15	0.43
100-199 beds	624	549	87.98	0.48	637	571	89.64	0.48
200-299 beds	397	368	92.70	0.48	406	374	92.12	0.51
300-399 beds	268	250	93.28	0.43	269	247	91.82	0.42
400-499 beds	123	112	91.06	0.46	123	121	98.37	0.42
500 or more beds	247	221	89.47	0.34	248	230	92.74	0.33
Rural hospitals	664	506	76.20	0.41	667	514	77.06	0.42
1-49 beds	312	203	65.06	0.31	315	213	67.62	0.32
50-99 beds	186	151	81.18	0.46	186	150	80.65	0.45
100-149 beds	92	82	89.13	0.39	92	83	90.22	0.44
150-199 beds	44	41	93.18	0.43	44	40	90.91	0.55
200 or more beds	30	29	96.67	0.40	30	28	93.33	0.32
By Teaching Status [e]								
Non-teaching	1,634	1,280	78.34	0.45	1,651	1,305	79.04	0.46
Fewer than 100 residents	910	806	88.57	0.44	932	833	89.38	0.43
100 or more residents	284	256	90.14	0.36	285	272	95.44	0.35
By Ownership Type								
Government	403	313	77.67	0.29	408	340	83.33	0.27
Proprietary	636	519	81.60	0.55	637	511	80.22	0.57
Voluntary	1,789	1,510	84.40	0.41	1,822	1,558	85.51	0.41
By Safety-net Status [f]								

	Current methodology (FY 2025 results: FFS only and 3-year performance period)				Newly Finalized Updates (Adding MA Stays to ERRs only and 2-year performance period)			
Hospital Characteristic	**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]**
Safety-net hospitals	544	453	83.27	0.34	556	470	84.53	0.35
Non-safety-net hospitals	2,284	1,889	82.71	0.44	2,312	1,940	83.91	0.43
By Disproportionate Share Hospital (DSH) Patient Percentage [g]								
0-24	1,058	828	78.26	0.48	1,079	879	81.46	0.49
25-49	1,469	1,273	86.66	0.39	1,478	1,274	86.20	0.38
50-64	177	147	83.05	0.36	181	149	82.32	0.40
65 and over	124	94	75.81	0.43	130	108	83.08	0.42
By Medicare Cost Report (MCR) Percentage [h]								
0-24	1,183	995	84.11	0.33	1,224	1,035	84.56	0.34
25-49	1,572	1,296	82.44	0.48	1,569	1,324	84.38	0.47
50-64	62	43	69.35	0.75	61	39	63.93	0.70
65 and over	10	7	70.00	0.29	11	9	81.82	1.18
By Region								
New England	122	106	86.89	0.64	123	115	93.50	0.55
Middle Atlantic	313	287	91.69	0.46	318	293	92.14	0.50
East North Central	444	379	85.36	0.43	446	386	86.55	0.45
West North Central	228	172	75.44	0.23	227	184	81.06	0.34
South Atlantic	483	421	87.16	0.46	489	439	89.78	0.43
East South Central	253	210	83.00	0.47	257	221	85.99	0.39
West South Central	425	342	80.47	0.39	425	314	73.88	0.35
Mountain	211	151	71.56	0.31	212	150	70.75	0.28
Pacific	349	274	78.51	0.34	371	308	83.02	0.36

Source: Newly Finalized 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; FFS DRG ratios and dual proportions from July 1, 2021, through June 30, 2023. The Current Methodology (FY 2025) 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.

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c. Updates and Codification of 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.[194] 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.[195] 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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18289), we proposed 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) Updates and Codification of the Extraordinary Circumstances Exception (ECE) Policy for the Hospital Readmissions Reduction Program

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18289), we proposed 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 § 412.154(d)(1), we proposed 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 proposed 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.[196] At § 412.154(d)(2)(i), we proposed that a hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred. Under this finalized 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 § 412.154(d)(2)(ii), we proposed 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 proposed 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 ECE policy will 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 final rule for similar updates to the ECE policy in the Hospital IQR Program, Hospital VBP Program, HAC Reduction Program, and PCHQR Program, respectively.

We invited public comment on our proposals.

We received many general comments regarding our ECE related proposals. We did not receive any comments specific to these updates for the Hospital Readmissions Reduction Program. For our responses to general comments we refer readers to our responses in the Hospital IQR Program section of this final rule (section X.C.8). As stated in section X.C.8 of this final rule in response to commenter concerns regarding the proposed 30-day deadline, we recognize that hospitals may not have the ability to assess the impact on quality data submissions and complete the necessary paperwork within 30 days of the extraordinary circumstance. Due to concerns regarding hospitals' ability to complete the ECE request within 30 days of the extraordinary circumstance and a commenter suggestion to increase to a 60-day deadline, we are modifying the timeframe to allow for 60 days to submit an ECE request. We believe this timeframe will provide sufficient time for hospitals to assess the impact on quality reporting without disrupting operational and care needs.

After consideration of the public comments we received, we are finalizing our proposals as proposed, except for the proposed 30-day deadline. In lieu of the 30-day deadline, we are finalizing an ECE request deadline of 60 days following an extraordinary circumstance. We are making conforming amendments to our regulation text at § 412.154(d)(2)(i) to reflect this policy change.

[194] 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.*

[195] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hrrp/participation#tab2.*

[196] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hrrp/participation#tab2.*

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 estimated in the proposed rule (90 FR 18289) 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 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 final 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 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 March 2025 update to the FY 2024 MedPAR file. The slope of the linear exchange function used to calculate these proxy factors was 4.5252441909, and the estimated amount available for value-based incentive payments to hospitals for FY 2026 remains approximately $1.7 billion. We stated our intent 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 and the finalized FY 2026 Hospital VBP program methodology as discussed in section VI.L.6. of the preamble of this final rule. 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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18290 through 18291), we proposed 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 proposed 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 final 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 proposed 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 modifications we previously adopted, as well as the additional modifications we proposed in the FY 2026 IPPS/LTCH PPS proposed rule.

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 was proposed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18290 through 18291).

(2) Overview of Measure Updates

The proposed substantive updates to the COMP–HIP–KNEE measure would (1) expand the measure's inclusion criteria to 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 percent 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 final 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.[197] [198] [199] We refer readers to section X.C. of the preamble of this final 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.[200] 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 on this measure on February 10, 2025, but did not reach consensus because only 73 percent of the committee voted to endorse or endorse with conditions, below the 75 percent required by the CBE to reach consensus.[201] As a result, the measure was not re-endorsed by the CBE. The E&M Cost and Efficiency 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.

The measure developer then submitted an appeal of the decision not to re-endorse the measure, citing the following rationales: (1) procedural error in the endorsement process with an excessive focus on outpatient setting exclusions; and (2) misapplication of measure evaluation criteria, particularly risk adjustment. The CBE convened the E&M Fall 2024 Appeals Committee meeting on March 31, 2025. The Appeals Committee voted to grant the appeal request, with a vote of 100 percent for both rationales, and overturn the decision not to re-endorse the measure. Thus, the COMP–HIP–KNEE measure was endorsed with the following conditions: (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 impact of case 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 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.

[197] 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*.

[198] Centers for Medicare and Medicaid Services. (2024) 2024 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/2024-MUC-List.xlsx*.

[199] 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.

[200] 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*.

[201] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Cycle Endorsement and

Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at: *https://p4qm.org/sites/default/files/Cost%2C%20Resource%20Use%2C%20and%20Efficiency/material/EM-Fall-2024-Cost-and-Efficiency-Final-Project-Report.pdf*.

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. Based on our evaluation of the endorsement criteria, the conditions for endorsement have been met.

(4) Data Source, Submission and Public Reporting

To continue to assess clinical outcomes, we proposed 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 final rule. We stated that, 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.[202] We also proposed 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 invited public comment on this proposal. Below, we summarize the public comments that we received and our responses.

Comment: Many commenters supported CMS's plans to include MA patients in the COMP–HIP–KNEE measure contingent on adoption of this update in the Hospital IQR Program. The commenters noted that this cohort change will more fully capture care quality in the Medicare Program and more accurately reflect the care quality provided in hospitals with high proportions of MA patients.

Response: We thank the commenters for their support.

Comment: Some commenters cautioned that CMS should ensure MA encounter data provides enough information to assess quality performance.

Response: We have studied the feasibility of incorporating MA encounter data and concluded MA data are feasible for use in CMS's claims-based hospital outcome measures. We refer readers to published methodology of incorporating MA inpatient data [203] for more information. We will continue monitoring MA encounter data as we incorporate it into the measure's cohort.

Comment: A commenter supported CMS's proposal to update quality measure populations to include MA beneficiaries, though the commenter also expressed concern that the new population has the potential to shift performance distributions meaningfully if not accounted for in risk adjustment. The commenter stated that some areas of the country have lower MA penetration and benchmarks, which may impact those hospitals disproportionately. The commenter recommended CMS continue with the proposal and communicate benchmark adjustments transparently, while also ensuring the risk model fully reflects the population's characteristics.

Response: We thank the commenter for their support. We note that the risk adjustment model has been updated to account for case mix in both fee-for-service (FFS) and MA. The clinical variables included in the risk adjustment model were selected based on analyses using a combined FFS and MA cohort, approximately evenly split between FFS and MA beneficiaries. This approach ensures the model captures the key risk factors relevant to the combined population. The model includes an indicator variable for FFS versus MA enrollment status, which accounts for any potential differences in readmission risk between these groups. We found that the prevalence of clinical risk factors and their associations with readmission outcomes were similar across FFS and MA beneficiaries. Stratifying the model by FFS and MA did not yield meaningful improvements in performance, supporting the decision to model them together with an indicator variable. Finally, keeping FFS and MA patients together for purposes of this measure's calculation will keep the hospitals' total volume higher for more precise measure scores.

We proposed for these changes to take effect beginning with the FY 2033 Hospital VBP Program year to provide time and data to monitor for any unintended consequences. We intend to provide hospitals with measure performance data with the expanded measure's patient cohort based on data collected while the 'Modification 2' version of the measure is in use in the Hospital IQR Program via annual confidential hospital-specific reports beginning with the FY 2027 program year, as well as via annual Provider Participation Summary Reports under the Hospital VBP Program beginning with the FY 2033 program year. In addition, Hospital VBP Program performance standards for this measure will be published at least 60 days prior to the beginning of each applicable performance period as required by section 1886(o)(3)(C) of the Act.

Comment: Several commenters supported improved measure reliability and accuracy by adding MA patients to the measure calculations, though urged caution given their questions about data collection. The commenters urged CMS to monitor MA data and its impact on quality measures carefully. A commenter expressed concern about data completeness due to the increased likelihood of MA patients having incomplete or missing Medicare Beneficiary Identifiers (MBIs) at the time of submission, which can lead to challenges in claims documentation. While supportive of adding MA data, the commenter stated hospitals could be penalized due to factors outside their control in high-penetration markets for MA beneficiaries.

Response: As stated above, we have studied the feasibility of incorporating MA encounter data and concluded that MA data are feasible for use in CMS's claims-based hospital outcome measures.[204] We intend to monitor the effects of the updated patient cohort for this measure carefully, including the impact of using MBIs, and will provide as much information as possible to participating hospitals. We would also like to clarify that the MA encounter data and FFS claims used in the measure are submitted by Medicare Advantage Organizations and providers, respectively, and already include MBIs. These data are processed and validated through CMS systems prior to being made available for use in quality measurement. Hospitals are not required to submit any additional data or ensure MBI completeness beyond their usual billing practices. As such, the inclusion of MA data does not introduce a new

[202] We noted 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.

[203] *See* Kyanko et. al. ''Processing and validation of inpatient Medicare Advantage data for use in hospital outcome measures.'' *Health Services Research,* vol. 59, issue 6. Available at: *https://doi.org/10.1111/1475-6773.14350.*

[204] *See* Kyanko et. al. ''Processing and validation of inpatient Medicare Advantage data for use in hospital outcome measures.'' *Health Services Research,* vol. 59, issue 6. Available at: *https://doi.org/10.1111/1475-6773.14350.*

responsibility for hospitals with respect to MBI submission. The modifications are intended to increase reliability and more accurately reflect the quality of care for both FFS and MA beneficiaries, thus providing hospitals more accurate data. We will continue working with hospitals to ensure that they fully understand any effects this change may have on their performance assessment under the Hospital VBP Program.

Comment: A commenter supported the addition of MA beneficiaries to this measure, noting the measure is episode-specific and reflects all of the major complications that can arise following elective THA/TKA procedures. The commenter recommended CMS consider reporting the inverse complication rate in the future, or the rate without major complications, to support the public's understanding of the measure's results, along with volume of associated procedures and patient risk profiles.

Response: We thank the commenter for this feedback and will consider it as we continue refining our public reporting policies in the future.

Comment: Several commenters requested that CMS conduct a dry run with scoring reports or a phased-in approach showing how the change would affect hospitals' performance before finalizing the update. The commenters requested that CMS provide a clearer understanding of data collections, assess the associated burden, and analyze potential shifts in performance. A few commenters opposing the proposed measure changes suggested, if we choose to move forward, CMS adopt a phased implementation approach focused on the Hospital IQR Program first, including a multi-cycle impact analysis, and postpone public reporting and payment adjustments.

Response: We thank the commenters for this feedback. We would like to clarify that the inclusion of MA data does not require any additional data collection or submission from hospitals beyond what is already reported for administrative and billing purposes. Specifically, the MA encounter data used for this measure are submitted by Medicare Advantage Organizations (MAOs) to CMS. Hospitals that receive disproportionate-share hospital or medical education payments from Medicare are required to submit information-only claims for inpatient stays of MA beneficiaries for years already. Similarly, FFS claims are submitted through existing hospital billing processes. As such, the proposed modifications do not impose additional data submission burden on hospitals.

We have also conducted testing to evaluate the effects of including MA data on the measure cohort and the results are detailed in the 2024 Readmission Measures Supplemental Methodology Report. This analysis found that, overall, more than 80% of hospitals remained in the same performance quintile or shifted by no more than one quintile after the addition of MA data. These findings suggest that the inclusion of MA data results in minimal disruption to hospital performance classification while offering a more comprehensive view of quality for hospitals serving both FFS and MA beneficiaries.

As proposed, we are finalizing these changes to take effect beginning with the FY 2033 Hospital VBP Program year. Per section 1886(o)(2)(C)(i) of the Act, measures must be specified for use in the Hospital IQR Program and publicly reported for at least one year prior to use in the Hospital VBP Program. This updated measure is being adopted in the Hospital IQR Program beginning with the FY 2027 payment determination, and hospitals will be able to preview their data on this measure in the Hospital IQR Program prior to it being publicly reported. This delay will give hospitals time and data to identify any performance impacts before this updated measure impacts payment under the Hospital VBP Program. We intend to continue to monitor and evaluate the performance of this measure for changes that may be a result of the measure updates, along with any unintended consequences.

Comment: A couple of commenters agreed with the reasoning of the Endorsement & Maintenance Cost and Efficiency Committee for not reaching initial consensus on endorsement of the updated measure and expressed concern endorsement was ultimately granted in the appeal process, and recommended CMS reconsider the measure in the Hospital VBP Program.

Response: On February 10, 2025,[205] the Endorsement & Maintenance Cost and Efficiency Committee voted, and did not reach consensus on this measure, resulting in the measure not being re-endorsed. The decision was appealed and the Appeals Committee unanimously voted to grant the appeal, overturning the initial endorsement decision and endorsing the measure 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.

Comment: A commenter, who generally supported CMS's plans to include MA beneficiaries in the measure's cohort, urged CMS to reconsider the utility of the measure in the Hospital VBP Program given complications may result from a variety of factors outside the hospital's control.

Response: We thank the commenter for their feedback and support. We continue to consider clinical outcomes for this measure a priority, including clinical outcomes for Medicare patients in MA, as the measure provides important patient safety and adverse events data to providers and patients. Empirically, fee for service and MA patients each represent approximately half of the cohort for this measure. The two groups have similar outcome rates, similar risk variable prevalence, and, with the addition of the MA indicator for risk adjustment, model performance and calibration was good in the combined cohort. Using the modified measure not only in the Hospital IQR Program, but also the Hospital VBP Program under which a portion of payments to hospitals is tied to measure performance, serves as an important incentive for quality improvement.

Comment: A commenter expressed concerns with the use of mortality measures and the COMP–HIP–KNEE measure for low reliability results. The commenter suggested that none of those measures reached what the commenter described as the minimum acceptable threshold of 0.7 for reliability.

Response: We thank the commenter for their feedback. The measure developer conducted rigorous testing and concluded that the addition of MA patients into the measure's cohort, in conjunction with the performance period changes, resulted in 75 percent of hospitals exceeding a 0.6 reliability score. Based on measures in the program, a 0.7 reliability score does not represent the minimum threshold for a measure's reliability in the Hospital VBP Program, and we note further that the CBE describes 0.6 as the accepted threshold for reliability when evaluating quality measures.[206] This result demonstrates the proposed measure

[205] Battelle—Partnership for Quality Measurement. (2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at: *https://p4qm.org/articles/now-available-final-fall-2024-e-m-reports.*

[206] Table 4, *Endorsement and Maintenance (E&M) Guidebook,* June 2025. Partnership for Quality Measurement. Available at: *https://www.p4qm.org/e-m-guidebook/e-m/e-m-guidebook-version-3-0.*

updates balance a focus on more recent data with a sufficiently reliable measure calculation that accurately reflects the quality of care provided by hospitals.

Comment: Some commenters opposed inclusion of MA data in quality measure cohorts until hospitals can validate and become comfortable with the data. While the commenters acknowledged MA enrollment is now over 50 percent of Medicare beneficiaries, the commenters stated that MA encounter data is less accessible and sometimes less accurate than FFS claims data. The commenters also noted that MA plans often use their own utilization management tools like lengthy authorization processes that can alter care patterns and recommended that CMS implement a transition period before fully including MA data in measurement. Other commenters requested that CMS allow time for hospitals to review MA performance data to understand how their performance cohorts have changed, stating that hospitals need time to determine MA patient data will not skew their performance assessments due to issues beyond the hospital's control. The commenters requested CMS delay implementation until CMS can provide more information for hospital's review and understanding or reconsider the proposal entirely.

Response: The Hospital VBP Program intends to drive quality improvement for the entire Medicare population and by extension, to all patients served by hospitals. As MA enrollment grows, it becomes necessary to expand the cohort population to more accurately reflect the quality of care for all beneficiaries. As stated earlier, we conducted testing to evaluate the effects of including MA data on the measure cohort and found more than 80% of hospitals remained in the same performance quintile or shifted by no more than one quintile after the addition of MA data. These findings suggest that the inclusion of MA data results in minimal disruption to hospital performance classification while offering a more comprehensive view of quality for hospitals serving both FFS and MA beneficiaries.

CMS is finalizing changes to the COMP–HIP–KNEE measure's cohort to take effect with the FY 2033 Hospital VBP Program year, following their implementation in the Hospital IQR Program beginning with the FY 2027 payment determination. This effective date will provide hospitals with sufficient time to understand if and how the new patient cohort will affect their performance assessment under the Hospital VBP Program.

Comment: Several commenters cautioned CMS about incorporating MA outcomes in FFS quality programs, arguing this policy could lead to duplicative penalties on hospitals. The commenters explained MA plans have their own value-based programs and MA patients often experience different post-acute care options due to MA plan structures. A commenter encouraged us to analyze performance variations between MA and FFS beneficiaries and provide annual confidential feedback reports to hospitals on any differences. Another commenter suggested that CMS work to develop improved measures of key outcomes rather than using MA data and requested that it not publicly report current measures by insurance type as such reporting contradicts the stated purpose of combining the populations.

Response: We thank the commenters for sharing their concerns and we intend to monitor the potential for differences between the MA and FFS populations' on this measure. While we understand MA plans have their own quality program, we remain concerned that omitting MA patients from the measure provides an incomplete picture of the care quality provided to Medicare beneficiaries by participating hospitals. As we stated in the proposed rule (90 FR 18290), the addition of MA data in the measure would approximately double the cohort size, and we have concluded that including these patients in the measure provides CMS, providers, patients, caregivers, and others a broader view of care quality. We appreciate the commenter's concern about public reporting and will take it into account as we refine our public reporting policies in the future.

Comment: Some commenters requested CMS release data on the modified THA/TKA measure and how performance changes with the addition of MA patients. The commenters were concerned that MA benefit design means hospitals will have less control over their MA patients' care, especially due to prior authorization requirements. A commenter recommended that CMS tie outcomes to fee-for-service patient performance within the hospital's control. The commenter explained that MA enrollees accept different benefit design than FFS patients and expressed concern that hospitals cannot control MA plans' requirements like prior authorization. The commenters also asked CMS to confirm that it does not intend to use MA payment information to assess hospitals under the Hospital VBP Program and suggested that CMS limit the expanded patient cohort for this measure to the Hospital IQR Program.

Response: We intend to provide annual confidential feedback reports to hospitals on their measured performance that they can use to assess the effects of the cohort change on their measure rates. We acknowledge commenters concerns regarding benefit design differences between MA plans and traditional Medicare, however, adding MA beneficiaries into the cohorts of the Hospital VBP Program measure set will provide a more robust and holistic view of quality of care provided to all Medicare beneficiaries despite these differences. For measure calculation, we identify index and subsequent admissions for patients enrolled in MA plans using MA encounter data and information-only claims for MA inpatient stays. We note, neither of these data sources are dependent on the MA plan's coverage determinations (including bundling or denying coverage) for that admission. Therefore, the measures would continue to encourage hospitals to focus on preventing readmissions, which are often an adverse event for patients and impose a financial burden on the patient and the healthcare system. Because an increasing portion of Medicare beneficiaries are covered by MA plans, including index admissions for these patients in our measure cohorts is an important step in ensuring high-quality, safe care for all Medicare beneficiaries. Including index admissions for Medicare beneficiaries enrolled in MA also increases the cohort size for the Hospital VBP Program measures, which in turn improves the measures' precision for each hospital.

CMS continues to encourage hospitals to work closely with insurers, including MA plans, to coordinate the highest quality care for their patients. We further note that this measure will not incorporate MA payment information into hospitals' assessments.

Comment: Several commenters supported our proposal to shorten the performance period of the COMP–HIP–KNEE measure. Commenters stated the change will more accurately reflect current care and simplify public reporting, thus providing hospitals and patients with more recent data. With this change, the hospitals will see results more quickly from their quality improvement efforts and avoid being scored on older information.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing the updates to the COMP–HIP–KNEE measure's cohort and performance period as proposed

beginning with the FY 2033 payment determination.

b. Technical Updates to the Specifications of the COMP–HIP–KNEE Measure To Update the Risk Adjustment Model Beginning With the FY 2033 Program Year [207]

In addition to the updates discussed previously and further updates we discuss below, we provided notice in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18291 through 18292) 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 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.[208] However, research has indicated that using individual ICD codes in place of HCCs could significantly improve the model performance of the mortality measures.[209] 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.

We received several comments on this technical update.

Comment: Many commenters supported our technical updates, noting that using ICD–10 codes rather than HCCs will allow more granular and individualized risk stratification. Some commenters stated that the increased granularity of ICD–10 coding better captures patients' clinical complexities, which results in fairer and more accurate evaluations of hospitals' performance.

Response: We thank the commenters for their support.

Comment: A commenter also suggested that CMS consider an active diagnosis of COVID–19 as a risk variable where appropriate.

Response: As we discuss in the following subsection of this final rule, we are removing the exclusion of patients with a principal or secondary diagnosis of COVID–19 in the measure denominators. We have concluded a risk variable is not appropriate because the broader patient cohort captured by the updated measures provides a more complete picture of the care quality provided in hospitals, which meets the goals of the Hospital VBP Program.

Comment: A commenter requested additional transparency when CMS develops new models, including clinical validation and extensive testing before public reporting.

Response: We intend to be transparent in developing models by providing feedback to participating hospitals and will continue providing feedback reports detailing hospitals' performance in the Hospital VBP Program so they fully understand how risk adjustment models affect their measured performance.

Comment: Some commenters expressed concern about CMS's plan to change the risk adjustment model from HCC to ICD–10. Concerns included misalignment of risk adjustment methods across programs and models and potential for unintended consequences. A commenter cautioned this was not a minor technical refinement and instead represented a foundational departure from the methods used in many CMS programs, including the TEAM model, deserving a phased approach to avoid operational risk and threats to data continuity and integrity.

Response: We do not agree that this risk adjustment change represents a foundational departure from prior CMS methods. As we discussed in the proposed rule (90 FR 18292), in depth data analysis conducted by the measure developer has indicated that using individual ICD codes in place of HCCs could significantly improve the model performance of mortality measures. Further, as discussed in the 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report, the new variable selection approach using ICD–10 codes in place of condition categories significantly improved the discriminative performance of the risk adjustment models, as measured by c-statistics, for stroke mortality while performance remained the same for THA/TKA complications.[210] Better risk adjustment models help quality measures more accurately reflect the quality of care provided to Medicare beneficiaries, allowing CMS to better leverage data and analytical advances since the measure was initially developed and hospitals and patients to receive more accurate quality data. We intend to keep participating hospitals informed about the effects of this policy change through our customary hospital-specific reports.

Comment: Some commenters expressed specific concern about the burden imposed on hospitals by the change in risk adjustment model.

Response: We note that hospitals are already submitting these data points through claims and there is no additional burden associated with this change to risk adjustment model. The change will only affect how CMS calculates measured performance.

We thank the commenters for their feedback on this technical update. We will implement the technical updates as notified in the proposed rule.

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-

[207] In the proposed rule, the section header was erroneously shown with the FY 2027 Program Year. We corrected this error in a Correction Notice that we published on June 5, 2025 (90 FR 23867).

[208] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[209] 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*.

[210] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report, Stroke/Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA). Available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*

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 final rule for more details on our subregulatory technical updates policy.

Accordingly, we are providing notice in this final 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 diagnosis code of COVID–19 or with a secondary diagnosis code of COVID–19 coded as present on admission on the index admission claim. 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.

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 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*).

We received several public comments on this technical update.

Comment: Many commenters supported the technical update to remove the COVID–19 exclusion from the Hospital VBP Program, a few commenting on the end of the public health emergency (PHE) and minimal impact to data.

Response: We thank the commenters for their support.

Comment: A commenter, supporting the removal of COVID–19 as an exclusion, suggested CMS consider whether an active diagnosis of COVID–19 should be a risk variable where appropriate.

Response: Given the analysis, we have concluded a risk variable is not appropriate because the broader patient cohort captured by the updated measures provides a more complete picture of the care quality provided in hospitals, which meets the goals of the Hospital VBP Program.

Comment: Some commenters recommended CMS adopt a phased implementation approach to ensure data integrity and support hospitals in adapting to the COVID–19 exclusion removal. The commenters requested CMS provide hospitals with reporting cycles of data for internal review, delay public reporting of measures with COVID–19 as a secondary diagnosis, and exclude these measures from value-based purchasing programs during initial reporting periods to avoid financial implications and ensure data accuracy.

Response: We appreciate concerns regarding the removal of the COVID–19 exclusion and its potential impact on hospital measure scores and financial implications. To inform this discussion, we conducted an analysis of the effect of removing the COVID–19 exclusion for the Hybrid Hospital-Wide Readmission (HKC) measure. Between July 2021 and June 2024, only 371 admissions out of 261,616 total index admissions (approximately 0.14%) were excluded due to a COVID–19 diagnosis. This demonstrates that the exclusion applied to a very small proportion of cases and, therefore, the impact of its removal on hospital-level measure scores is expected to be minimal. Given the limited number of affected admissions, we do not anticipate meaningful shifts in performance results due to this change. We will continue to monitor the impact over time, but current data indicate the removal of the exclusion does not warrant a phased implementation or exclusion from value-based purchasing programs. Hospitals will also have the chance to review their measure data during the 30-day preview period prior to public reporting. Additionally, including COVID–19 patients in the measure's cohort provides a broader view of the care quality hospitals provide to Medicare beneficiaries and meets the goals of the Hospital VBP Program.

Comment: A commenter was concerned about the removal of the COVID–19 exclusion, stating the clinical and operational impacts of the COVID–19 PHE continue to affect hospital performance, such as the long-term effects of COVID–19 on workforce capacity, patient outcomes, and systemic challenges, including access to post-acute care, all of which can affect quality outcomes independently of provider performance. The commenter suggested removing this exclusion may unfairly penalize hospitals that continue to admit high-acuity, complex patients. Another commenter suggested updated risk adjustment models account for the long-term clinical effects of COVID–19 to avoid unfairly penalizing hospitals with a higher number of post-COVID patients.

Response: We appreciate the commenters' concerns. Given the end of the federal COVID–19 PHE on May 11, 2023, it is important CMS provide hospitals and beneficiaries with a

complete picture of the care quality provided for all patients. While hospitals and other types of health care facilities may face continuing challenges due to the long-term effects of the COVID–19 PHE, we do not agree these challenges represent such a significant threat to health care operations that patients with a secondary COVID–19 diagnosis should be excluded from these measures' cohorts.

We thank the commenters for their feedback on the technical update to remove the COVID–19 exclusion from the five Condition- and Procedure-Specific Mortality Measures and the COMP–HIP–KNEE Measure Beginning with the FY 2027 Program Year. We will implement the updates as outlined in the proposed rule.

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 did not propose 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.

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TABLE VI.L.-02: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2026 PROGRAM YEAR

Measure Short Name	Domain/Measure Name	CBE #
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 #
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

*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
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
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

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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.

We received one general comment on our performance standards updates.

Comment: A commenter stated their support for the updates to Hospital VBP performance standards for the FY 2027 through FY 2031 program years.

Response: We thank the commenter for their support.

b. Technical Update to the Five National Healthcare Safety Network (NHSN) Healthcare-Associated Infection (HAI) Measures

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18296 through 18297), we provided 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,'' [211] 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.[212] Prior to 2016, calculated SIRs had different standard population years for each infection type and facility type.[213]

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 problem, we intend to use the 2015 baseline data to calculate performance standards as well as to calculate and publicly report measure scores until the FY 2029 program year, as depicted in the table. 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.

[211] ''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.*

[212] 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.*

[213] Centers for Disease Control and Prevention. Paving the Path Forward: 2015 Rebaseline. Available at:

https://www.cdc.gov/nhsn/2015rebaseline/index.html.

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.

We received public comments on the technical update.

Comment: Many commenters supported CMS's notification of the update to the standardized baseline year for the Hospital VBP Program's HAI measures, agreeing 2022 is a reasonable, recent, post-COVID–19 baseline for updated quality measurement. Some commenters acknowledged the importance of updating the baseline year for NHSN measures' risk adjustment. The commenters encouraged CMS to evaluate the potential impacts of CY 2022 data for the commenters' information.

Response: We thank the commenters for their support. Hospitals will receive confidential reports on their measure performance.

We thank the commenters for their feedback on this technical update and we will implement the updates as outlined in the proposed rule.

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 in section VI.L.2.c., 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.[214]

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TABLE VI.L.-11.: NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain		
CAUTI*,**	0.443	0
CLABSI*,**	0.519	0
CDI*,**	0.314	0
MRSA Bacteremia*,**	0.596	0
Colon and Abdominal Hysterectomy SSI*,**	0.73 0.907	0
SEP-1***	0.635714	0.86454
Clinical Outcomes Domain		
MORT-30-AMI♦	0.876418	0.89269
MORT-30-HF♦	0.885285	0.910502
MORT-30-PN♦	0.822345	0.858756
MORT-30-COPD♦	0.913612	0.929537
MORT-30-CABG♦	0.97103	0.980599
COMP-HIP-KNEE*♦	0.019126	0.013911
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 final rule are based on CY 2024 data.

*** We note that the numerical values for the performance standards for the SEP-1 measure in this final rule are based on CY 2024 data.

♦ As discussed in section VI.L.2.a. and b. of the preamble of this final rule, we are providing notice of a technical update for all measures in the Clinical Outcomes Domain. As a result, these performance standards have been calculated with the inclusion of COVID-19 data.

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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

[214] NOTE TO REVIEWERS: Table VI.L.-11 has been updated.

(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 performance standards for the six unchanged dimensions for the FY 2028 program year are set out in Table VI.L.-12.[215]

TABLE VI.L.-12: 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	57.00	77.81	86.65
Communication with Doctors	55.70	77.79	86.52
Responsiveness of Hospital Staff**	X	X	X
Communication about Medicines	37.55	58.47	70.19
Hospital Cleanliness & Quietness	40.30	64.05	78.10
Discharge Information	65.76	86.34	91.63
Care Transition**	X	X	X
Overall Rating of Hospital	35.22	69.45	84.37

*We note that the numerical values for the performance standards for the HCAHPS Survey in this final rule are based on CY 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.[216]

[215] NOTE TO REVIEWERS: Table VI.L.-12 has been updated.

[216] NOTE TO REVIEWERS: Table VI.L.-13 has been updated.

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	0.873295	0.891834
MORT-30-HF	0.87976	0.906894
MORT-30-PN	0.801554	0.842898
MORT-30-COPD	0.905582	0.924775
MORT-30-CABG	0.970801	0.979861
COMP-HIP-KNEE**	0.031509	0.023706
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 final rule, we are providing notice of a technical update 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.

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.[217]

[217] NOTE TO REVIEWERS: Table VI.L.-14 has been updated.

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	0.872557	0.892486
MORT-30-HF	0.87823	0.908997
MORT-30-PN	0.805539	0.849398
MORT-30-COPD	0.902955	0.924203
MORT-30-CABG	0.972039	0.981517
COMP-HIP-KNEE**	0.034757	0.024614
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 final rule, we are providing notice of a technical update 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.

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.[218]

[218] NOTE TO REVIEWERS: Table VI.L.-15 has been updated.

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	0.877505	0.895401
MORT-30-HF	0.882399	0.912122
MORT-30-PN	0.831029	0.870506
MORT-30-COPD	0.90878	0.929579
MORT-30-CABG	0.974896	0.983693
COMP-HIP-KNEE**	0.036571	0.025288
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 final 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. Update to 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.[219]

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 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 proposed 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) Update to the Extraordinary Circumstances Exception (ECE) Policy for the Hospital VBP Program

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18300 through 18301), we proposed 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 proposed 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 proposed 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.[220] At proposed § 412.165(c)(2)(i), we proposed 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 clarified 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 proposed that CMS notify the requestor with a decision in writing. In the event that CMS grants an ECE to the hospital, the written decision would specify whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an

[219] *https://qualitynet.cms.gov/inpatient/hvbp/participation#tab6.*

[220] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

extension of time to comply with one or more reporting requirements.

Additionally, at § 412.165(c)(3), we noted 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 ECE policy would provide further reporting flexibility for hospitals and clarify the ECE process.

We invited public comment on our proposals. We received many general comments regarding our ECE-related proposals. However, we did not receive any comments specific to these updates for the Hospital VBP Program. For our responses to general comments, we refer readers to our responses in the Hospital IQR section of this final rule (section X.C).

After consideration of the public comments, we will finalize our ECE proposals as proposed, except for the proposed 30-day deadline. In lieu of the 30-day deadline and as discussed further in the Hospital IQR section of this final rule (section X.C.), we will finalize an ECE deadline of 60 days following an extraordinary circumstance. We are making conforming amendments to our regulation text (at 412.165(c)(2)(i)) to reflect this policy change.

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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18301), we proposed to remove the HEA because simplifying the Hospital VBP Program's scoring methodology by removing the HEA would 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 the 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 from the Hospital VBP Program for FY 2026 is 0.170 percent and without the HEA, the average net percentage payment adjustment is 0.168 percent. 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 proposed to remove the HEA. We refer readers to ''Supplementary Information'' section of this final 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 would require time to develop and test a new adjustment and, if pursued, would be addressed in future rulemaking.

We did not anticipate any serious reliance interests as a result of this proposal since the HEA does not require any additional reporting burden.

We proposed 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 referred readers to Table I.G.6.-01 (90 FR 18471 through 18472) and Table I.G.6.-02 (90 FR 18473) in Section 6: Effects of Changes Under the FY 2026 Hospital Value-Based Purchasing (VBP) Program in the proposed rule, which reflected 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 invited public comment on these proposals.

Comment: A few commenters supported the proposal to remove the HEA, while noting their continued commitment to providing high-quality care for all, and did not suggest other alternative adjustments.

Response: We thank the commenters for their feedback and support their commitment to providing high-quality care to all patients.

Comment: Several commenters acknowledged the importance of providing additional resources to hospitals serving a high proportion of dually eligible beneficiaries but did not take a strong position on supporting or opposing the proposal to removal HEA. Instead, the commenters suggested CMS explore other mechanisms, such as the beneficiary economic risk adjustment variable proposed for TEAM, noting the importance of transparency and simplicity. One commenter acknowledged the calculation's complexity but suggested that other policies such as the dual-eligible patient index have also created confusion.

Response: We thank the commenters for this feedback. As stated in the proposed rule (90 FR 18301), it would require time to develop and test an alternative, simplified structure for the HEA's bonus methodology. If we decide to propose a different adjustment in the future, we would review adjustments adopted in other CMS quality programs to enhance cross-program alignment whenever feasible and effective and then propose the adjustment in future rulemaking.

Comment: Most commenters strongly opposed the proposal to eliminate the HEA, noting the HEA shifted much-needed financial support towards hospitals operating on thin margins and serving high-risk, complex communities. Some commenters recommended CMS delay the HEA's removal until a robust, data-driven alternative is in place, and suggested CMS convene stakeholder panels to develop the new adjustment.

Response: As we discussed in the proposed rule (90 FR 18301), the effect of the HEA on the average net percentage payment adjustment provided by the Hospital VBP Program is small. We proposed to remove the adjustment beginning with the FY 2026 program year. This timing avoids burden by removing it before it was implemented for the first time. If we were to delay removal, burden would be incurred in the years the adjustment

was in effect. As described above, if we decide to propose a different payment adjustment in the future, we would review other programs' adjustments as well as stakeholder input and propose in future rulemaking.

Comment: Many commenters opposed the proposal to remove the HEA, stating HEA helps hospitals that face challenges providing care to the patients in their communities. The commenters also suggested that CMS has not had sufficient time to evaluate the adjustment's impact on health outcomes and expressed worry that the removal may have unintended consequences for health outcomes. A commenter recommended that CMS continue the HEA for at least five years to fully evaluate the impact of the adjustment on health outcomes. Other commenters worried that the adjustment's removal would have a disproportionate effect on safety net hospitals that often care for dually eligible beneficiaries and hospitals in rural areas, both of which frequently operate under financial strain because they provide critical but unprofitable services.

Response: As we explained in the proposed rule, we are addressing the additional complexity provided by the HEA in the Hospital VBP Program. As stated in the proposed rule, simplifying the program's scoring methodology by removing the HEA will enhance providers' understanding of the program's quality incentives and its quality improvement goals, and we do not believe it would be appropriate to wait five years to simplify the program. We will continue monitoring safety net hospitals and rural hospitals as part of our monitoring and evaluation work as we work to maintain access to high-quality care for all Medicare beneficiaries. We remind commenters that, as we discussed above, the effect of the HEA on the average net percentage payment adjustment provided by the Hospital VBP Program is small, and by removing it effective for the FY 2026 Hospital VBP program year before it has taken effect, we will avoid burdening participating hospitals with the adjustment's complexity.

Comment: A commenter stated that removing the HEA would return healthcare provision to an era where healthcare systems that provide care for the most medically and socially complex patients are no longer recognized for that additional burden. A few commenters rejected the need to remove HEA as a means of simplifying the scoring methodology, providing clearer incentives to hospitals, or reducing burden, thus opposing HEA removal and disagreeing with the intended goals of its removal. One commenter suggested CMS could resolve that complexity by providing better education to hospitals.

Response: We appreciate the commenters' concerns for hospitals that care for the most medically and socially complex patients. As outlined in the proposal, simplifying the program's scoring methodology by removing the HEA will enhance providers' understanding of the program's quality incentives and its quality improvement goals, and is consistent with the Administration's priority to streamline regulations on those participating in the Medicare program. We intend to continue working to educate participating providers on the mechanics of our quality programs to promote their understanding and their ability to compete for quality incentive payments. We note, however, that the complexity added to the program's scoring methodology by the Health Equity Adjustment makes such educational efforts, particularly for new hospitals, more challenging.

Comment: Some commenters opposed HEA removal and stated that the Hospital VBP Program should consider differences in a provider's patient population, including social risk factors, to counter the challenges faced in achieving good clinical outcomes. The commenters recommended considering an alternative design for the Hospital VBP Program if HEA is removed, with one commenter suggesting a new hospital value incentive program that accounts for social risk factors through a peer grouping approach and another suggesting the alternative design focus on upstream factors related to patients' health.

Response: We thank commenters for their feedback and suggestions on potential Hospital VBP Program methodology adjustments. The program remains a pay-for-performance quality program designed to make the quality of care better for hospital patients and hospital stays a better experience by encouraging hospitals to improve the quality, efficiency, patient experience and safety of care that Medicare beneficiaries receive during acute care inpatient stay. We note further that the program's design is specified by statute and is intended to address the care quality provided by inpatient hospitals. CMS will continue to evaluate the Hospital VBP program and support alignment between the program's goals and methodology.

Comment: Some commenters opposed the proposal to remove HEA, arguing the adjustment helps protect vulnerable and historically underserved populations, including patients with severe mental illness, complex social needs, low socioeconomic status, and dual eligibility status. Multiple commenters noted the adjustment will help underfunded safety net hospitals and hospitals in rural communities drive culture change and serve patients with medical complexities and financial hardships. Other commenters stated that the HEA encourages hospitals to focus on providing high-quality care to vulnerable patients, including maternal and psychiatric patients, and can lead to reduced health care costs in the long run. A commenter stated that hospitals working on care quality issues for vulnerable patients need appropriate infrastructure to be sustainable for all the communities they serve and suggested that eliminating the HEA risks penalizing hospitals that are working to address gaps in health outcomes.

Response: We appreciate the commenters' insights and remarks on safety net hospitals' financial needs, as well as the complexities associated with high-risk patient populations. CMS will continue monitoring the quality of care provided by these hospitals and the effects of the Hospital VBP Program as parts of our monitoring and evaluation efforts. However, as discussed above, we note that the average net percentage payment adjustment provided by the Hospital VBP Program is small. We have concluded that the merits of the additional payment adjustment are outweighed by the complexity it adds to the program's scoring methodology. We expect that all hospitals strive to provide the best possible care to all of their patients and we do not agree that the adjustment's removal will impair those efforts by hospitals, doctors, and other medical staff.

We agree with the commenter that hospitals need appropriate infrastructure to be able to serve all their patient communities. We will continue monitoring the effects of Medicare payment policy on numerous aspects of care quality and delivery, including maternal health and mortality.

Comment: A commenter stated that the Hospital VBP Program represents a step towards a ''total cost of care'' model, and that removing the HEA would harm hospitals that serve higher proportions of dually eligible patients. The commenter estimated that safety-net hospitals will receive an estimated $29 million in additional payment adjustments from the HEA and that as a result, those hospitals and their patients will bear the brunt of the negative impact if the adjustment is removed. The commenter suggested that the HEA was a notable step to

strengthen value-based care reforms and aligns with the Trump Administration's repeated emphasis on a new approach to health care that factors in nutrition and environmental impacts.

Response: The original intention of the adjustment was to develop a methodology to reward top performing hospitals serving higher proportions of patients with dual eligibility status. However, we do not view the incorporation of these additional topics as a new payment model. CMS intends to identify potential avenues for the Hospital VBP Program to address nutrition, environmental impacts, and other potential factors that may affect the provision of high-quality health care in the inpatient hospital setting in the future. We will continue to evaluate the program's methodology for alignment with the program's objectives.

After consideration of the public comments that we received, we are finalizing our proposal to remove the Health Equity Adjustment from the Hospital VBP Program effective with the FY 2026 program year. We are also finalizing our proposal to codify this policy 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 in 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 without the HEA.

M. Hospital-Acquired Condition Reduction Program Updates and Changes (HAC Reduction Program)

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 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

HAC Reduction Program Measures for FY 2026 and Subsequent Years		
Short Name	**Measure Name**	**Consensus-Based Entity (CBE)#**
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 did not propose to add or remove any measures in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18302). We refer readers to section I.G.7. of Appendix A of this final 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,'' [221] but referred to here as

[221] ''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

Continued

''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.[222] Prior to 2016, calculated SIRs had different standard population years for each infection type and facility type.[223]

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.[224] 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 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.[225] 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 final rule, where we provided notice of technical 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 invited public comment on this technical update.

Comment: Many commenters expressed strong support for updating the CDC NHSN HAI measure baseline year from 2015 to 2022 baseline data. Commenters emphasized that utilizing current CDC data not only enhances the accuracy of infection control performance measurement in a post-pandemic context but also aligns benchmarks with modern clinical practices. A commenter recommended that CMS publish comparative data showing the impact of the updated baseline on historical performance, stratified by hospital type and size.

Response: We thank commenters for their support. We agree that utilizing current CDC data enhances the accuracy of infection control performance measurement in a post-pandemic context and aligns benchmarks with modern clinical practices. We appreciate commenters' recommendation to publish comparative data showing the impact of the updated baseline on historical performance, stratified by hospital type and size. We will take this recommendation into consideration to determine the feasibility of providing that data.

Comment: A few commenters expressed support for updating the CDC

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.*

[222] 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.*

[223] Centers for Disease Control and Prevention. Paving the Path Forward: 2015 Rebaseline. Available at: *https://www.cdc.gov/nhsn/2015rebaseline/index.html.*

[224] For more information on the Scoring Calculations Review and Correction Period, see: *https://qualitynet.cms.gov/inpatient/hac/payment#tab2.*

[225] For more information on the Care Compare Preview period, see: *https://qualitynet.cms.gov/inpatient/public-reporting/public-reporting/hospital-compare-preview.*

NHSN HAI measure baseline year from 2015 to 2022 baseline data but recommended postponing implementation of the technical update. A few of these commenters recommended aligning the baseline year for the HAC Reduction Program with that of the Hospital VBP Program, beginning with FY 2029 for both programs, as it would allow for a coordinated approach that would enhance clarity, reduce administrative burden, and ensure more meaningful comparisons across programs using the same underlying measures. Another commenter stated that there were challenges and delays that had been noted by healthcare providers updating to the new baseline due to technical issues with the NHSN reporting system. These issues include frequent changes to module tables, acceptance of incomplete data, and errors during data uploads. Another commenter noted that some of the rebaseline models were not yet published at the time of the proposed rule. These commenters recommended that CMS delay implementation of the 2022 baseline in the HAC Reduction Program to provide time for hospitals to understand their data and align with federal requirements and reimbursement practices without penalty.

Response: We thank commenters for their support. While we understand commenters' recommendation to align with the Hospital VBP Program, we note that the Hospital VBP Program's scoring methodology differs from the HAC Reduction Program in that it uses a one year performance period and that it calculates improvement points using comparisons between data collected from hospitals in a baseline period and data collected in a performance period. At this time, we still 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, CY 2025 and CY 2026, will use the 2022 update to the standard population for the CDC's NHSN measures.

We appreciate commenters' input on the technical updates to the standard population data for the CDC's NHSN HAI measures for the HAC Reduction Program.

3. Codification of 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.[226] 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.[227] 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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18303 and 18304), we proposed 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. Codification of the Extraordinary Circumstances Exception (ECE) Policy for the HAC Reduction Program

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18303 and 18304), we proposed to codify the ECE policy at 42 CFR 412.172(c) and include extensions of time as a form of relief. Specifically, at § 412.172(c)(1), we proposed 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 proposed 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.[228] At § 412.172(c)(2)(i), we proposed 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 § 412.172(c)(2)(ii), we proposed 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

[226] 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.*

[227] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/hac/participation#tab2.*

[228] CMS QualityNet. Available at: *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

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 final rule for similar ECE policy changes in the Hospital IQR Program, Hospital VBP Program, Hospital Readmissions Reduction Program, and PCHQR Program, respectively.

We invited public comment on our proposals.

Comment: Many commenters supported the proposal to formally codify and clarify the ECE policy in the HAC Reduction Program. Commenters stated that this policy will provide hospitals with needed clarity and flexibility when facing events beyond their control that impede timely data submission, is practical, and recognizes the varying needs of different facilities and different circumstances.

Response: We thank commenters for their support.

Comment: Several commenters recommended that CMS explicitly include cyber-attacks as a qualifying event for granting an ECE because cyber-attacks can disable data systems for extended periods. Another commenter recommended that ECE include infectious disease emergencies due to their downstream impacts on health care systems.

Response: We thank commenters for their recommendations. We note that extraordinary circumstances are not limited to the examples provided in the CFR language and proposal. We have received and accepted multiple ECE requests due to cyber-attacks across reporting programs. We recommend that hospitals submit an ECE request anytime an event beyond the control of a hospital affected the ability of the hospital to comply with one or more reporting requirements with respect to a fiscal year regardless of whether it was included in the examples provided in the CFR language and proposal.

Comment: Several commenters, while supporting this proposal, expressed concern that CMS may replace reporting exemptions with extensions, regardless of the circumstances, and recommended that CMS continue to grant complete reporting exemptions in the case of an extraordinary circumstance, and to use extensions when appropriate. Commenters requested that CMS provide additional details on how the determination of an exception versus an extension will be made.

Response: We thank commenters for their recommendation. We will continue to consider ECE applications on a case-by-case basis and offer any exception or extension based on the nature of the extraordinary circumstance and the capacity of the provider, as well as CMS operational feasibility to grant an exception versus an extension. We note our preference to grant an extension when it can be feasibly granted because of the importance of having quality measure data particularly for public reporting purposes, as transparency is a paramount goal of the program.

Comment: A few commenters recommended that CMS produce publicly available guidance for ECE requests to set consistent expectations to ensure that ECE eligibility criteria are applied equitably across all facilities, with particular attention to hospitals serving medically complex, high-risk, or underserved patient populations in order to maintain fairness in the HAC Reduction Program that carries financial penalties for hospitals in the bottom quartile of performance. One commenter requested CMS provide additional clarification on its processes and policies associated with approving ECE requests related to cyberattacks, including publicly posting any supplemental ECE questionnaires that could aid a hospital in an initial ECE application.

Response: We thank commenters for their recommendations. We note that QualityNet provides the ECE Request Form, ECE Information and Resources document, and ECE Quick Reference document, all of which are updated as necessary. We will continue to update these documents to provide updated information, resources, and references.[229]

Comment: Several commenters did not support the reduced timeframe for hospitals to submit an ECE request from 90 days to 30 days. Commenters stated that, following these extraordinary events, hospitals focus on staying operational and continuing to provide care for their patients and communities, and they do not have sufficient bandwidth to assess the impact on quality data submissions and complete the necessary paperwork within 30 days. For example, one commenter cited recent flooding in Virginia and North Carolina, noting that hospitals remained in crisis mode even 30 days after the event, and suggested that a 60-day deadline might be a more realistic compromise. Another commenter cited a significant ransomware attack which adversely affected their Certified Electronic Health Record Technology (CEHRT) applications and multiple data systems across their health system which caused them to request multiple ECEs related to various data reporting requirements during that time. Commenters also recommended that CMS retain the discretion to accept late requests in truly extraordinary circumstances, thereby safeguarding hospitals from unfair penalties for delayed submissions amid disasters.

A few commenters supported the 30-day time period to request an exemption.

Response: We appreciate commenters' responses. After reviewing the concerns raised by commenters regarding the timeframe for making an ECE request, we have further considered what constitutes an appropriate number of days based on commenters' feedback and examples. Nevertheless, we wish to reduce the timeframe for ECE applications across hospital settings for operational improvement while balancing the possible need for additional time by providers depending on the particular extraordinary circumstance. Therefore, we are finalizing a modified policy that states that a hospital may request an ECE within 60 calendar days of the date that the extraordinary circumstance occurred. We believe this timeframe will provide significant time for hospitals to assess the impact on quality reporting without disrupting operational and care needs.

After consideration of the public comments we received, we are finalizing our proposal to codify and update our ECE proposal with modification. After consideration of concerns identified in public comments regarding the proposed 30 calendar day timeframe during which a hospital may request an ECE, and for the reasons described above, we are finalizing a different timeframe in which an ECE can be requested. We will allow up to 60 calendar days for ECE requests after the precipitating event. We amended the

[229] We note that the HACRP ECE QualityNet site is available at: *https://qualitynet.cms.gov/inpatient/hac/participation#tab2,* which links to the Hospital IQR ECE web page, available at: *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3* for reference materials.

proposed CFR text to reflect this extended deadline.

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. Later in this section 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. All finalized cost reports for FY 2020 were available for the FY 2026 IPPS/LTCH final rule at this time.

Last year we published a new solicitation (89 FR 105049, December 26, 2024) 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; 11 additional hospitals were selected to join the demonstration 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 the December 26, 2024 solicitation will run 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. In CY 2025, there are currently 30 hospitals participating in the demonstration. In addition to the ten selected initially, one additional hospital was selected to replace one that voluntarily withdrew from the demonstration; in total, we added 11 new hospitals from the new solicitation.

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 final 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 20 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 final market basket percentage increase for FY 2026, which can be found at section VI.B.1. of the preamble to this final 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 final applicable percentage increase, per section VI.B.1. of the preamble of this final 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 final rule, the resulting amount is $47,586,847 and will be incorporated into the budget neutrality offset adjustment for FY 2026. An offset of $47,527,557 was proposed in the FY 2026 IPPS/LTCH PPS proposed rule, and this has adjusted slightly based on the incorporation of the final FY 2026 market basket percentage increase (0.1 percentage point higher than the proposed rule) and the final FY 2026 applicable percentage increase (0.2 percentage point higher than the proposed rule). 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. We proposed to include final 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 2026 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 FY2026 final rule, all of the FY2020 finalized cost reports are available and will be reconciled in FY2026.

(3) Total Proposed Budget Neutrality Offset Amount for FY 2026

For this FY 2026 IPPS/LTCH PPS final 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 final 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 amount is $47,586,847.

After consideration of the public comments we received, primarily requesting to expand the number of hospitals participating in the program, we are finalizing our policy without modification.

VII. 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 Pub. L. 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. Annual Update for FY 2026

The annual update to the national capital Federal rate, as provided in 42 CFR 412.308(c), for FY 2026 is discussed in section III. of the Addendum to this FY 2026 IPPS/LTCH PPS final rule.

We also note that in section II.D. of the preamble of this final rule, we discuss our 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 of this final rule for additional details on the finalized payment adjustment for these cases.

VIII. Changes for Hospitals Excluded From the IPPS

A. 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 final rule, we proposed to rebase and revise the IPPS operating basket to a 2023 base year. Therefore, as discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18246 through 18247 and 18307 through 18308), we proposed 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 estimated that the proposed 2023-based IPPS operating market basket percentage increase for FY 2026 was 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 would 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 was 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we proposed that if more recent data became 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.

As discussed in section IV of the preamble of this FY 2026 IPPS/LTCH PPS final rule, we finalized the rebasing of the IPPS operating market basket to a 2023 base year without modification. However, more recent data has become available. Based on IGI's second quarter 2025 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2026 is 3.3 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2026 rate-of-increase percentage that we will apply 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 3.3 percent, which is based on IGI's second quarter 2025 forecast.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.3 percent 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)) was the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which was 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 was 3.2 percent, which was based on IGI's fourth quarter 2024 forecast. Furthermore, we proposed that if more recent data became 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.

As discussed in section IV of the preamble of this FY 2026 IPPS/LTCH PPS final rule, we finalized the rebasing of the IPPS operating market basket to a 2023 base year without modification. However, more recent data has become available. Based on IGI's second quarter 2025 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2026 is 3.3 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2026 rate-of-increase percentage that we will apply to the FY 2025 target amounts in order to calculate the FY 2026 target amounts to an extended neoplastic disease care hospital is 3.3 percent, which is based on IGI's second quarter 2025 forecast.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.3 percent update for FY 2026.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, reviewing, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested in order to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2024.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2024. As indicated previously, the adjustments made during FY 2024 only pertain to cost reporting periods ending in years prior to FY 2024. Total adjustment payments made to IPPS-excluded hospitals during FY 2024 are $93,308,651. The table depicts for each class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	11	$216,664,056	$92,248,544
Children's Hospitals	5	$1,254,210	$586,277
RNHCIs	2	$157,569	$149,246
Psychiatric Hospitals	2	$3,165,442	$324,784
Total	**20**	**$221,241,277**	**$93,308,651**

C. 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 final 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.

Comment: Commenters expressed support of the FCHIP demonstration, and conveyed the demonstration ''Intervention Payment and Payment Waivers'' are vital for improving access and care coordination in extremely rural communities, where workforce shortages, travel distances, and infrastructure limitations pose persistent barriers to timely, high-quality care.

Commenters recommended CMS publicly report key findings from the FCHIP evaluation and/or preliminary reports. The commenters expressed these reports would be essential to understanding whether the demonstration has improved access and reduced disparities in the targeted regions. Commenters expressed lessons learned from the demonstration findings could be essential to help inform future innovations in rural health care delivery and to ensure that Medicare payment policy supports sustainable models of care in frontier communities. The commenters expressed the importance of transparency as CMS implements the demonstration project to help build trust and to maintain stable participation among rural stakeholders. Commenters urge CMS, as the demonstration progresses, to clearly communicate the demonstration budget neutrality methodology and analytical approach timeline and describe any potential future budget neutrality payment adjustments associated with FCHIP demonstration and payment waivers.

In addition, the commenters requested CMS to increase the number of hospitals participating in the demonstration. Specifically, commenters explained CMS should explore options for scaling successful components of the FCHIP model more broadly, particularly to other rural areas with similar access challenges.

Response: We appreciate the commenter's support of the demonstration project and the demonstration intervention payment and payment waivers. The authorizing legislation under section 123(h)(2) of Public Law 110–275 requires CMS to submit a final report to the Congress, no later than 1 year after the completion of the demonstration project. In 2020, CMS published a *final report* to Congress and an *evaluation report* covering the initial period of the demonstration. CMS will submit a final report to Congress covering the demonstration extension period of performance no later than 1 year after completion of the extension period. Currently, rural stakeholders may monitor the progress of the demonstration, and any preliminary findings and reports via the FCHIP demonstration *website.*

We acknowledge the commenter's request for CMS to expand the number of hospitals participating in the demonstration. However, we note that section 129(b)(2)(C) of Public Law 116–260, stipulates ''[a]n entity shall only be eligible to participate in the demonstration project under this section during the extension period if the entity participated in the demonstration project under this section during the initial period.'' As such, expanding the number of hospitals participating within the demonstration would require legislative action to increase the number of eligible entities, as defined in section 129(b)(2)(C) of Public Law 116–260. After consideration of the public comments we received, we are continuing our previously stated policy to adopt the same budget neutrality methodology and analytical approach used during the demonstration initial period for the demonstration extension period without modification.

f. Total Budget Neutrality Offset Amount for FY 2026

At this time, for the FY 2026 IPPS/LTCH PPS final 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 did 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. 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 final 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.

We received comments that are outside the scope of the proposed rule. For example, we received comments related to providing additional payments for end-stage renal disease (ESRD) patients in LTCHs, similar to the ESRD add-on payment for IPPS hospitals. Because we did not make any proposals related to additional payments for ESRD patients in LTCHs in the proposed rule, we consider these public comments to be outside the scope of the proposed rule, therefore we are not addressing the comment in this final rule.

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 will be 772 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the changes, as discussed in section II.C. of the preamble of this final 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 final 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. 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 final rule, as we proposed, we updated the MS–LTC–DRG classifications effective October 1, 2025, through September 30, 2026 (FY 2026), consistent with the changes to specific MS–DRG classifications presented in section II.C. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2026 are the same as the MS–DRGs being used under the IPPS for FY 2026. In addition, because the MS–LTC–DRGs for FY 2026 are the same as the MS–DRGs for FY 2026, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 43, as discussed in section II.C. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2026.

3. 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 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 methodology). For FY 2026, we are continuing 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18314 through 18320), we presented our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2026.

Comment: We received several comments requesting that CMS modify certain high-volume MS–LTC–DRGs to better account for the variation in patient severity and costs among the cases grouped to these MS–LTC–DRGs. A few commenters recommended that CMS split certain high-volume MS–LTC–DRGs based on the presence or absence of a CC or a MCC, which is not currently done for these particular MS–LTC–DRGs.

Response: Since these comments were primarily focused on the impact these high-volume MS–LTC–DRGs have on the FY 2026 outlier fixed-loss amount, we have fully summarized and responded to these comments in section V.D.3. of the Addendum to this final rule.

Comment: We received comments urging CMS to adjust the proposed methodologies for determining the FY 2026 LTCH PPS rates to account for the impact of the COVID–19 pandemic on the underlying ratesetting data. A commenter expressed particular concern about the use of FY 2023 cost report data in the determination of the

MS–LTC–DRG relative weights, noting that these data reflect patient acuity and cost trends unlikely to persist in FY 2026.

Response: We thank the commenter for their feedback. As discussed in Step 6 of our methodology, the MS–LTC–DRG relative weights are calculated using the hospital-specific relative weights methodology, which relies on charges from historical Medicare LTCH claims data rather than data from historical cost reports. As discussed in Step 1 of our methodology, we proposed to use charge data from the FY 2024 MedPAR file. Therefore, we do not agree that a modification to our methodology for determining the relative weights is warranted.

After consideration of the comments we received, we are finalizing, without modification, our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2026. In the remainder of this section, we present our finalized methodology. We first list and provide a brief description of our steps for determining the FY 2026 MS–LTC–DRG relative weights. We then, later in this section, discuss in greater detail each step. We note that, as we did in FY 2025, we used 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 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 steps for calculating the FY 2026 MS–LTC–DRG relative weights in greater detail.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

For the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18315), 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 proposed 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. Accordingly, for this final rule, we are establishing the FY 2026 MS–LTC–DRG relative weights based on updated FY 2024 Medicare LTCH claims data from the March 2025 update of the FY 2024 MedPAR file, which is the best available data at the time of development of this final rule, and the finalized Version 43 of the GROUPER to classify LTCH cases.

To calculate the FY 2026 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we 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 proposed to identify FY 2024 cases that meet the statutory patient criteria depending on date of admission as follows. First, we proposed 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 proposed 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 2025 IPPS/LTCH PPS final rule (89 FR 69425).

We did not receive any specific comments on the proposed methodology to identify FY 2024 cases that meet the statutory patient criteria, depending on the date of admission. Therefore, we are finalizing this methodology without modification.

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 final 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 March 2025 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 March 2025 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 steps to calculate the 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 calculation of the 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 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, as we proposed, consistent with our existing relative weight methodology, in determining the FY 2026 MS–LTC–DRG relative weights, we removed 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, as we proposed, we are continuing 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 final rule, based on the best available data (that is, the March 2025 update of the FY 2024 MedPAR file), we identified 242 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 final 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 48 MS–LTC–DRGs (242/5 = 48 with a remainder of 2). As we proposed, we employed 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, as we proposed, we adjusted the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our methodology.

To determine the FY 2026 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we used 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 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 final rule, we are providing the list of the composition of the 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 final 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 calculation of the 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, as we proposed, we are continuing 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 final 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 calculation of the FY 2026 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted 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, as we proposed, we made 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 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 are continuing 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 final rule, as we proposed, we are continuing 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, as we proposed, we calculated the 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 continued 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 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 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 FY 2026 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued 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 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 final 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 March 2025 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 final 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, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of the preamble of this final rule).

Of the 772 MS–LTC–DRGs for FY 2026, we identified 414 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 414 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 final rule, such that we identified 386 MS–LTC–DRGs that for which, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $414 - 11 - 2 - 15 = 386$). As we proposed, we assigned relative weights to each of the 386 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 358 ($772 - 414 = 358$) 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 358 MS–LTC–DRGs to which we cross-walked each of the 386 ''no-volume'' MS–LTC–DRGs.) Then, in general, we assigned the 386 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 March 2025 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 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 final 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 final 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 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 final rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 064 of 1.1687 for FY 2026 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final 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, as we proposed, we used 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, as we proposed, we are establishing 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 establishing 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 establishing 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 establishing 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, as we proposed, we continued to apply budget neutrality adjustments in determining the FY 2026 MS–LTC–DRG relative weights so that our update of the MS–LTC–DRG classifications and relative weights for FY 2026 are made in a budget neutral manner. For FY 2026, as we proposed, we applied 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 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 budget neutrality

factor that accounts for the application of the 10-percent cap policy (step 11).

In this final rule, to ensure budget neutrality for the 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 continued 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 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 normalization factor for FY 2026, we used 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 FY 2026 GROUPER (that is, Version 43 for FY 2026) and the 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 MS–LTC–DRG relative weights for FY 2026, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the normalization factor of 1.24155 (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 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 final rule, for FY 2026, we determined 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 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 FY 2026 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a budget neutrality factor of 1.0142528 (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 final 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, as we proposed, we limited the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the low-volume MS–LTC–DRGs identified in Step 3 or the no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each 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 normalization and 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 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 FY 2026 relative weight equal to the FY 2025 weight $\times$ 0.90).

In section II.C. of the preamble of this final rule, we discuss our 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 did not propose any changes to this policy for FY 2026, and as such any new or renumbered MS–LTC–DRGs for FY 2026 were not 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 continued 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 determined the 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 capped relative weights for FY 2026 (determined in Step 10) and GROUPER Version 43; (b) simulate estimated total FY 2026 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2026 (determined in Step 9) and 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 FY 2026 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a budget neutrality factor of 0.9983146 (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 final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and 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 MS–LTC–DRG relative weights prior to the application of the 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding cap budget neutrality factor.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2026

1. Overview of Development of the 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 used 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 final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2026.

The update to the LTCH PPS standard Federal payment rate for FY 2026 is presented in section V.A. of the Addendum to this final rule. The components of the 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 final rule). As we proposed, we made 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 final rule).

2. 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. 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 PPS 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 final rule, as we proposed, we used 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. 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 final rule.)

d. 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 was 3.4 percent. The proposed productivity adjustment for FY 2026 based on IGI's fourth quarter 2024 forecast was 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 proposed 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18322), in accordance with the statute, we proposed 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 proposed 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 proposed 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 proposed 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 proposed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18322) that if more recent data subsequently became 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 also proposed 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 final rule).

Comment: A few commenters appreciated and supported the proposed rate increase for LTCHs with a commenter stating it will help hospitals meet patient needs and improve access to care. Several commenters were concerned about the proposed 3.4 percent market basket increase based on the LTCH market basket and whether it will adequately support the operational and clinical demands faced by LTCHs. Commenters stated they believe the proposed payment increase is insufficient in light of the current rate of inflation and escalating costs (including labor, drugs, supplies, and equipment) facing LTCHs due to health care workforce shortages and supply chain disruptions.

Commenters provided data and cited recent studies and reports regarding increasing labor costs, state minimum wage requirements, medical supply and pharmaceuticals costs, dialysis costs, total operating costs, administrative costs, impact of tariffs, and hourly rates for contract labor, which the commenters stated highlights the need for additional increases in payments to cover these significant increases in costs. Commenters stated that these increases in costs, combined with the reimbursement pressures on LTCHs, have resulted in a significant decline in the number of LTCHs in operation and the total number of Medicare discharges from LTCHs.

Commenters requested that CMS either modify its methodology used to determine the market basket update, provide for a special increase to the proposed market basket update, or apply a special payment adjustment to account for significantly higher labor and supply costs incurred by LTCHs in recent years and in FY 2026. Another commenter urged CMS to provide a more adequate market basket update in the final rule that reflects actual inflation in the LTCH cost structure and use all available administrative flexibilities to increase the net payment update. A commenter stated that the cumulative impact of inflationary pressure coupled with the proposed low Medicare payment increases for FY 2026 will continue to have negative effects on LTCH PPS operating margins. The commenter urged CMS to use more current data that includes the recent inflationary increases in cost and in the absence of such data, the commenter urged CMS to consider an alternative approach to better align the market basket increases with the rising cost of treating patients.

Response: CMS has historically used a market basket to account for input price increases in the services furnished by fee-for-service providers. Since the inception of the LTCH PPS, the LTCH PPS standard Federal payment rates (with the exception of statutorily mandated updates) have been updated based on a projection of a market basket percentage increase. The LTCH market basket (as well as other CMS market baskets) is a fixed-weight, Laspeyres type index that measures price changes over time and does not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the index is rebased. As such, the LTCH market basket percentage increase reflects the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices) but does not inherently reflect other factors that might increase the level of costs, such as the quantity of labor used (which may be associated with intensity of services). However, the impact of changes in quantity or use of services on the market basket cost weights are captured when the market basket is rebased.

We appreciate the commenters' concern regarding inflationary pressure, including labor and supply costs, encountered by LTCHs. We would highlight that the market basket percentage increase is a forecast of the price pressures that LTCHs are expected to face in FY 2026. We also note that when developing its forecast for the various price indexes used in the LTCH market basket, IGI considers industry-specific and overall economic conditions. More specifically for the Employment Cost Index (ECI) for hospital workers, IGI considers overall labor market conditions (including the impact of wage pressures on skill mix) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

As is our general practice, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2026 LTCH market basket increase for the final rule. For this final rule, we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy. Based on IGI's second quarter 2025 forecast with historical data through the first quarter of 2025, the projected 2022-based LTCH market basket percentage increase for FY 2026 is 3.4 percent, the same increase as in the proposed rule.

As discussed earlier, we believe the LTCH market basket percentage increase appropriately reflects the expected input price growth (including compensation price growth) that LTCHs incur in providing medical services. We also believe the LTCH market basket is methodologically sound and uses the best available data for FY 2026. Therefore, we disagree with the commenters that CMS should increase the market basket update or apply a ''special'' payment adjustment to the LTCH PPS rates.

Comment: A commenter also expressed concern about the lack of transparency from CMS regarding the LTCH market basket and the use of the IHS Global Inc. data. The commenter referenced CMS' responses in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986, 69450) regarding commenter's concerns about the lack of transparency in the market basket. The commenter stated that in the FY 2026 IPPS/LTCH PPS proposed rule, CMS did not provide greater transparency about the IHS Global Inc. data used for the market basket update that CMS is proposing for FY 2026. The commenter claimed that it is still not possible to replicate exactly how CMS arrived at the proposed 3.4 percent market basket update for FY 2026. The commenter requested that CMS provide more transparency in the final rule regarding the IHS Global Inc. data that led to this proposed market basket update.

Response: As discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69450), information on the CMS market baskets can be found at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-research-and-information*. This website provides information including, but not limited to, how a top-line market basket level is derived from the detailed cost categories, how a four-quarter percent change moving average is calculated, and a link to a spreadsheet containing an example of how the detailed market basket cost weights are calculated for the 2006-based IPPS market basket, which is similar to the approach followed for the LTCH market basket as well as most of the other CMS market baskets. In addition, the latest publicly available CMS market baskets are available at the CMS website: *https://www.cms.gov/data-research/statistics-trends-and-reports/medicare-program-rates-statistics/market-basket-data*. We note that publicly available market baskets on the CMS website would reflect an updated forecast only after a proposed or final rule is published. Using these spreadsheets, stakeholders are able to replicate the top-line market

basket index levels in the historical time period by multiplying the detailed index level for each cost category by the associated cost weight. These products (weight multiplied by index level) can then be summed up to derive the aggregate market basket index level.

In response to the commenter's request for more transparency, in this final rule, we are also providing the projected increase for FY 2026 for some of the aggregated cost categories that underlie the most recent forecast of the FY 2026 LTCH market basket increase (3.4 percent). This detail is consistent with the level of information that we publish on the CMS website on a quarterly basis as described previously. We note that prices for the compensation cost weight, which accounts for about 62 percent of the market basket are projected to increase 3.4 percent in FY 2026; prices for All Other Products and Services, which accounts for about 28 percent of the market basket are projected to increase 3.2 percent; and prices for Capital-Related costs, which accounts for about 8.5 percent of the LTCH market basket are projected to increase 3.5 percent. While the projected market basket increase is calculated using the aggregation of the detailed price forecasts multiplied by their respective cost weights for each of the 26 individual cost categories, we want to provide an estimate of how the broader cost categories are contributing to the overall increase. We strive for transparency regarding our methods. Stakeholders are free to ask further questions or request further clarifications regarding the market baskets via email at *dnhs@cms.hhs.gov*.

Comment: Several commenters were concerned about the proposed productivity adjustment of 0.8 percentage point. A commenter stated that the market basket update is effectively eroded by the excessive 0.8 percentage point productivity cut—a reduction that is especially damaging for hospitals already operating on slim or negative margins. Commenters stated that CMS should at least temporarily suspend the productivity adjustment because COVID–19, inflation, increased labor costs, and labor shortages have reduced hospital productivity.

A commenter also requested that CMS provide more transparency about how the productivity adjustment is calculated. The commenter cited CMS' response to similar comments in the FY 2025 IPPS/LTCH PPS final rule; however, the commenter stated that CMS did not address the obvious incongruity of applying the productivity adjustment during periods when the actual productivity of hospitals is clearly declining. The commenter stated that if CMS believes it lacks statutory authority to temporarily suspend the productivity adjustment, then CMS should use its broad ratesetting authority to make other changes that would reduce the impact of the productivity adjustment. For example, the commenter stated that CMS could either apply an offsetting payment adjustment to reduce the productivity adjustment, in whole or in part; or modify the data used by IHS Global Inc. in a manner that would reduce the amount of the productivity adjustment. The commenter claimed that either of these changes would be an appropriate use of the broad authority granted by Congress.

Commenters stated that the productivity adjustment is flawed as it is unlikely that productivity for LTCHs is increasing at the same rate as other non-hospital industries because of the unique challenges facing hospitals. A commenter requested that CMS make an adjustment for LTCHs to account for flaws in the productivity adjustment. Commenters urged CMS to eliminate the proposed 0.8 percentage point productivity cut and use all available administrative flexibilities to increase the net payment update.

A commenter stated that the use of private nonfarm business total factor productivity effectively assumes the hospital field can mirror productivity gains achieved by private nonfarm businesses. However, the commenter claimed that it is well proven by the economic literature that the hospital and health care field cannot do this. For example, the commenter stated that by focusing only on private businesses, this measure excludes nonprofit and government businesses, which account for more than 60 percent of hospitals and health systems. Thus, the commenter stated that this measure is not an appropriate or reliable predictor of productivity for the hospital field. The commenter stated that CMS itself has acknowledged that hospitals are unable to achieve the same productivity gains as the general economy over the long run. Thus, the commenter stated that using the private nonfarm business sector TFP to adjust the market basket inappropriately exacerbates Medicare's chronic underpayments to LTCHs. The commenter stated that it is puzzling how an indicator based on a 10-year moving average could yield such an increase in the productivity cut from FY 2025 to FY 2026; however, the commenter was unable to fully analyze the projections due to a lack of transparency from CMS. In addition, the commenter found it troubling that the productivity adjustment is used only when it decreases Medicare payments. Given all of this, the commenter asked CMS to re-examine the magnitude of this adjustment and its impact on Medicare payments.

Response: Section 1886(m)(3)(A)(i) of the Act requires the application of the productivity adjustment. As set forth in section 1886(b)(3)(B)(xi) of the Act, the FY 2026 productivity adjustment is derived based on the 10-year moving average growth in economy-wide private nonfarm business total factor productivity for the period ending in FY 2026. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, as we explained in response to similar comments in the FY 2023, FY 2024 and FY 2025 IPPS/LTCH PPS final rules, section 1886(m)(3)(A)(i) of the Act requires the application of the specific productivity adjustment described in section 1886(b)(3)(B)(xi) of the Act.

We have always made available on the CMS website the general method for calculating the productivity adjustment. This includes providing a link to the most recent BLS historical TFP data (*http://www.bls.gov*), which allows interested parties to obtain historical TFP annual index levels for 1987 through 2024. We also provided the IGI projection model (*https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/medicareprogramratesstats/downloads/tfp_methodology.pdf*), which is used to derive annual TFP growth rates for 2025 and 2026. The annual index level derived from this method is then interpolated to quarterly levels, and the FY 2026 productivity adjustment is equal to the percent change in the 40-quarter moving average projected level for the period ending September 30, 2026 relative to the 40-quarter moving average projected level for the period ending September 30, 2025. We believe our methodology for the productivity adjustment is consistent with section 1886(b)(3)(B)(xi)(II) of the Act, which states that the productivity adjustment is equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multi-factor 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).

At the time of this final rule, the FY 2026 productivity adjustment reflects BLS historical TFP data through 2024 (released on March 21, 2025) and IGI's forecasted TFP growth for 2025 and

2026. The average annual growth rate of historical TFP published by BLS for 2017 through 2024 is currently 0.9 percent and IGI is projecting average TFP growth of about 0.0 percent for 2025 and 2026 based on IGI's second-quarter 2025 forecast. Combining the historical and projected TFP data over the entire 10-year time period results in a compound annual growth rate of TFP of 0.7 percent for 2026. The productivity adjustment (based on the 10-year period ending with FY 2026) for this FY 2026 IPPS/LTCH PPS final rule is 0.1 percentage point lower than in the FY 2026 IPPS/LTCH PPS proposed rule, and primarily reflects the incorporation of a revised outlook from IGI that has lower projected economic growth over 2025 and 2026. The 0.7 percentage point productivity adjustment for FY 2026 in this final rule is larger than the productivity adjustment in prior final rules for FY 2023 and FY 2024 mainly due to the incorporation of updated BLS historical data.

Comment: Several commenters stated that CMS has ''under-forecast'' the market basket used to update Medicare payments to LTCHs for FY 2021 through FY 2025, which the commenters claimed has resulted in a cumulative underpayment to LTCHs of 5.1 percent, or $130 million per year. A commenter requested CMS also provide for a forecast error adjustment of 4.3 percentage points for the combined understatement of the FY 2021 through FY 2024 LTCH market baskets. The commenter stated that adopting this one-time forecast error adjustment to address the exceptional and unprecedented circumstances surrounding the COVID–19 PHE would make the LTCH PPS update equal to 3.4 percent plus 4.3 percentage points for forecast error less 0.8 percentage point productivity adjustment, or a net 6.9 percent. Commenters stated that even more problematic is the fact that these forecast errors will be incorporated into the LTCH PPS payment rates indefinitely because all future updates are based on the current year's payment rate.

The commenters cited CMS' response in the FY 2024 IPPS/LTCH PPS final rule of evaluating the FY 2012 through FY 2020 market baskets for ratesetting and finding that they were higher than the actual market baskets as unreasonable as they failed to account for the unprecedented COVID–19 pandemic and its lasting impact on hospital costs. The commenters stated that CMS' response in the FY 2025 IPPS/LTCH PPS final rule that upward price pressures were expected to slow in 2025 relative to 2022 and 2023 was inadequate because CMS set the market basket update for FY 2025 at 3.5 percent, but the commenter stated that the four-quarter moving averages of the IHS Global Inc. forecast for Q4 2024 through Q3 2025 are currently 3.9 percent, 3.8 percent, 3.7 percent, and 3.6 percent and have exceeded this increase, suggesting that CMS is underpaying LTCHs in FY 2025.

Therefore, the commenters stated that CMS should use the most recent forecast data to apply a special, one-time payment adjustment to account for the differences between the FYs 2021 through 2025 market basket updates and the actual market baskets for those years. The commenter also stated that going forward, CMS must ensure that the market basket update reflects the actual increase in the cost of LTCH goods and services.

Response: In responding to similar comments in the FY 2023, FY 2024 and FY 2025 IPPS/LTCH PPS final rules (87 FR 49165, 88 FR 59136, 89 FR 69434), we explained that under the law, the LTCH PPS is a per-discharge prospective payment system that uses a market basket percentage increase to set the annual update prospectively. This means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. (For instance, the 2022-based LTCH market basket growth rate for FY 2026 in this final rule is based on IGI's second quarter 2025 forecast with historical data through the first quarter of 2025.) While there is currently no mechanism to adjust for market basket forecast error in the LTCH PPS payment update, the forecast error for a market basket update is equal to the actual market basket percentage increase for a given year less the forecasted market basket percentage increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative.

While the projected LTCH market basket updates for FY 2021 through FY 2024 (the last historical fiscal year) were under forecast (actual increases less forecasted increases were positive), this was largely due to unanticipated inflation and labor market pressures as the economy emerged from the COVID–19 PHE. The forecast error of the LTCH market basket has been both positive and negative during past years, and over longer periods of time the cumulative forecast has not deviated significantly from the historical measures. For these reasons, we are not adopting the commenters' requests to implement an adjustment for FY 2026 to account for the difference between the actual and forecasted LTCH market basket updates for FYs 2021 through 2024, and, for the reasons stated previously, we disagree that we wrongly dismissed commenters' requests to apply an adjustment that accounts for forecast errors in the FY 2023, FY 2024 and FY 2025 IPPS/LTCH PPS final rules.

Comment: A commenter expressed concern that there is a more systemic issue with IHS Global Inc.'s forecasting that biases towards under-forecasting growth. The commenter stated that one such factor may be the use of the ECI to measure changes in labor compensation in the market basket. The commenter stated that the use of the ECI may not be adequately capturing employment and labor cost growth and stated that they continue to stand ready to work with CMS to examine the market basket compensation indices and proxies to improve the accuracy of these measures.

Response: We believe that the ECI for wages and salaries for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care. The ECI appropriately does not reflect other factors that might affect the rate of price changes associated with labor costs, such as a shift in the occupations that may occur due to increases in case-mix or shifts in hospital purchasing decisions (for instance, to hire or to use contract labor). We believe that the prices of employed staff and contract labor are influenced by the same factors and should generally grow at similar rates.

In most periods when there are not significant occupational shifts or significant shifts between employed and contract labor, the data has shown that the growth in the ECI for wages and salaries for hospital workers has generally been consistent with overall hospital wage trends. For example, our more recent analysis of the Medicare cost report data shows from 2018 to 2023, the compound annual growth rate of IPPS Medicare allowable salaries, benefits and contract labor costs per hour was about 4 percent, consistent with the growth rate of the compensation price increases in the 2022-based LTCH market basket as measured by the ECIs for hospital workers over the same period.

After consideration of public comments, we are finalizing the LTCH PPS payment rate update using the most recent forecast of the 2022-based LTCH market basket percentage increase and productivity adjustment. As such, based on IGI's second quarter 2025 forecast, the FY 2026 market basket percentage increase for the LTCH PPS using the 2022-based LTCH market basket is 3.4

percent. The current estimate of the productivity adjustment for FY 2026 based on IGI's second quarter 2025 forecast is 0.7 percentage point. 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 establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2025 of 2.7 percent (that is, the most recent estimate of the LTCH PPS market basket percentage increase of 3.4 percent less the productivity adjustment of 0.7 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), as we proposed, we are further reducing 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 establishing an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (that is, the 2.7 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.

X. Quality Data Reporting Requirements for Specific Providers

A. Overview

In section X. of the proposed rule, we sought comment on and proposed changes to the following Medicare quality reporting programs:

- In section X.B. of the proposed rule, we included the Toward Digital Quality Measurement in CMS Quality Programs—Request for Information.
- In section X.C. of the proposed rule, the Hospital IQR Program.
- In section X.D. of the proposed rule, the PCHQR Program.
- In section X.E. of the proposed rule, the LTCH QRP.
- In section X.F. of the proposed rule, the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

We respond to public comments on each of these sections.

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.[230] In the FY 2026 IPPS/LTCH PPS proposed rule, we issued this RFI (90 FR 18323 through 18328) and provided updates on our progress and sought input as we continue our path forward in the dQM transition.

In the RFI, we solicited 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 sought feedback on FHIR-based eCQM activities in these programs. We included 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 (90 FR 32685).

In this RFI, we solicited comments on our anticipated approach to FHIR-based patient assessment reporting in the Inpatient Psychiatric Facility Quality Reporting (IPFQR) Program. While we sought comments in this RFI for the IPFQR Program in the FY 2026 IPPS/LTCH PPS proposed rule (as a majority of IPFs are hospital-based),[231] we sought similar feedback in the FY 2026 Inpatient Psychiatric Facility (IPF) Prospective Payment System (PPS) proposed rule (90 FR 18520).

We thank commenters for their feedback and we will continue to consider the feedback received as we refine our dQM transition efforts and plan the strategic modernization of our quality measurement enterprise.

[230] 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).

[231] 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.

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.[232]

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)[233] 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/ONC 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/ONC on future versions of the United States Core Data for

[232] 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.*

[233] 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).

Interoperability (USCDI),[234] 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/ONC USCDI+ program supports identification and establishment of domain-specific datasets that build on the USCDI foundation.[235] The USCDI+ Quality domain,[236] which we discuss in more detail in section X.2.b. of the preamble of this final 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/ONC 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.[237]

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/ONC, the National Institutes of Health (NIH), and the National Cancer Institute (NCI).[238]

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 response.[239] 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.[240] 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)) [241] 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).[242] 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.[243] 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.[244] 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.[245]

We thank the public for providing feedback through industry conferences, direct conversations with CMS and our Federal partners, and submitting comments to RFIs in this and previous rulemaking. As we support healthcare providers, facilities, and clinicians, the health IT industry, and Federal partners in their respective activities, we requested 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 described the current state and requested 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.[246]

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

[234] *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.*

[235] *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[236] *https://uscdiplus.healthit.gov/uscdiplus?id=uscdi_record&table=x_g_sshh_uscdi_domain&sys_id=7ddf78228745b95098e5edb90cbb3525&view=sp.*

[237] *https://pacioproject.org/.*

[238] *https://www.cms.gov/priorities/innovation/innovation-models/enhancing-oncology-model.*

[239] *https://www.cdc.gov/nhsn/fhirportal/index.html.*

[240] *https://www.cdc.gov/nhsn/cms/index.html.*

[241] *https://build.fhir.org/ig/HL7/nhsn-dqm/.*

[242] *https://www.cdc.gov/nhsn/fhirportal/about.html.*

[243] *https://bphc.hrsa.gov/data-reporting/uds-training-and-technical-assistance/uniform-data-system-uds-modernization-initiative.*

[244] *https://www.fhir.org/guides/hrsa/uds-plus/dataelements.html.*

[245] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=about-dqms.*

[246] *https://ecqi.healthit.gov/sites/default/files/eCQM-Basics-508.pdf.*

clinician's, provider's, facility's, or organization's performance on a measure concept.[247]

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.[248] 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. We also stated 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 sought 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 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.[249] It also aims to incorporate industry-developed standards for the exchange of quality measurement data using FHIR.

In this section we discussed 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.[250] 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[251] 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/ONC 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/ONC 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.[252] Specifically for CMS programs, USCDI+ Quality includes the data elements to support program-specific measures.[253]

We are also considering the Data Exchange for Quality Measures (DEQM) IG[254] 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[255] or through the DEQM IG.[256] 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/ONC has adopted the Bulk Data Access IG STU 1, version 1.0.0, published on August 22, 2019 (hereafter referred to as version 1), and has incorporated it into the ONC Health IT Certification Program.[257] The Bulk Data Access IG has recently seen

[247] *https://ecqi.healthit.gov/sites/default/files/Digital%20Quality%20Measurement%20eCQMs%20reference%20brief_508ed.pdf.*

[248] 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.*

[249] See 45 CFR 170.315(g)(10)—*Standardized API for patient and population services* FHIR certification in the ONC Health IT Certification program.

[250] *https://hl7.org/fhir/us/qicore/index.html.*

[251] 45 CFR 170.315(g)(10).

[252] *https://www.healthit.gov/topic/interoperability/uscdi-plus.*

[253] For more information about the USCDI+ Quality data element list please visit *https://uscdiplus.healthit.gov/.*

[254] *https://build.fhir.org/ig/HL7/davinci-deqm/.*

[255] *https://hl7.org/fhir/uv/bulkdata/.*

[256] *https://hl7.org/fhir/us/davinci-deqm/OperationDefinition-bulk-submit-data.html.*

[257] 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).

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.[258] 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.[259] Bulk Import is already being used by HRSA in their UDS+ IG,[260] 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 sought 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 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 referred to this concept as the ''reporting options'' period.

We acknowledged 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 sought 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.[261] 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.[262] MADiE supports QI-Core profile-informed authoring, testing, and verification of the behavior of FHIR-based eCQMs.[263] 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).[264] After further consideration and testing, we have decided not to advance the MCT as previously described.

We sought 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 focused on the Hospital IQR Program, the Hospital OQR Program, and the Medicare Promoting Interoperability Program, we also sought similar feedback in the CY 2026 PFS proposed rule for MIPS (90 FR 32685). In the CY 2026 PFS proposed rule we sought 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

[258] See Argonaut Bulk Optimize project: *https://confluence.hl7.org/spaces/AP/pages/227213555/Bulk+Optimize.*

[259] *https://confluence.hl7.org/spaces/AP/pages/325453837/Bulk+Import.*

[260] *https://www.fhir.org/guides/hrsa/uds-plus/OperationDefinition-import.html.*

[261] *https://mmshub.cms.gov/cms-tools.*

[262] *https://www.emeasuretool.cms.gov/.*

[263] *Ibid.*

[264] *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=dqm-strategic-roadmap.*

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. In that RFI, we sought feedback on how the transition to FHIR-based reporting of eCQMs could help to mitigate these challenges.

We received several comments on the topics in section X.B.2. of the preamble of this final rule. We provide a summary of comments received.

Comment: Many commenters supported the transition to FHIR-based eCQMs to improve data standardization and collection. Several commenters stated that this transition would allow digital quality reporting to be less burdensome on providers, patients, and payers and lead to more accurate results. A few commenters added that the dQM transition would achieve broader interoperability goals and support timely insights that drive patient outcomes.

Many commenters shared overarching challenges they believe may impact the dQM transition. A few commenters noted the need for clear FHIR versioning policies, backward compatibility, and for adequate notice for transitions between standards. A few commenters additionally noted challenges with specifying QRDA-based eCQMs in FHIR due to inconsistent measure specifications, measure logic complexity, data elements not routinely captured in structured EHR fields, and disparity in how EHRs store and utilize data in comparison to how QI-Core expects data to be stored. The lack of EHR functionality to trigger electronic reporting notifications, the timing of diagnosis data entered in the system, and secondary capabilities such as secure authentication and connections between FHIR systems were also noted as potential challenges by a few commenters.

Several commenters mentioned challenges from their experiences reviewing, implementing, or testing QI-Core, DEQM, or Bulk FHIR standards. Some of the challenges shared include what they believe are misalignment of several QI-Core profiles and US Core profiles. A few commenters with FHIR Bulk Export experience indicated that it improves the ability to extract large-scale patient data, but challenges remain with EHR implementations that limit the number of patient records placed per query. Several commenters recommended CMS work with HL7, Argonaut, and the FHIR community to align to a limited and common standard for Bulk Import, offer enhanced mapping guidance, and provide implementation examples.

Many commenters provided feedback on the FHIR-based eCQM transition timeline—in support, against, and in support with recommendations. Several commenters expressed support for the potential 24-month timeline from effective date to the start of the reporting options period. However, many commenters expressed concerns around the 24-month timeline, stating that it is not sufficient. Commenters offered recommendations, including a longer timeframe that would allow for technical assistance and resources to be integrated, resolve any troubleshooting delays, and permit testing and validation prior to full implementation.

Many commenters provided feedback on tools to support quality data reporting. Several commenters recommended CMS provide the ability for providers to track their performance through real-time feedback (on elements such as measure calculations, errors, and data quality) and provider-facing EHR dashboards to compare CMS results with their internal systems. In addition to Connectathons, several commenters suggested CMS provide testing tools to health IT developers and eligible hospitals and CAHs, fund pilots, and use education and outreach opportunities to engage a cross section of hospitals in real-world testing. Several commenters also recommended the provision of incentives or scoring bonuses for early adopters, for pilot projects, and for technical assistance for small and rural hospitals to help support the dQM transition.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future dQM transition work and potential future rulemaking in our efforts toward a patient-centric digital health ecosystem.

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, December 29, 2022) [265] 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 [266] 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) [267] 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 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18326), the questions in this section sought 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 aimed to identify the extent of technology adoption beyond certified health IT and EHRs and sought a better understanding of how FHIR-standardized data can be generated, used, and shared through other technologies, without use of EHRs. Our objective was to explore how IPFs typically integrate technologies with varying complexity into existing systems and how this affects IPF workflows. We sought 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

[265] *https://www.congress.gov/117/plaws/publ328/PLAW–117publ328.pdf.*

[266] ''Patient Assessment Instrument Under IPFQR Program (IPF PAI) to Improve the Accuracy of PPS'' (89 FR 23200 through 23204).

[267] *https://del.cms.gov/DELWeb/pubHome.*

use with the IPF–PAI and quality data reporting.

We sought 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? [268] 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 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*) [269] 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 [270] 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.

We received several comments on these topics. The following is a summary of the comments received from both the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18326 through 18327) and the FY 2026 IPF PPS proposed rule (90 FR 18520 through 90 FR 18523), where this RFI was also included.

Comment: Many commenters expressed support for CMS' intent to transition to the FHIR-based standard in IPFQR, particularly for the IPF–PAI. A few commenters noted the opportunity for a FHIR-based standard to improve care coordination, enable actionable insights, and integrate structured data into EHRs. A few commenters highlighted the potential for FHIR to modernize behavioral health data reporting, enhance discharge planning, and enable meaningful performance measurement.

Many commenters asserted that there are challenges that may hinder interoperability efforts in IPFs. Commenters specifically described the following challenges: Inconsistent state laws governing data sharing and outdated provider directories, expense and complexity caused by non-standard reporting requirements, internet connectivity issues (particularly in rural areas), lack of ability for some IPFs to accept direct messaging, and outdated systems, particularly in stand-alone IPFs. A few commenters noted the high cost and burden of implementing FHIR-based technologies for facilities without certified EHRs.

A few commenters described variability in EHR adoption and infrastructure readiness across IPF facilities. A few commenters reported adopting EHRs capable of utilizing USCDI, with one commenter indicating that most of their members have or are currently implementing EHRs that support both USCDI and FHIR. Several commenters noted that while adoption continues to improve, they expressed concern about the low adoption rate of certified EHRs in IPFs compared to other healthcare settings. A few commenters urged CMS to provide financial incentives and technical assistance to support rural and resource-constrained IPF facilities in transitioning to FHIR-based systems. A few commenters specifically highlighted IPFs' exclusion from the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009 [271] as a cause for many IPFs having outdated systems that are incapable of interoperable data exchange and urged

[268] For instance, see standards adopted by ONC on behalf of HHS in 45 CFR part 170, subpart B.

[269] 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.*

[270] *https://smarthealthit.org/.*

[271] The Heath Information Technology for Economic and Clinical Health (HITECH) Act of 2009, part of the American Recovery and Reinvestment Act of 2009, Title XIII of Division A and Title IV of Division B of Public Law 111–5.

CMS to provide equitable support for IPFs. Lastly, a few commenters noted that many freestanding IPFs rely on non-EHR vendors for data submission, which further complicates their ability to transition to FHIR-based reporting.

A few commenters provided recommendations to support the dQM transition in IPFs. Recommendations to CMS included: Updating USCDI standards to incorporate specific FHIR-based data elements, providing consistent reporting processes to reduce provider burden, encouraging collaboration with health IT vendors, testing FHIR-enabled data submission methods, ensuring solutions reflect the unique needs of IPFs, and allowing 18 to 24 months for FHIR API development and testing.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future dQM transition work and potential future rulemaking in our efforts toward a patient-centric digital health ecosystem.

4. General Solicitation of Comments

In conjunction with the previous questions, we also sought 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.[272] 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 data for secondary uses such as treatment and research?

We received several comments on these topics. We provide a summary of comments received.

Comment: Commenters provided feedback on additional considerations that may foster data harmonization and reduce reporting burden. A commenter suggested CMS minimize the frequency and magnitude of changes to quality measures. Another commenter suggested reporting for multiple quality programs via one FHIR-based submission system.

Commenters also provided feedback on how the QHINs can support data exchange in CMS quality programs. Many commenters supported CMS' use of the TEFCA framework for quality measure and patient assessment submission as they believe it would allow for the following: Ease of provider and payer submission of quality data to CMS, more consistent and wider data exchange, and easier exchange of data. A few commenters provided existing barriers and opportunities for TEFCA including the need for the development of additional use cases to support submission of quality measure and patient assessment data.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future dQM transition work and potential future rulemaking in our efforts toward a patient-centric digital health ecosystem.

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.[273] We also refer readers to 42 Code of Federal Regulations (CFR) 412.140 for the Hospital IQR Program regulations. We note that we are discontinuing the practice of retaining all subsections of the preamble 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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18328), we sought input on measure concepts of well-being and nutrition for future years in the Hospital IQR Program. We invited comments on tools and measures that assess overall health, happiness, and life satisfaction, including emotional well-being, social connectedness, purpose, and fulfillment, that fall into concepts of well-being. We additionally sought comments on tools and measures that assess optimal nutrition and preventive care in the Hospital IQR Program (90 FR 18328).

We received public comments on these RFIs. The following is a summary of the comments we received:

1. Well-Being and Nutrition

Comments: Many commenters expressed concerns about the applicability of well-being and nutrition measures in the hospital acute care setting, due to their observation that care in this environment is focused on resolving acute conditions as opposed to addressing emotional health, social connections, and food access. These commenters stated that measures related to well-being and nutrition are better suited for outpatient or primary care settings.

Many commenters expressed concern that implementing measures related to well-being and nutrition in hospitals,

[272] For more information about TEFCA, see *https://www.healthit.gov/topic/interoperability/policy/trusted-exchange-framework-and-common-agreement-tefca.*

[273] 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).

particularly in rural or resource-limited settings, may be administratively burdensome and would hold hospitals accountable for factors outside their control. Some commenters were also concerned that measures of well-being and nutrition would be difficult to implement in hospitals, while others stated that assessing well-being during hospital stays may yield unreliable data due to the stress and disruption inherent in inpatient care. Some commenters recommended the use of standardized tools and existing data sources, such as electronic health records (EHRs), to simplify administration and integration into clinical workflows. Commenters encouraged engagement with providers, patients, and caregivers to ensure that new domains reflect both clinical relevance and patient experience. Some commenters recommended pilot testing in diverse settings and populations to ensure reliability, practicality, and applicability of new measures before full implementation.

Many commenters supported the utilization of the Malnutrition Care Score (MCS) electronic clinical quality measure (eCQM), noting it plays a critical role in identifying and addressing malnutrition in hospital settings. Some commenters supported making the MCS eCQM mandatory and recommended continuing to focus on this measure's performance. A few commenters did not support adopting additional nutrition measures, stating that the MCS eCQM already addresses nutritional concerns.

Many commenters supported the inclusion of evidence-based and actionable nutrition measures, noting that hospitals play a vital role in identifying and addressing nutrition needs during inpatient stays. Some commenters emphasized the importance of aligning nutrition measures with clinical workflows and addressing both food insecurity and diet quality.

Commenters noted that barriers to nutrition and well-being, such as food insecurity and social isolation, should be addressed through targeted interventions and community partnerships. Some commenters stressed the need to address resource gaps through federally funded programs that impact nutrition and well-being while others recommended incentivizing hospitals to partner with community organizations to expand access to nutrition services, including medically tailored meals and food pharmacies. Commenters emphasized the importance of ensuring continuity of care through discharge planning and community referrals. To support long-term health outcomes, commenters recommended expanding hospital-based measures to include post-discharge follow-up and integration with community resources.

Commenters recommended developing patient-centered measures that address the full spectrum of well-being, including emotional, social, and physical health. Commenters also recommended incorporating measures that assess care transitions, patient activation, and personalized goals to support pathways to well-being. Commenters specifically recommended developing outcome-based measures that reflect meaningful improvements in patient health and quality of life.

Commenters recommended aligning any future well-being and nutrition measures with existing social determinants of health (SDOH) screening tools and identified food insecurity screening as a foundational tool for addressing nutrition and well-being. Many commenters expressed concern over CMS's proposal to remove SDOH measures, arguing that these screenings provide critical insights into patient needs and support holistic care delivery.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the Hospital IQR Program.

(b) Background

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 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.[274]

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.[275] 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[276] for a more detailed discussion on the updated pre-rulemaking measure reviews (PRMR) process (89 FR 69457 through 69459).

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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18328 through 18335), we proposed 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 1, 2023–March 31, 2025 reporting period/FY 2027 payment determination.

a. 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.[277] In 2022, strokes were the fifth leading cause of death in the U.S.[278] 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.[279] 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.[280]

Stroke outcomes can vary greatly depending on the facility where patients receive care.[281] This was demonstrated

[274] 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.*

[275] See section 1890A(a)(2) of the Social Security Act (42 U.S.C. 1395aaa–1(a)(2)).

[276] Battelle, Partnership for Quality website. Available at: *https://p4qm.org/.*

[277] CDC. (2024). Stroke Facts. Available at: *https://www.cdc.gov/stroke/data-research/facts-stats/index.html.*

[278] CDC. (2024). Leading Causes of Death. Available at: *https://www.cdc.gov/nchs/fastats/leading-causes-of-death.htm*

[279] CDC. (2024). Stroke Facts. Available at: *https://www.cdc.gov/stroke/data-research/facts-stats/index.html.*

[280] *Ibid.*

[281] Neves, G., Cole, T., Lee, J., Bueso, T., Shaw, C., & Montalvan, V. (2022). Demographic and institutional predictors of stroke hospitalization

Continued

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.[282] This association is likely due to high-volume hospitals having more experience in treating strokes and developing improved processes of care.[283] 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.[284]

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.[285] However as of November 2024, roughly 50 percent of Medicare beneficiaries—34.4 million people—were enrolled in Medicare Advantage (MA) plans.[286] 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.[287] [288] 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

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18329 through 18331), we proposed modifications to the current MORT–30–STK measure with updates in the Hospital IQR Program beginning with the FY 2027 payment determination. Specifically, we proposed 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 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.[289] 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 modifications to the measure would better reflect overall patient outcomes in each hospital and inform quality improvement activities.

We proposed (90 FR 18329 through 18331) to implement these changes beginning with the FY 2027 payment determination. The 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 principal diagnosis code of COVID–19 or 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 final rule for further discussion on removal of the COVID–19 diagnosis 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.[290] However, research has indicated that using individual ICD–10 codes in place of HCCs could significantly improve the model performance of the mortality measures.[291] 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

mortality among adults in the United States. eNeurologicalSci, 26, 100392. *https://doi.org/10.1016/j.ensci.2022.100392.*

[282] 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.

[283] *Ibid.*

[284] 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.

[285] 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/.*

[286] Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard.* Accessed: March 25, 2025.

[287] 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/.*

[288] 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.*

[289] Centers for Medicare & Medicaid Services. (2025). Cascade of Meaningful Measures. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/cascade-measures.*

[290] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Mortality Measures Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology.*

[291] 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.*

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).[292] 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.[293]

For measure specification details on the updates to this measure, we refer readers to the Condition-Specific Mortality Measures Updates and Specifications Report available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

(4) Measure Calculation

The 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 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.[294] 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.[295]

The 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 proposed (90 FR 18329 through 18331) 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 proposed 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 2-year reporting period. The median reliability for the 2-year performance period is 0.911, ranging from 0.623 to 0.994.[296] 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 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 (MUC2024–043),[297] [298] 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.[299] 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

[292] 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://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[293] *Ibid.*

[294] 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*.

[295] Centers for Medicare & Medicaid Services. 2024 Condition-Specific Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[296] Yale New Haven Health Services Corporation—Center for Outcomes Research and Evaluation. (November 2024). Stroke Mortality Measure Submission to PQM: Figures and Tables. Available at: *https://p4qm.org/measures/4595*.

[297] 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*.

[298] 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*.

[299] 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*.

measure within the Hospital IQR Program with conditions.[300]

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.[301] 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 proposed (90 FR 18329 through 18331) to update the MORT–30–STK measure to shorten the reporting period from 3 to 2 years, which our 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.

Regarding the third condition, upon further review of the model, the proposed ICD–10 stroke mortality risk indeed includes stroke model ICD–10 Code Z66 (Do not resuscitate).[302] We have thus taken into consideration the conditions raised by the PRMR Hospital Committee in connection with the proposed modifications to the MORT–30–STK measure in the Hospital IQR Program.

(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.[303] The CBE voted to endorse the measure on February 7, 2025.[304]

(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 proposed (90 FR 18329 through 18331) 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 invited public comment on our proposal to modify the MORT–30–STK measure beginning with the FY 2027 payment determination.

Comment: Many commenters supported the proposed inclusion of MA beneficiaries in hospital quality measures, citing the growing proportion of MA beneficiaries and emphasizing that this change would improve the reliability and accuracy of performance data. A few commenters supported the proposal to include MA data and requested that CMS monitor the quality and reliability of MA encounter data to ensure the accuracy and fairness of the MORT–30–STK measure.

Many commenters supported the proposed shortening of the performance period for this measure from 3 years to 2 years, agreeing that the shorter measurement window would better reflect current care quality by reducing the lag between quality improvement efforts and their impact on measure scores. A commenter further recommended the measure transition to a 1 year timeframe in the future, as data would be even more actionable and reflective of recent care.

Response: We thank commenters for their support.

Comment: Some commenters did not support the proposed inclusion of MA beneficiaries to the MORT–30–STK measure. Commenters were concerned about the risk of hospitals being unfairly penalized for factors outside their control, such as MA plan prior authorization delays and denials of post-acute services, noting these are well-documented adverse practices in MA plans that could impact post-discharge stroke outcomes. A commenter urged CMS to provide increased oversight to ensure that MA plans are providing the same services to patients post-discharge that are available to Medicare FFS patients.

Several commenters encouraged CMS to conduct additional evaluation of MA data for accuracy and comparability between FFS and MA populations before including MA data in the measure. Several commenters recommended a phased implementation approach with confidential feedback reports to allow hospitals to validate their measure results before the start of public reporting. A few commenters recommended stratifying measure results by MA and FFS beneficiaries to allow hospitals to identify demographic or clinical differences between the two populations. A few commenters requested CMS determine whether including MA data would lead to administrative burden for hospitals.

Response: We appreciate the commenters' concerns regarding the inclusion of MA beneficiaries and the potential for challenges around data accuracy, transparency, and the impact of MA plan practices. We continue to encourage hospitals to work closely with insurers, including MA plans, to coordinate the highest quality care for their patients. Over half of the Medicare population receives Medicare benefits through the MA program. Inclusion of MA beneficiaries in the population supports the program's goal of incentivizing high-quality care for all patients and improves the reliability and validity of the hospital outcome measures. The increased size of the measure's cohort leads to more hospitals reaching the minimum threshold for reporting and receiving results,

[300] *Ibid.*

[301] *Ibid.*

[302] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[303] 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*.

[304] Battelle—Partnership for Quality Measurement. (April 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Management of Acute Events and Chronic Conditions. Available at: *https://p4qm.org/articles/now-available-final-fall-2024-e-m-reports*.

therefore increasing the opportunity to identify meaningful differences in quality for some low-volume hospitals.

We agree that transparency is important for both beneficiaries and providers, and we provide hospitals with annual confidential feedback reports on their measure performance. Additionally, routine measure evaluation reports are publicly available through the QualityNet website at: *https://qualitynet.cms.gov*. For the complete measure methodology report and measure risk adjustment statistical model, we refer readers to the QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology* and the Partnership for Quality Measurement's website at: *https://p4qm.org/measures/4595*. Additionally, as a part of our routine monitoring and evaluation of measures, we will monitor for any unintended consequences resulting from this change.

We also thank commenters for their feedback on potential differences between Medicare FFS and MA populations and plan designs. In our analysis using admissions from January 1–December 30, 2022, on mortality rates between FFS beneficiaries and MA beneficiaries, we found the unadjusted mortality rate for the FFS and MA beneficiaries combined cohort to be 12.9 percent. The observed mortality rate for FFS beneficiaries was 13.5 percent compared to 12.2 percent for MA beneficiaries, showing a difference of 1.3 percentage points between FFS and MA beneficiaries.[305] This measure does not show significant variation in mortality rates between the two cohorts and therefore the risk for being penalized is low based on the available sample. Also, keeping FFS and MA patients together for purposes of this measure's calculation will keep the hospitals' total volume higher for more precise measure scores. Based on this information, we did not propose a phased implementation approach.

As for potential administrative burdens, hospitals would not be required to submit data other than claims data, which is already routinely generated and submitted to CMS for all Medicare beneficiaries, including both MA and FFS beneficiaries. Therefore, this modification will not impose additional reporting burden on hospitals. We refer readers to section XIII.B.4.b. for additional details on our information collection burden estimate for the proposal to modify the MORT–30–STK measure (90 FR 18408).

Comment: Many commenters supported the notification of technical updates. Many commenters supported CMS's notification of the transition of risk adjustment methodologies from HCCs to ICD–10 codes. Many commenters noted this change would enhance the accuracy of risk adjustment by better capturing patient comorbidities and clinical factors influencing outcomes, ultimately leading to fairer performance measurement. A few commenters recommended CMS monitor the impact of the updates on the measure's predictive accuracy.

Many commenters supported CMS's notice of the technical update to remove the COVID–19 exclusion from the MORT–30–STK measure, given that the Public Health Emergency (PHE) has ended and COVID–19 cases have significantly declined.

Response: We thank commenters for their support.

Comment: Several commenters raised concerns about CMS's notification to switch risk adjustment methodologies from HCCs to ICD–10 codes, emphasizing the potential for unintended consequences. A commenter noted that HCCs are used in other CMS programs, such as the Transforming Episode Accountability Model (TEAM), and questioned the rationale for adopting ICD–10 codes in quality measures while retaining HCCs elsewhere. A commenter recommended a phased implementation approach, to ensure that hospitals have time to understand the impact to their performance scores and provide feedback. A commenter recommended parallel reporting of measure results from HCC and ICD–10-based models and extensive testing to ensure accuracy and reliability. Another commenter suggested increasing the number of allowable diagnosis codes on claims to better capture patient complexity.

Response: We appreciate the commenters sharing their concerns regarding the change from HCC to ICD–10 based models. As a part of our routine monitoring and evaluation we will watch for any unintended consequences from this updated risk model. The measure developer conducts annual measure re-evaluations to ensure the risk-standardized complication model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time.[306] Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns.[307] We solicited input from a workgroup composed of up to 20 clinical and measure experts, inclusive of internal and external consultants and subcontractors. As a part of annual re-evaluations, one of the activities we undertook was reviewing select pre-existing ICD–10 code-based specifications with our workgroup to confirm appropriateness unaffected by the updates, as well as reviewing any potentially clinically relevant codes that ''neighbor'' existing codes used in the measure to identify any warranted specification changes.[308] We will consider this feedback as we continue to assess and update the measure.

Comment: Several commenters were concerned with the notice of the technical update to remove COVID–19 exclusions, citing the ongoing clinical complexity and variability of COVID–19 as a factor in patient recovery. A few commenters recommended CMS closely monitor the impact of this change and remain flexible in reinstating exclusions if conditions change.

Response: We appreciate the commenter's concerns. Given the end of the federal COVID–19 PHE on May 11, 2023, it is important CMS provide hospitals and beneficiaries with a complete picture of the care quality provided for all patients. While hospitals and other types of health care facilities may face continuing challenges due to the long-term effects of the COVID–19 PHE, we do not agree these challenges represent such a significant threat to health care operations that patients with a secondary COVID–19 diagnosis should be excluded from the measure's cohorts.

After consideration of the public comments received, we are finalizing modifications of the MORT–30–STK measure as proposed beginning with administrative claims and encounter data from July 1, 2023, through June 30, 2025, associated with the FY 2027 payment determination. We will also be implementing all technical updates as outlined in the proposed rule.

[305] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[306] Centers for Medicare & Medicaid Services. 2025 Condition-Specific Mortality Measures Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/mortality/methodology*.

[307] *Ibid.*

[308] *Ibid.*

b. 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.[309] From April 1, 2018–March 31, 2021, there were 563,236 THA and TKA procedures performed on Medicare FFS patients 65 years and older.[310] 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.[311] 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.[312] Complications such as joint infections and sepsis following elective THA and TKA 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.[313] From 2011 to 2021, reported 30- and 90-day death rates following THA are 0.49 percent and 0.47 percent, respectively.[314] Rates for pulmonary embolism following THA range from 0.5 percent to 1.22 percent[315] and range from 0.5 percent to 0.9 percent[316] following TKA. Rates for wound infection in Medicare population-based studies vary between 0.21 percent and 1.0 percent.[317] 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.[318]

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 53518). 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. Therefore, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18331 through 18335), we proposed 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 final 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 as proposed (90 FR 18331 through 18335), the 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 proposed (90 FR 18331 through 18335) modifications to the current COMP–HIP–KNEE measure in the Hospital IQR Program beginning with the FY 2027 payment determination. Specifically, we proposed (90 FR 18331 through 18335) 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. We will 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 modifications of the updated COMP–HIP–KNEE measure would support the Meaningful Measures 2.0

[309] 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.*

[310] 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.*

[311] 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.*

[312] Wilson, N.A., et al., Hip and knee implants: current trends and policy considerations. Health Aff (Millwood), 2008. 27(6): p. 1587–98.

[313] 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.*

[314] 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.*

[315] 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.

[316] 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.

[317] 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.

[318] 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.

priority area of ''Chronic Conditions'' that aims to improve disease-specific outcomes, reduce preventable emergency department usage and admissions, and reduce mortality.[319]

(3) Technical Updates

We are also making two technical updates to the 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 principal diagnosis code of COVID–19 or 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 final 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.[320] However, research has indicated that using individual ICD codes in place of HCCs could significantly improve the model performance of the mortality measures.[321] 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.[322] 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/files/67eea958e8ad069a97a9ccc5?filename=2024_ArchiveMethodologyComp.zip.*

(4) Measure Calculation

The outcome for the 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 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 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 proposed (90 FR 18331 through 18335) 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.[323] 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.[324] 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

[319] Centers for Medicare & Medicaid Services. (2025). Cascade of Meaningful Measures. Available at: *https://www.cms.gov/medicare/quality/cms-national-quality-strategy/cascade-measures.*

[320] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/files/67ee94ebe8ad069a97a9bbbb?filename=2024_MortComp_SuppMthdRpt_IQR.pdf.*

[321] 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.*

[322] 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.*

[323] 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.*

[324] *Ibid.*

more actionable insights for quality improvement.

Consistent with the COMP–HIP–KNEE measure currently reported in the Hospital IQR Program, the proposed (90 FR 18331 through 18335) 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.[325]

The 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/files/67eea958e8ad069a97a9ccc5?filename=2024_ArchiveMethodologyComp.zip*.

(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 MUC List, including the COMP–HIP–KNEE measure (MUC2024–042),[326] 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.[327] 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.[328]

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.[329]

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 percentage points between Medicare FFS only and MA only beneficiaries.[330] 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 proposed (90 FR 18331 through 18335)

[325] 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*.

[326] 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*.

[327] 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*.

[328] *Ibid.*

[329] *Ibid.*

[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://qualitynet.cms.gov/files/67eea958e8ad069a97a9ccc5?filename=2024_ArchiveMethodologyComp.zip*.

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 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.[331] The updated 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 proposed (90 FR 18331 through 18335) to adopt as well as the technical updates to the risk methodology. The E&M Cost and Efficiency Committee voted on this measure on February 10, 2025, but did not reach consensus because only 73 percent of the committee voted to endorse or endorse this measure with conditions, below the 75 percent required by the CBE to reach consensus.[332] [333] As a result, the measure was not re-endorsed by the CBE. The E&M Cost and Efficiency 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.

The measure developer then submitted an appeal of the decision not to re-endorse the measure, citing the following rationales: (1) procedural error in the endorsement process with an excessive focus on outpatient setting exclusions; and (2) misapplication of measure evaluation criteria, particularly risk adjustment.[334] The CBE convened the E&M Fall 2024 Appeals Committee meeting on March 31, 2025. The Appeals Committee voted to grant the appeals request, with a vote of 100 percent for both rationales, and overturn the decision not to re-endorse the measure. Thus, the COMP–HIP–KNEE measure was endorsed with the following conditions: (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 impact of case 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 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, the conditions for endorsement have been met.

(6) Data Source, Submission and Public Reporting

The 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 MA 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18290 through 18291), we also proposed to adopt the modifications to the COMP–HIP–KNEE measure in the Hospital VBP Program, beginning with the FY 2033 program year, after the updated measure has been publicly reported in the Hospital IQR Program for 1 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.1

[331] 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.*

[332] Battelle—Partnership for Quality Measurement. (March 2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report: Cost and Efficiency. Available at: *https://p4qm.org/articles/now-available-final-fall-2024-e-m-reports.*

[333] 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.*

[334] 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.*

TABLE X.C.1. SUMMARY OF 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 finalized in this final rule.

We proposed (90 FR 18331 through 18335) to publicly report the updated COMP–HIP–KNEE measure in accordance with our previously established public reporting policy for the Hospital IQR Program.[335] 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 invited 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.

Comment: Most commenters supported the proposed inclusion of MA beneficiaries in hospital quality measures, citing the growing proportion of MA beneficiaries and the need for measures to reflect the full Medicare population served by hospitals. Many commenters emphasized this change would improve the reliability and accuracy of performance data, particularly for hospitals with a large proportion of MA beneficiaries. Many commenters supported the proposed shortening of the performance period of this measure from 3 years to 2 years, noting that this change would provide more timely and actionable data for hospitals, payers, and patients. Many commenters agreed that shorter measurement windows would better reflect current care quality and reduce the lag between quality improvement efforts and their impact on metrics. Commenters highlighted that a 2-year period strikes a balance between statistical reliability, timeliness, and relevance, particularly with the inclusion of MA beneficiaries, which increases the denominator size.

Response: We thank commenters for their support.

Comment: Many commenters expressed concerns about the challenges of data collection and reporting with the proposed addition of MA encounter data. Some commenters did not support the proposed inclusion of MA beneficiaries in this measure cohort, citing potential challenges with data accuracy, transparency, and the differences between MA and FFS plans and populations. Many commenters stated concerns about the risk of being unfairly penalized for factors outside their control, such as MA plan prior authorization delays and denials of post-acute services, noting these are observed adverse practices by some MA plans that could impact surgical outcomes from THA or TKA. Commenters recommended addressing these data collection challenges, increasing the number of allowable diagnosis codes on claims, and ensuring transparency in measure development.

Response: We appreciate the commenters' concerns regarding the inclusion of MA beneficiaries and the potential for challenges around data accuracy, transparency, and accessibility. We reiterate that with over half of the Medicare population now receiving its benefits through the MA program, including this population in the Hospital IQR Program supports quality improvement goals of high-quality, safe care for all patients. Additionally, the inclusion of MA beneficiaries has several important benefits for the reliability and validity of the hospital outcome measures. The increased size of the measure's cohort leads to more hospitals reaching the minimum threshold for reporting and receiving results, therefore increasing the opportunity to identify meaningful differences in quality for some low-volume hospitals.

We thank commenters for their feedback on potential differences between Medicare FFS and MA populations and plan designs. In our statistical analysis of complication rates using unique admissions, to potentially include MA beneficiaries, using FFS beneficiaries and MA beneficiaries, we found the unadjusted complication rate for the FFS and MA beneficiaries combined cohort to be 3.4 percent. The observed complication rate for FFS beneficiaries was 3.2 percent compared to 3.7 percent for MA beneficiaries, showing a difference of 0.5 percentage points between FFS and MA beneficiaries.[336] Based on this analysis, the rates of complication did not vary significantly between the two populations on average and therefore hospitals are not likely to be unfairly penalized with the inclusion of MA beneficiaries into the measure's cohort. Further, this risk-adjusted complication measure methodology does account for additional medical conditions that might impact higher complication rates such as malignant neoplasm of the pelvis, sacrum, coccyx, lower limbs, or bone/bone marrow or a disseminated malignant neoplasm coded in the principal discharge diagnosis field on the index admission claim.

We agree that transparency is important for both beneficiaries and

[335] 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.

[336] Centers for Medicare & Medicaid Services. 2024 Condition- and Procedure-Specific Mortality/Complication Measures Supplemental Methodology Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology.*

providers, and we provide hospitals with annual confidential feedback reports on their measure performance. Additionally, routine measure evaluation reports are publicly available through QualityNet on our website at: *https://qualitynet.cms.gov*. For the complete measure methodology report and measure risk adjustment statistical model, we specifically refer readers to QualityNet on our website at: *https://qualitynet.cms.gov/inpatient/measures/complication/reports* and the Partnership for Quality Measurement's website at: *https://p4qm.org/measures/1550*. Additionally, as a part of routine monitoring and evaluation of measures, we will monitor for any unintended consequence of this change.

Comment: A few commenters raised concerns about the potential for increased administrative burden with the addition of MA beneficiaries, noting the prior authorization process used by MA plans places a significant administrative burden on both acute care hospitals and post-acute care providers. A commenter recommended providing a clearer understanding of data collection methods, assessing the associated burden, and determining whether the benefits outweigh the new reporting challenges.

Response: We would like to clarify that the inclusion of MA encounter data in COMP–HIP–KNEE does not require any additional data collection or submission from hospitals. As we previously discussed (90 FR 18335), the inclusion of MA encounter data in this measure uses readily available administrative claims data routinely generated and submitted to CMS for all Medicare beneficiaries, which includes MA and Medicare FFS beneficiaries. Specifically, the MA encounter data used for this measure are submitted by Medicare Advantage Organizations (MAOs) to CMS. Similarly, FFS claims are submitted through existing hospital billing processes. As such, the proposed modifications do not impose additional data submission burden on hospitals. We refer readers to section XIII.B.4.b. for additional details on our information collection burden estimate for the proposal to modify the COMP–HIP–KNEE measure (90 FR 18408). Lastly, we will continue to monitor for unintended consequences as a part of our routine monitoring and evaluation of the Hospital IQR Program measure set.

Comment: Several commenters recommended a phased implementation approach, including confidential feedback reports and dry runs, or a delay to allow hospitals to validate MA data, ensure robust risk adjustment methodologies, and assess its impact before public reporting or payment penalties.

Response: We thank the commenters for their feedback and recommendations to possibly delay or use a phased implementation approach. We will provide confidential feedback reports to hospitals on their measure performance. Additionally, we will continue to monitor for unintended consequences as a part of our routine monitoring and evaluation of the Hospital IQR Program measure set. We note the current approach to first adopt the modified COMP–HIP–KNEE measure, to include MA beneficiaries and shorten the reporting period, into the Hospital IQR Program beginning with the FY 2027 payment determination, followed by adoption into the Hospital VBP Program beginning with the FY 2033 program year, is a phased implementation approach. This phased approach allows for hospitals to have about 6 years to assess the impact of MA beneficiary inclusion before payment adjustments would take effect.

Comment: A commenter stated concerns that THA and TKA procedures differ significantly in recovery timelines, patient satisfaction, and functional improvement. The commenter recommended separate reporting pathways for each procedure to yield more accurate data and promote informed decision-making based on the measure results.

Response: We thank commenters for the recommendation to separately report THA and TKA complication rates and highlight that there may potentially be differences in recovery timelines, patient satisfaction, and functional improvement. We note the risk model adjusts for the procedure type by knee or hip replacement, which demonstrated good calibration in our risk model. Combining the TKA and THA in the same cohort while adjusting for procedure type allows for a large enough sample size to both improve reliability and increase the number of hospitals eligible to report on this measure.

Comment: A commenter was concerned that the CBE's E&M Cost and Efficiency Committee's reasons for not re-endorsing the updated COMP–HIP–KNEE measure have not been adequately addressed. The commenter also shared the same concerns regarding the need to evaluate differences in patient populations between inpatient and outpatient settings, as well as exploring additional approaches to adjust performance for low-volume facilities.

Response: We acknowledge the commenter's concerns regarding the need to evaluate differences in patient populations between inpatient and outpatient settings. However, we wish to note that the Appeals Committee voted to grant the appeals request, with a vote of 100 percent for both rationales, and overturn the decision not to re-endorse the measure. Based on our evaluation of the endorsement criteria, the conditions for endorsement have been met. We refer readers to section X.C.3.5.b. for additional details regarding endorsement considerations.

Comment: Many commenters supported the technical update notifications for this measure. Many commenters supported CMS's notification of the technical update to transition risk adjustment methodologies from HCCs to ICD–10 codes, noting the increased granularity and clinical relevance of ICD–10 codes. Many commenters noted this change would enhance the accuracy of risk adjustment by better capturing patient comorbidities and clinical factors influencing outcomes. Commenters highlighted that ICD–10 codes align with current documentation practices and provide greater specificity, which is important for fair performance measurement.

Many commenters supported CMS's notice of the technical update to remove the COVID–19 exclusion from the COMP–HIP–KNEE measure, given that the PHE has ended and COVID–19 cases have significantly declined.

Response: We thank commenters for their support.

Comment: Some commenters raised concerns about CMS's notice of technical update to switch risk adjustment methodologies from HCCs to ICD–10 codes, emphasizing the potential for unintended consequences and operational challenges. Commenters noted that HCCs are widely used in other CMS programs, such as TEAM, and questioned the rationale for adopting ICD–10 codes in quality measures while retaining HCCs elsewhere. Commenters noted the risk of inconsistencies across programs and the possibility of hospitals seeing changes in performance scores due to the model itself rather than actual care quality, especially for rural or safety-net hospitals. Concerns were also raised about the abrupt nature of the transition, with commenters recommending a phased approach, parallel reporting of HCC- and ICD–10-based models, and extensive testing to ensure accuracy and reliability. Some commenters suggested increasing the number of allowable diagnosis codes on claims to better

capture patient complexity. Some commenters recommended monitoring the impact of this transition on predictive accuracy and ensuring transparency in the implementation process. Others emphasized the need for transparency in developing the new models, including clinical validation and stakeholder feedback. Recommendations included delaying the transition, aligning methodologies across programs, and providing hospital-specific reports to help facilities understand the impact of the changes.

Response: We appreciate commenter concerns regarding the change from HCC- to ICD–10 based models. As a part of our routine monitoring and evaluation we will watch for any unintended consequences of this updated risk model. We wish to note that we conduct annual measure re-evaluations to ensure that the risk-standardized complication model is continually assessed and remains valid, given possible changes in clinical practice and coding standards over time.[337] Modifications made to the measure cohort, risk model, and outcomes are informed by review of the most recent literature related to measure conditions or outcomes, feedback from various stakeholders, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns.[338] We solicited input from a workgroup composed of up to 20 clinical and measure experts, inclusive of internal and external consultants and subcontractors. As a part of annual re-evaluations, one of the activities we undertook was to review select pre-existing ICD–10 code-based specifications with our workgroup to confirm appropriateness unaffected by the updates, as well as review any potentially clinically relevant codes that ''neighbor'' existing codes used in the measure to identify any warranted specification changes.[339] We agree transparency is important, and additional details on our annual re-evaluation can be found on the QualityNet website (available at: *https://qualitynet.cms.gov/inpatient/measures/complication/reports*).

Comment: Several commenters were concerned with the notice of the technical update to remove COVID–19 exclusions, citing the ongoing clinical complexity and variability of COVID–19 as a factor in patient recovery. Commenters noted concerns that hospitals still experiencing pandemic-related patient-risk disparities may face unintended consequences from the inclusion of COVID–19 cases in outcome measures. Commenters recommended that CMS closely monitor the impact of this change and remain flexible in reinstating exclusions if conditions change.

Response: We appreciate the commenter's concerns. Given the end of the federal COVID–19 PHE on May 11, 2023, it is important we provide hospitals and beneficiaries with a complete picture of the care quality provided for all patients. While hospitals and other types of health care facilities may face continuing challenges due to the long-term effects of the COVID–19 pandemic, we do not agree that these challenges continue to represent such a significant threat to health care operations that patients with a secondary COVID–19 diagnosis should be excluded from the measure's cohorts. Such patients, as with all patients treated by hospitals, should receive the best quality care from their providers, and incorporating them into quality measures represents the best way for us to incentivize high-quality care for all.

After consideration of the public comments received, we are finalizing modifications of the COMP–HIP–KNEE measure as proposed and implementing the technical updates, beginning with administrative claims and encounter data from April 1, 2023, through March 31, 2025, associated with the FY 2027 payment determination.

4. Removals in the Hospital IQR Program Measure Set

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18336 through 18337), we proposed 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. 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). In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18336), we proposed 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. As stated in section XIII.B.4.d, removal of this measure would alleviate an estimate annual burden of approximately 509 hours, at a cost of $28,188, across all participating IPPS hospitals.

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

[337] Centers for Medicare & Medicaid Services. 2025 Procedure-Specific Complication Measure Updates and Specifications Report. Available at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

[338] *Ibid.*

[339] *Ibid.*

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 invited public comment on our proposal to remove the HCHE measure from the Hospital IQR Program beginning with the FY 2026 payment determination.

Comment: Many commenters supported the removal of the HCHE measure, emphasizing concerns about its administrative burden and limited impact on improving patient outcomes, with several commenters questioning the value of structural measures. Commenters stated that the burden outweighs the benefits, highlighting challenges in implementation such as a lack of infrastructure, training, and staff capacity to collect and act on the data meaningfully. Some commenters stated these challenges were particularly acute for small and rural hospitals.

A few commenters supported the removal of the measure, citing the lack of CBE endorsement, measure testing, and validity. Commenters expressed concern about the measure's scoring methodology, specifically the complexity of the reporting requirements and the actionability of the data.

A few commenters supported the removal as part of broader efforts to streamline quality reporting programs and reduce regulatory burden. They agreed that eliminating measures like HCHE would allow hospitals to redirect resources toward higher-priority initiatives and patient care, focusing on more tangible interventions and measurable outcomes rather than attestation-based requirements. A commenter noted that the measure duplicates efforts already met through existing standards, such as The Joint Commission's National Patient Safety Goal NPSG.16.01.01—Improve Health Care Equity; the commenter encouraged CMS to align measures with existing standards.

Response: We thank the commenters for their support. We agree that the removal of this measure will reduce the administrative burden on hospitals. We note that the HCHE measure went through the rigorous measure development lifecycle outlined at the CMS Measures Management System website [340] which includes measure testing and reliability analysis. Further, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act permits the Secretary to specify a measure without endorsement if a feasible and practical measure has not been endorsed by the CBE, provided due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Comment: A few commenters supported the removal of the measure and stated they remain committed to ensuring quality care for all patients and investing in culturally responsive care models.

Response: We appreciate commenters' support and commitment to maintaining quality care for all patients.

Comment: Many commenters opposed the removal of the HCHE measure, emphasizing its critical role in advancing health equity and addressing disparities in care delivery. Commenters highlighted that the measure provides structured accountability for hospital leadership to prioritize equity work, collect data on social determinants of health, and implement quality improvement initiatives.

Several commenters noted that removing the measure would signal a retreat from CMS's stated goals of reducing disparities and improving care for vulnerable populations, including those with severe mental illness, racial and ethnic minorities, rural populations, those with low socioeconomic status, and dual eligibles. Other commenters stated that removing the HCHE measure contradicts the goals of the Make America Healthy Again initiative.

Response: We acknowledge commenters' concerns. We agree that holding hospitals accountable for high-quality healthcare delivery to all beneficiaries is important and remains a priority for the Hospital IQR Program. We remain focused on identifying measures that balance feasibility, burden, and impact, while aligning with shifting national priorities as the health system continues to evolve. We are identifying ways to reduce provider reporting burden, while continuing to hold hospitals accountable for measurable clinical health outcomes and patient safety. We appreciate the commenters' support for the Make America Healthy Again initiative, and will review suggestions received on the new measure RFI in section XX.X of this final rule as we consider relevant measures to introduce in the future.

Comment: A few commenters stated concern that removal of the measure could result in decreased quality of care, reduce transparency and accountability, and exacerbate gaps in care quality, ultimately resulting in worsened health outcomes and higher costs. Several commenters cited examples of persistent disparities in care, including maternal mortality rates across the population and differences between urban and rural health outcomes. A commenter noted removal of this measure would widen an existing gap between medical and behavioral health institutions, emphasizing that addressing social needs such as food insecurity, housing instability, and transportation barriers is essential for improving health outcomes, particularly chronic diseases, and reducing preventable hospital admissions.

Response: We acknowledge commenters' concerns and encourage hospitals to continue to close identified gaps in patient care. We urge hospitals and health systems to continue to incorporate industry standards that may address challenges that could impact safe high-quality healthcare delivery. Despite removal of these measures, hospitals will still be able to collect data that is important to their patient care initiatives and reflects the unique needs of their specific patient population.

Comment: Several commenters stated that the benefits of this measure, that is reducing the costs associated with health inequities, outweigh CMS's estimated burden of implementing the HCHE measure. A few commenters

[340] CMS. Blueprint Measure Lifecycle Overview. Available at: *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview. Accessed: June 21, 2025.*

stated that structural measures incur a low reporting burden, as hospitals do not incur financial penalties provided they report complete and accurate data. A commenter stated that CMS should prioritize the benefits for Medicare beneficiaries and taxpayers, with burden to providers as a secondary consideration.

Response: We appreciate commenters' input regarding the burden associated with reporting on the HCHE measure. We agree with commenters that the reporting burden associated with structural measures is typically small; however, we believe that costs are multi-faceted and include administrative costs to hospitals, maintaining information collection systems, and analyzing reported data. At this time, we remain focused on identifying outcome measures that balance feasibility, burden, and impact, while aligning with national priorities. We are identifying ways to reduce provider reporting burden, while continuing to hold hospitals accountable for measurable clinical health outcomes and patient safety. We have determined the multi-faceted costs associated with this measure outweigh the benefits of its continued use in the program at this time.

Comment: Several commenters expressed concerns about the proposed effective date for the removal of the HCHE measure, which is the FY 2026 payment determination. Some commenters suggested extending submission deadlines until after the final rule is published or waiving penalties for non-submission of 2024 data to reduce unnecessary burden for hospitals. A few commenters expressed concern about the timing of the removal of the measure, given its recent adoption. Some commenters noted that hospitals have already invested resources in collecting and submitting data for the 2024 reporting year, stating that hospitals should not be penalized for anticipating regulatory requirements and urged CMS to avoid changes applicable to past reporting years in future rulemaking. A commenter expressed concern that the removal of the HCHE measure may discourage future engagement if hospitals feel their prior efforts are rendered obsolete by abrupt shifts in program direction. The commenter requested CMS provide advance notice and justification when removing newly adopted measures and minimize disruptive reversals to foster long-term strategic planning.

Response: We acknowledge commenters' concern regarding the timing around removal of this measure. However, because we have determined that the cost of reporting on this measure outweighs the benefits of retaining it in the program, we are removing this measure at the earliest feasible reporting period so that hospitals will not need to expend additional resources on reporting a measure for which we have determined that the costs outweigh the benefits. Hospitals that do not report their CY 2024 reporting period data for the HCHE measure to CMS will 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 will not be penalized for FY 2026 payments due to this measure). Any HCHE measure data received by CMS will not be used for public reporting or payment purposes.

Comment: A commenter stated that this proposal is misaligned with the Conditions of Participation (CoPs) at 42 CFR 482.21(b)(4), which require hospitals to measure quality indicators on patient outcomes and address disparities in processes of care, services, and operations. The commenter requested that CMS clarify how hospitals continuing to collect SDOH data voluntarily, consistent with Domain 3 of the HCHE measure, will be evaluated and ensure that regulatory expectations across programs are aligned to avoid confusion and conflict.

Response: While both the Hospital IQR Program and the Quality Assessment and Performance Improvement (QAPI) Program require hospitals to report performance data; they are separate programs. The Hospital IQR Program measures the quality of hospital inpatient services while QAPI is a comprehensive intra-facility approach for quality improvement. QAPI allows hospitals to choose which topics and data analysis methods to use in meeting these standards so that their QAPI programs may be tailored to their unique patient populations and facility needs. Hospitals have the flexibility to develop their own quality initiatives/projects or join other local/state/federal quality efforts as part of their QAPI program; as such, facilities may choose to use their Hospital IQR Program data in their QAPI program. We regularly update Hospital IQR Program requirements without interfering with QAPI; hospitals must still comply with the requirement at § 482.21(b)(4) independent of the change removing the measure. If a hospital chooses to use data from the measure in their QAPI program, they may continue to collect that data at their own discretion. The removal of this measure does not have an impact on other quality programs or initiatives in which the hospital may participate or other mandated requirements.

Comment: Many commenters recommended refining the HCHE measure rather than removing it entirely. They suggested modifications to reduce the administrative burden while preserving the measure's intent and improving value. Commenters proposed adjustments to scoring methodologies, reporting frequency, or voluntary submission to make the measure more feasible for hospitals to implement. A few commenters encouraged CMS to explore alternative mechanisms for tracking equity-related efforts and integrating social needs into care delivery, such as voluntary documentation of Z-codes.

Response: We thank the commenters for their recommendations and will consider them as we evaluate any potential future measures in this subject. We are identifying ways to reduce provider reporting burden, while holding hospitals accountable for measurable clinical outcomes and patient safety. Hospitals are encouraged to continue to engage in activities to close gaps in care and collect data that is important to their patient care initiatives and reflect the needs of their patient population regardless of whether it is required for the Hospital IQR Program.

After consideration of the public comments we received, we are finalizing our proposal to remove the HCHE measure from the Hospital IQR Program beginning with the FY 2026 payment determination.

b. 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).

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18336 through 18337), we proposed 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 noted 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 final 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 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.[341] 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.[342] 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 invited 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.

Comment: Many commenters supported the removal of the HCP COVID–19 Vaccination measure and agreed the burden imposed by tracking COVID–19 vaccination among healthcare personnel outweighs the benefits of its continued use in the Hospital IQR Program. Many commenters supported removal of this measure because it is labor-intensive, particularly due to changing vaccination definitions, and requires significant staff time and resources that are diverted from other clinical priorities. Many commenters agreed that this measure no longer aligns with an urgent public health priority or provides meaningful or actionable data for quality improvement. Commenters supported removal of this measure noting it has become outdated, especially since the COVID–19 PHE declaration ended in May 2023.

Response: We thank commenters for their support.

Comment: Several commenters did not support the removal of this measure, emphasizing that tracking COVID–19 vaccination coverage among healthcare personnel is essential for infection prevention and control in healthcare settings. Commenters expressed concern that removing this measure could lead to decreased vaccination rates among healthcare personnel, thereby increasing the risk of hospital-acquired infections and compromising patient safety for vulnerable patient populations, such as those who are immunocompromised, undergoing cancer treatment, or pregnant. Several commenters highlighted that vaccination is a critical strategy to minimize preventable harm and maintain safe healthcare environments. A few commenters did not support the removal of this measure because it would contradict the healthcare industry's obligation to uphold high standards of care and infection prevention.

A few commenters did not agree with removing this measure because they stated this measure is important for maintaining vaccination data for public health surveillance. Commenters noted that systematic reporting of healthcare personnel vaccination rates is essential for monitoring and responding to future infectious disease outbreaks. Some commenters were concerned that removing this measure could hinder institutional accountability and reduce attention to vaccination programs, potentially compromising healthcare system resilience.

Response: We acknowledge commenter concerns about patient safety, protecting vulnerable populations, and maintaining public health surveillance and readiness. We agree that patient safety practices and high-quality healthcare for all patients is a priority, and we expect participating hospitals to support safe practices that protect patients from infections and other preventable harms. The removal of the HCP COVID–19 Vaccination measure is not intended to interfere with infection control practices, but rather to balance the associated tracking and reporting burden against the benefit of collecting this data now that the PHE has ended.

Comment: A few commenters did not agree with removing the HCP COVID–19 Vaccination measure based on their assertion that it undermines efforts to address health equity and persistent disparities in healthcare outcomes. Commenters noted that vulnerable populations, including racial and ethnic minorities, rural communities, economically disadvantaged groups, and pregnant women, remain disproportionately affected by infectious diseases like COVID–19. Commenters recommended retaining the HCP COVID–19 Vaccination measure or delaying its removal until alternative indicators are developed to ensure continuity in health equity monitoring.

Response: We acknowledge commenters' concerns about protecting vulnerable populations. We reiterate that preventing the spread of COVID–19 remains a public health goal and that the removal of the HCP COVID–19 Vaccination measure is not intended to place vulnerable populations at higher risk, but rather to alleviate the associated tracking and reporting burden now that the PHE has expired. We note that this measure was not proposed for removal from certain quality programs, such as PCHQR, that focus on care settings for especially vulnerable patients. We expect all

[341] *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html.*

[342] Provisional COVID–19 Deaths, by Week, in The United States, Reported to CDC. Available at: *https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00. Accessed: March 27, 2025.*

hospitals to continue to strive toward the highest quality of care for all patients.

Comment: A few commenters did not agree with removing this measure, asserting that the benefits of tracking vaccination coverage outweigh the costs. Commenters stated that this measure is important for transparency and promotes vaccine uptake. Commenters expressed concern that removing the measure could lead to gaps in accountability and preparedness, ultimately resulting in higher costs associated with preventable infections.

Response: We acknowledge commenters' concerns. We note that hospitals are not restricted from tracking HCP vaccinations that are appropriate for the setting of care and the population served. The removal of the HCP COVID–19 Vaccination measure is intended to alleviate the burden associated with data collection and reporting on a monthly cadence.

Comment: A few commenters expressed concerns about the proposed applicability date of the removal of the HCP COVID–19 Vaccination measure which is the FY 2026 payment determination. Commenters noted this creates confusion and burden among hospitals and that hospitals have already invested significant resources to complete the process of submitting CY 2024 quality data. Commenters recommended avoiding proposing to remove measures applicable to past reporting periods, especially for relatively new measures.

Response: We understand commenters' concern regarding the timing around removal of these measures and the confusion and burden this may impose on hospitals who have already submitted CY 2024 quality data. However, because we have determined that the cost of reporting on these measures outweighs the benefits of retaining them in the program, it would place an undue burden on hospitals to continue requiring reporting on these measures for an additional year. We note that hospitals that do not report their CY 2024 reporting period data for the HCP COVID–19 Vaccination measure to CMS will 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 will not be penalized for FY 2026 payments due to this measure). Any HCP COVID–19 Vaccination measure data received by CMS will not be used for public reporting or payment purposes.

After consideration of public comments we received, we are finalizing our proposal to remove the HCP COVID–19 Vaccination measure beginning with the FY 2026 payment determination.

c. Removal of Two Social Drivers of Health Measures Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18337), we proposed 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).

As discussed in the proposed rule, we proposed 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 (90 FR 18337). 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. As stated in section XIII.B.4.f., removal of SDOH–1 would alleviate an estimated annual burden for hospitals and patients of 626,009 hours, at a cost of $16,059,753, across all participating IPPS hospitals (90 FR 18409). Also, as stated in section XIII.B.4.g., removal of SDOH–2 would alleviate an estimated annual burden of 509 hours, at a cost of $28,188, across all participating IPPS hospitals (90 FR 18409). Further, we noted (90 FR 18337) that these measures document an administrative process and report aggregate level results, and do not measure the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings. We stated that the costs of the 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 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.

We stated in the proposed rule (90 FR 18337) that, 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), as well as that any SDOH measure data received by CMS would not be used for public reporting or payment purposes.

We additionally stated that, 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 invited public comment on our proposal to remove the SDOH measures from the Hospital IQR Program beginning with the FY 2026 payment determination.

Comment: Many commenters were supportive of removing these measures and emphasized that the measures require significant resources for data collection, which could distract hospitals from focusing on direct patient outcomes and other quality improvement initiatives. Several commenters supported the measures' removal because the measures do not show whether hospitals are addressing the specific risk factors impacting patients in response to screenings.

Response: We thank the commenters for their support.

Comment: A few commenters supported removal due to concerns about a lack of testing and the measures' scoring reliability, or that the measures have not been endorsed by the CBE.

Response: We thank the commenters for their insights. We note that the two SDOH measures went through the

rigorous measure development lifecycle outlined at the CMS Measures Management System website [343] which includes measure testing and reliability analysis. Further, section 1886(b)(3)(B)(viii)(IX)(bb) of the act permits the Secretary to specify a measure without endorsement if a feasible and practical measure has not been endorsed by the CBE, provided due consideration is given to measures that have been endorsed or adopted by a consensus organization.

Comment: Many commenters did not support CMS's proposal to remove the two SDOH measures from the Hospital IQR Program. Many commenters described how SDOH significantly impacts health outcomes and the types of care and services patients may require in the hospital. These commenters stated that screening for SDOH is fundamental to patient-centered care, including clinical outcomes, treatment adherence, and reducing preventable healthcare utilization (for example, emergency department visits and readmissions).

Response: Removal of these measures from the Hospital IQR Program does not prevent hospitals from measuring and addressing patients' social needs, as clinically appropriate. Further, these SDOH measures are only reported in the aggregate and do not measure the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings.

Comment: Many commenters disagreed that the SDOH measures' removal would reduce burden. Many commenters also highlighted the ultimate cost savings arising from SDOH screening, through improved chronic disease management and prevention of avoidable hospitalizations. Commenters also noted that hospitals have already incurred the cost to set up the systems to collect these data, and that removal now would have minor impacts on costs. Several commenters stated that eliminating these measures without a transition plan could disrupt established care practices, undermine quality, and present ethical challenges.

Response: We are removing these measures from the Hospital IQR Program to reduce the burden incurred by patients and providers for screening, data storage, and data reporting. Removal of these measures does not prevent hospitals from measuring and addressing patients' social needs as is clinically appropriate. We acknowledge that hospitals may have expended resources to implement SDOH screenings, however, removing these measures at this time will alleviate additional burden with regard to data collection and submission requirements, especially with screening patients via manual processes and other manual collection and data storage mechanisms.

Comment: Several commenters recommended against removing measures for the FY 2026 payment determination because hospitals must proceed with collecting data for CY 2024, or else face penalties if the measures are not removed.

Response: We understand commenters' concern regarding the timing around removal of these measures. These measures are being removed on this timeline to maximize the alleviation of burden on patients and providers, rather than continuing to require collection and reporting of measures whose benefit has been determined to be outweighed by the cost and burden of implementation at this time which includes operational cost and IT infrastructure. Hospitals that do not report to CMS their CY 2024 reporting period data for the SDOH measures will 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 will not be penalized for FY 2026 payments due to this measure), and any SDOH measure data received by CMS will not be used for public reporting or payment purposes

Comment: Several commenters suggested that CMS retain these measures and improve data collection and interoperability to address hospital concerns about burden. Several commenters requested that CMS allow for voluntary reporting of the SDOH measures or pause the measures to avoid disrupting ongoing efforts to collect social risk data. A few commenters expressed the importance of identifying and documenting Z codes and noted the importance of SDOH-related screening for capturing applicable Z codes. A commenter suggested stratifying performance reports based on SDOH-associated ICD–10 diagnoses.

A few commenters recommended maintaining the current SDOH measures and developing an additional measure to encourage hospitals to connect patients to community resources. As an example, some commenters specifically identified the National Committee for Quality Assurance's (NCQA's) Healthcare Effectiveness Data and Information Set (HEDIS) Social Needs Screening and Interventions (SNS–E) measure. Some commenters requested that CMS help hospitals connect patients with social needs to resources and community-based organizations in order to link SDOH screening with patient outcomes.

Response: We appreciate the commenters' concerns and feedback regarding the importance of collecting SDOH data from patients and acknowledge that some patients may face challenges following discharge that may be related to SDOH. We recognize that some clinicians may find value in obtaining SDOH information as part of clinical decision making, such as discharge planning and patient care, and acknowledge feedback from some commenters stating that they value collection of this information. We agree that healthcare outcomes may be different for those experiencing unstable housing or food insecurity. Hospitals may find ways to address these concerns in their workflow because they recognize the importance of these items and the removal of this requirement should not, in any way, preclude hospitals from collecting and using this information.

Comment: Many commenters stated that the SDOH measures align with CMS's broader goals, including ensuring high-quality healthcare for all patients and implementing the Make America Healthy Again initiative. In response to the request for comment, ''Measure Concepts under Consideration for Future Years in the Hospital IQR Program—Request for Information (RFI): Well-Being and Nutrition,'' several commenters urged CMS to keep the SDOH measures and invest resources into improving the applicability and actionability of these measures as a way to improve well-being and nutrition.

Response: We appreciate commenters' support for the goals of the Make America Healthy Again initiative and the constructive role that quality measures can play in ensuring quality healthcare for all. Because we have determined that the cost of reporting on these measures outweighs the benefits of retaining them in the program, it would place an undue burden on hospitals to require reporting on these measures as we explore alternative approaches to implementing measures related to well-being and nutrition. We will consider the feedback commenters provided in future policymaking.

Comment: A commenter stated that this proposal is misaligned with the Conditions of Participation (CoPs) at 42 CFR 482.21(b)(4), which require hospitals to measure quality indicators

[343] CMS. Blueprint Measure Lifecycle Overview. Available at: *https://mmshub.cms.gov/blueprint-measure-lifecycle-overview. Accessed: June 21, 2025.*

on patient outcomes and address disparities in processes of care, services and operations. The commenter requested that CMS clarify how hospitals continuing to collect SDOH data voluntarily will be evaluated and ensure that regulatory expectations across programs are aligned to avoid confusion and conflict.

Response: While both the Hospital IQR Program and the Quality Assessment and Performance Improvement Program (QAPI) require hospitals to report performance data; they are separate programs. The Hospital IQR Program measures the quality of hospital inpatient services while QAPI is a comprehensive intra-facility approach for quality improvement. QAPI allow hospitals to choose which topics and data analysis methods to use in meeting these standards so that their QAPI programs may be tailored to their unique patient populations and facility needs. Hospitals have the flexibility to develop their own quality initiatives/projects or join other local/state/federal quality efforts as part of their QAPI program; as such, facilities may choose to use their Hospital IQR Program data in their QAPI program. We regularly update the Hospital IQR Program requirements without interfering with QAPI; hospitals must still comply with the requirement at 482.21(b)(4) independent of the changes removing the measures. If a hospital chooses to use data from these measures in their QAPI program, they may continue to collect that data at their own discretion. The removal of this measure does not have an impact on other quality programs or initiatives in which the hospital may participate or other mandated requirements.

After consideration of the comments we received, we are finalizing our proposal to remove the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures 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 notified the public of our intent to apply a technical update to remove 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 modified in this final rule.
- COMP–HIP–KNEE, most recently discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267) and modified in this final 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), updated in the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499), and modified in this final 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 modified in this final 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 Hospital Readmissions Reduction Program, stating our position 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 final 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 to promote quality care for all.

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*).

Comment: Several commenters supported removing the COVID–19 exclusion from quality measures in the Hospital IQR Program and agreed that it is reasonable to treat COVID–19 like other comorbid conditions since the PHE ended over two years ago. A few commenters agreed that hospitals have improved treatments and infection control, making the exclusion unnecessary. One commenter recommended the importance of flexibility, urging CMS to remain vigilant and prepared to reinstate the exclusion if needed.

Response: We thank the commenters for their support.

Comment: A few commenters were concerned with removing the exclusion and recommended delaying public reporting until hospitals have had sufficient time to assess the data and address any discrepancies or concerns. One commenter recommended additional analysis before removing the exclusion from these measures to provide an accurate reflection of hospital quality.

Response: We acknowledge commenter concerns about having sufficient time to address discrepancies in data prior to public reporting. We note that our internal analysis using data from July 2021–June 2024, 371 admissions out of 261,616 admissions (0.14 percent) were excluded for a COVID–19 diagnosis, also showing a decline in the number of patients excluded from the various measure cohorts. We wish to reiterate that removing the exclusion of COVID–19

patients is intended to ensure that these measures continue to account for outcomes as intended and to meet the goals of the Hospital IQR Program. As a part of our routine monitoring and evaluation of measures we will continue to watch for any unintended consequences of this change and be prepared to make updates as necessary.

We will implement these technical updates as outlined in the proposed rule.

6. Summary of Previously Finalized and Newly Modified Hospital IQR Program Measures

a. Summary of Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the newly modified and previously finalized Hospital IQR Program measure set for the FY 2027 payment determination:

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TABLE X.C.2. MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short Name	Measure Name	CBE Number*
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage Among Healthcare Personnel	0431
Claims-Based Patient Safety Measures		
ISCMR**	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
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

* 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 Thirty-day Risk-Standardized Death Rate among Surgical Inpatients with Complications measure short name has been updated to Inpatient Surgical Complications Mortality Rate (ISCMR).

**** In this final rule, we are finalizing modifications 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 final rule for more detailed discussion.

**** In this final rule, we are finalizing 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 final 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 Hospital IQR Program Measures for the FY 2028 Payment Determination

This table summarizes the newly modified 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
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		
ISCMR***	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
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

* 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.

** 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 final 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 (ISCMR).

**** In this final rule, we are finalizing modifications 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 final rule for more detailed discussion.

***** In this final rule, we are finalizing 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 final 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 Hospital IQR Program Measures for the FY 2029 Payment Determination and for Subsequent Years

This table summarizes the newly modified 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
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		
ISCMR***	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	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
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

* 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.
** 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 final 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 (ISCMR).
**** In this final rule, we are finalizing modifications 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 final rule for more detailed discussion.
***** In this final rule, we are finalizing 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 final 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.

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7. Updates to the Form, Manner, and Timing of Hospital IQR Program Data Submission

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18342 through 18344), we proposed changes to our reporting and submission requirements for eCQMs and hybrid measures. We provide more details on these proposals in the subsequent sections.

We did not propose 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 sections 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 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 parts 160 and 164, subparts A, C, and E.

c. 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 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 49701). 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) 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 future rulemaking.

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.[344] 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.[345] [346] [347]

Therefore, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18343 through 18344), we proposed 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.[348] We also proposed (90 FR 18343 through 18344) 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 invited 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 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.

Comment: Many commenters stated support for CMS's proposal to reduce the data completeness thresholds for CCDEs and linking variables from 90 and 95 to 70 percent, as well as to allow up to two missing lab values and two missing vital signs. Many commenters noted that these changes would significantly reduce the reporting burden on hospitals, increase feasibility for compliance, improve participation rates, and provide CMS with more data to evaluate hospitals' reporting performance.

A few commenters emphasized that the proposed reductions acknowledge data capture workflows and real-world challenges, such as technical limitations in EHR systems and operational barriers, while others noted that the reduced threshold would assist in the transition to incorporating more granular clinical data into quality measurement. A commenter supported maintaining the first mandatory reporting year of July 1, 2025-June 30, 2026 as this provides hospitals with the stability and predictability needed for successful implementation while recognizing the substantial investments many organizations have already made in the reporting of hybrid measures. A few commenters expressed support for the overall philosophy behind the hybrid measures as they provide a more comprehensive perspective on readmissions and mortality.

Response: We thank commenters for their support.

Comment: A few commenters urged CMS to provide transparency regarding the rationale for the 70 percent threshold.

Response: We conducted an internal analysis examining hospital's ability reach different reporting thresholds based on voluntary reporting data and selected the threshold of 70 percent to ensure successful submission for as many hospitals as possible, while still maintaining statistical validity.[349] Internal results demonstrate that comparing admissions with and without CCDEs have similar outcome rates and similar claims-based risk variable prevalences. As such, a threshold of 70 percent maximizes hospitals' ability to meet the threshold, while maintaining scientific rigor. We note that the hybrid measures utilize CCDE for risk adjustment, based on stakeholder feedback that the claims-only measures did not adequately account for clinical risk factors.

Comment: A few commenters requested clarification on the application of the missing data allowance and whether the allowance of up to two missing clinical data elements and two missing linking variables applies per patient on an individual

[344] CMS. Internal Analysis. September 2024.

[345] CMS. Internal Analysis. September 2024.

[346] 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*.

[347] 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*.

[348] CMS Internal Analysis. September 2024.

[349] CMS Internal Analysis. September 2024.

basis, or if it must be the same elements missing across all patients for the allowance to apply.

Response: We wish to clarify that the allowance of missing data applies to CCDEs only, specifically up to two missing lab values and two missing vital signs. This missing data allowance applies per patient on an individual basis. We refer readers to the eCQI Resource Center for more details on the measure specifications.[350] [351]

Comment: A commenter requested clarification on whether the reporting period of July 1, 2024 through June 30, 2025 included the addition of MA patients as finalized in the FY 2024 IPPS/LTCH PPS final rule.

Response: We wish to clarify that the July 1, 2024 through June 30, 2025 performance period impacting the FY 2027 payment determination did include MA patients as finalized in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59161 through 59168). We refer readers to the eCQI Resource Center for more details on the 2024 reporting period measure specifications.[352] [353]

Comment: A few commenters recommended CMS lower the threshold even further, such as 60 percent, to alleviate reporting burdens and encourage broader participation. A commenter recommended allowing an additional missing lab value for a total of three to better align with clinical workflows. A commenter urged CMS to eliminate the linking variable and CCDE threshold requirements altogether.

Response: We thank the commenters for their recommendations. We selected the 70 percent threshold and the allowance of two missing lab values and two missing vital signs to maintain statistical validity, while providing opportunity for more successful submissions for more hospitals, based on the results of an internal analysis. Results show that the majority of hospitals can meet the 70 percent threshold, which was selected to retain the integrity of the data for statistical calculation amongst missing data.[354]

Comment: Commenters urged CMS to continue monitoring hospital experiences with reporting on these measures by reviewing performance data, particularly under the new proposed thresholds, and work with hospitals and stakeholders to refine the measure specifications and adjust voluntary reporting as necessary. A commenter noted that the internal analysis performed by CMS suggested an improved ability to meet the proposed measure reporting thresholds but emphasized that hospitals participating in voluntary reporting are likely those with more resources. A few commenters specifically suggested examining the impacts of the thresholds on small and rural hospitals and urged CMS to consider the lack of bed availability at skilled nursing facilities.

Response: We remain committed to monitoring hospital experiences on reporting the hybrid measures, particularly for small and rural hospitals and for hospitals/facilities with fewer resources, and working with stakeholders toward future measure refinement and improvement.

Comment: Many commenters raised concerns about the feasibility of mandatory reporting for the Hybrid Hospital-Wide Readmission (HWR) and Mortality (HWM) measures. Many commenters emphasized the need for CMS to address multiple technical and data processing issues before transitioning to mandatory reporting. A few commenters urged CMS to conduct further analysis and testing to ensure the measures are clinically valid and equitable before making them mandatory, particularly under the new reporting thresholds. Many commenters recommended extending voluntary reporting for at least one or two additional years to allow hospitals to address operational challenges, refine workflows, and ensure accurate data submission.

Response: We appreciate the commenters raising their concerns about mandatory reporting. In the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499), we addressed several technical and data processing issues in response to feedback we received from hospitals from the 2024 Voluntary Reporting period. After conducting an internal analysis on hospitals' submission data from this reporting period, we extended voluntary reporting for an additional two years to allow hospitals more time to address any technical issues, with mandatory reporting beginning with the FY 2028 payment determination (89 FR 94499). We refer readers to the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) for further details and a discussion surrounding the challenges faced by hospitals, as well as our corresponding updates to the measures.

Our proposal to lower the thresholds to 70 percent and allow up to two missing lab values and two missing vital signs will provide hospitals with even greater flexibility to continue to address operational challenges and refine workflows as mandatory reporting approaches. We remain committed to monitoring hospitals' ability to report on these measures and will work with stakeholders to make any necessary measure refinements in the future.

Comment: A few commenters highlighted delays and inaccuracies regarding the calculation of CCDE values in the CMS feedback reports. A commenter acknowledged the ''Update to Hospital-Specific Reports for Hybrid HWR and HWM Measures'' that CMS released on June 2, 2025, but expressed concern that they would not receive the corrected results until well after the next filing deadline.

Response: As we stated in our Update to Hospital-Specific Reports for Hybrid HWR and HWM Measures,[355] there was an issue impacting the reports released on May 14, 2025 that marked CCDE values as missing for excluded patients even though they were correctly submitted. This resulted in incorrect percentages of successfully linked vital signs and lab test results to be calculated and displayed on the Hospital-Specific Reports. We would like to notify commenters that as of June 9, 2025, the updated Hospital-Specific Reports with the corrected CCDE values and percentages are now available on the Measure Details Dashboard in the Hospital Quality Reporting (HQR) System.[356]

Comment: A few commenters suggested that CMS provide more robust support, such as more comprehensible hospital-specific reports, technical

[350] eCQI Resource Center. May 2025. Core Clinical Data Elements for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data—HWR. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2026/cms0529v6?qt-tabs_measure=specifications-and-data-elements*.

[351] eCQI Resource Center. May 2025. Core Clinical Data Elements for the Hybrid Hospital-Wide All-Condition All-Procedure Risk-Standardized Mortality Measure—HWM. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2026/cms0844v6?qt-tabs_measure=specifications-and-data-elements*.

[352] eCQI Resource Center. May 2025. Hybrid HWR Measure Information. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2024/cms0529v4*.

[353] eCQI Resource Center. May 2025. Hybrid HWM Measure Information. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2024/cms0844v4*.

[354] Jakobsen, J.C., Gluud, C., Wetterslev, J. *et al.* When and how should multiple imputation be used for handling missing data in randomised clinical trials—a practical guide with flowcharts. *BMC Med Res Methodol* 17, 162 (2017). *https://doi.org/10.1186/s12874-017-0442-1*

[355] CMS. June 2025. Update to Hospital-Specific Reports for Hybrid HWR and HWM Measures. Available at: *https://www.qualityreportingcenter.com/globalassets/listserves/2025/iqr/2025-57-ip_listserve_update-to-hsrs-for-hybrid-hwr-and-hwm-measures_06022025_vfinal-508.pdf*.

[356] eCQI Resource Center. (June 2025). Updated Hospital-Specific Reports for Hybrid HWR and HWM Measures Now Available. Available at: *https://ecqi.healthit.gov/updated-hospital-specific-reports-hybrid-hwr-and-hwm-measures-now-available*.

guidance, and dedicated office hours for questions.

Response: We wish to note there are several additional ways for hospitals and EHR vendors to receive technical assistance to support implementation of these measures, which include CCSQ Support Central [357] and ONC JIRA.[358] Additional resources about the hybrid measures, including fact sheets, frequently asked questions, and webinar recordings, are available on our QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/hybrid/resources*. We will continue to identify opportunities to improve our responsiveness and the quality of available technical assistance.

Comment: A few commenters noted a lack of transparency regarding the discussion surrounding challenges and outcomes experienced by hospitals during the voluntary submission period for discharges in 2024 Voluntary Reporting. A commenter requested public release of this information before making reporting mandatory to allow hospitals the chance to learn from the data that resulted from this reporting period.

Response: We received feedback directly from hospitals via email and help desk questions, in addition to soliciting public comment on the CY 2025 OPPS/ASC proposed rule (89 FR 59502) regarding challenges faced by hospitals when reporting on these measures. We refer the commenter to the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) for further details and a discussion surrounding the challenges faced by hospitals, as well as our corresponding updates to the measures. In addition, we will continue to provide hospital-specific reports to allow hospitals to learn from the data resulting from the prior reporting period.

Comment: A few commenters suggested that, if CMS retains the hybrid measures as mandatory for FY 2028, CMS should remove any completeness thresholds, until it can perform a thorough analysis of submissions during the voluntary period. A commenter recommended that CMS maintain the mandatory reporting requirement, while postponing the requirement to meet the data completeness thresholds until reporting and measure definition issues with the inclusion of MA patients are resolved. A few commenters suggested postponing mandatory reporting until hospitals achieve a threshold of 90 percent, as commenters were concerned with the validity of a 70 percent threshold. A commenter recommended CMS allow hospitals to submit data using the 70 percent threshold for internal feedback and data analysis only but avoid any payment update penalties or publicly reporting these results until data completeness improves significantly.

Response: We thank the commenters for their recommendations. Based on our internal analysis, we concluded that a 70 percent threshold significantly improves hospitals' ability to meet the reporting requirements while still maintaining statistical validity. At this time, we are requiring mandatory reporting beginning with the FY 2028 payment determination as hospitals were already given an extended voluntary reporting period to properly adjust to reporting on these measures in the CY 2025 OPPS/ASC Final Rule (89 FR 94499). Mandatory reporting will provide CMS with a larger data set, especially with the 70 percent thresholds, that will be useful to analyze hospital performance and ensure all patients are being provided quality care. We remain committed to monitoring hospitals' ability to report on these measures and intend to raise these thresholds accordingly as hospital performance improves.

Comment: Several commenters expressed concerns about the inclusion of MA patients in the measure cohorts, noting challenges with capturing Medicare Beneficiary Identifiers (MBIs) for MA patients, as these identifiers are often incomplete or missing due to third-party data integration issues or format variability in claims documentation. A few commenters recommended that CMS monitor the impact of MA inclusion on data completeness and consider temporary exclusions or adjustments where MA data completeness is lower. Additionally, a few commenters suggested stratifying performance data by coverage type to ensure fair assessment and providing technical guidance to improve MBI capture rates. A commenter urged CMS to provide hospitals with feedback reports for at least the first reporting period in which MA patients are included, before the inclusion of MA patients becomes mandatory.

Response: We thank commenters for their feedback regarding reporting MBIs for MA patients and acknowledge these challenges. We note that the inclusion of MA patients was finalized in the FY 2024 IPPS/LTCH PPS final rule beginning with the FY 2027 payment determination (88 FR 59161 through 59168) which corresponds to the performance period of July 1, 2024 through June 30, 2025. We subsequently made the submission of CCDE and linking variable requirements for this reporting period voluntary per the CY 2025 OPPS/ASC final rule (89 FR 94499).

We expanded the measure cohort to include MA patients because MA beneficiary enrollment has been rapidly increasing as a share of overall beneficiaries. As of March 2025, 51 percent of Medicare beneficiaries—or 35.1 million people—were enrolled in MA plans.[359] The Congressional Budget Office estimates that by 2034, 64 percent of beneficiaries will be covered by MA plans. MA coverage also varies across counties and states with lower enrollment in rural states.[360] Including MA beneficiaries in hospital outcome measures will help ensure that hospital quality is measured across all Medicare beneficiaries.[361] [362]

As July 1, 2024 through June 30, 2025 is the first performance period in which MA patients were included, we will examine the data submitted by hospitals and evaluate the need for measure adjustments to ensure successful submission of MBIs. In addition, we will include MA data in the feedback reports for admissions July 1, 2024 through June 30, 2025 performance period to allow hospitals to address any reporting issues.

Comment: Several commenters highlighted technical and operational barriers to meeting the reporting requirements for hybrid measures. A few commenters noted challenges with capturing specific clinical data elements, such as vital signs and lab values, due to variability in EHR systems and coding standards. Commenters highlighted specific

[357] Available at: *https://cmsqualitysupport.servicenowservices.com/ccsq_support_central.*

[358] Available at: *https://oncprojectracking.healthit.gov/olp/.*

[359] Centers for Medicare & Medicaid Services. (2025). Medicare Enrollment Dashboard. Available at: *https://data.cms.gov/tools/medicare-enrollment-dashboard. Accessed: July 11, 2025.*

[360] Freed M, Biniek JF, Damico A, Neuman T. Medicare Advantage in 2024: Enrollment Update and Key Trends. Kaiser Family Foundation. Accessed July 11, 2025. Available at: *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/.*

[361] Ochieng N and Biniek JF. Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature. Accessed July 11, 2025. 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/.*

[362] Medicare Payment Advisory Commission. The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. Accessed July 11, 2025. Available at: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf.*

examples such as ''first heart rate'' being marked as missing due to hospitals recording the first measurement as a ''pulse'' and the inability to submit platelets due to a different unit (femtoliter) being used. A few commenters emphasized the complexity and specificity required of the linking variables, and stated it leaves no margin for error.

A few commenters also noted that the narrow 24-hour lookback period for CCDE collection may exclude relevant clinical data, particularly for transfer patients and patients with extended emergency department or observation stays as these tests are often performed at the originating facility or during the ED/observation period and may not be repeated within the 24-hour window. A commenter expressed their desire for patients under observation status to have their lab values extracted within 24 hours before inpatient status to avoid redundant labs being drawn when a patient is transferred. Another commenter proposed extending the lookback period to 48 hours prior to admission.

Response: We thank the commenters for their feedback regarding technical and operational barriers to meeting reporting requirements for the hybrid measures. We refer readers to the CY 2025 OPPS/ASC final rule (89 FR 94495 through 94499) in which many of these issues were raised by commenters and discussed in more detail.

We recognize that variability in EHR systems and coding standards, such as the documentation of heart rate, present challenges with capturing CCDEs. However, our approach to CCDEs allows hospitals to map codes and is not specific to any particular EHR system, meaning that all hospitals should be able to successfully capture and submit CCDEs. Additionally, by lowering the reporting thresholds, particularly the allowance of up to two missing lab values and two missing vital signs, we provide hospitals with more flexibility regarding these potential technical challenges. Specific to concerns that platelets counted as ''missing'' in performance reports, we note that beginning with July 1, 2023, through June 20, 2024 performance period data, associated with FY 2026 payment determination, platelet laboratory test values with the unit of femtoliter (fL) were accepted.

Regarding concerns about the current timing requirements for CCDEs, we have made updates to address these points. Specifically, we extended the anchor timestamp requirement for CCDEs to increase flexibility regarding data collection. We refer readers to the eCQI Resource Center for more details on the measure specifications.[363] [364] We will continue to work with stakeholders and monitor hospital feedback to address any technical and operational issues with reporting on the hybrid measures.

Comment: A few commenters raised broader concerns about the validity and impact of the hybrid measures. A few commenters questioned whether the measures accurately reflect patient care and outcomes, particularly given challenges with data completeness and linking variables.

Response: The hybrid measures are designed to provide a more comprehensive assessment of patient care and outcomes by combining administrative claims data with clinical data extracted from EHRs, allowing us to account for important clinical variables that are not available in claims data alone. By incorporating these additional data points, hybrid measures aim to improve risk adjustment and provide a more detailed understanding of hospital performance, ultimately supporting efforts to improve patient care. We will continue working with stakeholders and monitoring hospitals' experiences with reporting on these measures.

Comment: A few commenters raised concerns about the potential unintended consequences of readmission measures as a whole, such as increased mortality rates and disproportionate penalties for hospitals serving low-income populations.

Response: We acknowledge commenters' concerns about readmission measures. The Hybrid HWM measure was developed as a balancing measure to the Hybrid HWR measure to decrease the potential unintended consequence of increasing mortality due to reducing readmissions. We note that since the implementation of the condition-specific mortality and readmission measures, there has been a reduction in readmission rates, without an accompanying increase in mortality.[365] Additionally, the hybrid measures aim to improve upon existing readmission measures by incorporating clinical data that better accounts for patient complexity and social risk factors. This enhanced risk adjustment aims to ensure a more comprehensive evaluation of hospital performance, particularly for hospitals serving low-income populations.

Comment: A commenter urged CMS to remove the hybrid measures altogether until standardized EHR interoperability and infrastructure are universally available, and they shared that these measures present a disproportionate burden on hospitals with little clinical value due to costly manual abstraction of certain data elements and unfairly penalize smaller resource-constrained hospitals. Another commenter emphasized the burden of reporting this measure and urged CMS to simplify the measure requirements due to the complexity and labor costs associated with implementation that take away from direct patient care, especially during ongoing workforce shortages.

Response: We thank the commenters for their input. While we recognize that standardized EHR interoperability is not yet universally available, the hybrid measures are an important step toward leveraging clinical data to improve quality measurement. The hybrid measures utilize EHR data for risk adjustment, based on stakeholder feedback that the claims-only measures did not adequately account for clinical risk factors.

We acknowledge the concerns about the reporting burden associated with hybrid measures, particularly with ongoing workforce shortages. The hybrid measures are designed to leverage data that hospitals are already collecting as part of routine clinical care, which should help minimize additional workload. We have already taken steps to reduce manual abstraction by promoting the use of automated data extraction from EHRs and will continue working with stakeholders to refine the measures as necessary.

After consideration of the public comments we received, we are finalizing our proposal to decrease the hybrid measures CCDE and linking variable submission thresholds beginning with the FY 2028 payment determination.

8. Hospital IQR Program Extraordinary Circumstances Exception (ECE) Policy

a. Background

Under our current Extraordinary Circumstances Exception (ECE)

[363] eCQI Resource Center. May 2025. Core Clinical Data Elements for the Hybrid Hospital-Wide Readmission Measure with Claims and Electronic Health Record Data—HWR. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2026/cms0529v6?qt-tabs_measure=specifications-and-data-elements.*

[364] eCQI Resource Center. May 2025. Core Clinical Data Elements for the Hybrid Hospital-Wide All-Condition All-Procedure Risk-Standardized Mortality Measure—HWM. Available at: *https://ecqi.healthit.gov/ecqm/hosp-inpt/2026/cms0844v6?qt-tabs_measure=specifications-and-data-elements.*

[365] Ko, D., Khera, R., Lau, G. et al. Readmission and Mortality After Hospitalization for Myocardial Infarction and Heart Failure. JACC. 2020 Feb, 75 (7) 736–746. *https://doi.org/10.1016/j.jacc.2019.12.026.*

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.[366] 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.[367]

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 proposed 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. Update to the Extraordinary Circumstances Exception (ECE) Policy for the Hospital IQR Program

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18344), we proposed 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 proposed 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 proposed (90 FR 18344) 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.[368] At proposed § 412.140(c)(2)(ii)(A), we proposed 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 change would align the Hospital IQR policy with CMS systems implementation requirements across all quality reporting programs. Under this proposed codified policy, we clarified 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 proposed that CMS would 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 proposed 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 updated ECE policy would provide further reporting flexibility for hospitals and clarify the ECE process.

We invited public comment on our proposals.

Comment: Many commenters expressed support for CMS' proposal to update and codify the ECE policy across hospital quality reporting programs. Commenters appreciated CMS' efforts to codify its authority to grant reporting deadline extensions or exceptions in response to extraordinary circumstances, recognizing this flexibility as critical for hospitals facing natural disasters or other emergencies. Commenters also noted that codifying updates to the ECE policy would provide hospitals with greater clarity and consistency in navigating quality reporting requirements during extraordinary events. A few commenters specifically supported the proposal to update and codify CMS' ability to grant ECEs to hospitals even if those hospitals have not requested an exception. A commenter supported the proposal to allow hospitals 30 days to submit an ECE request.

Response: We thank the commenters for their support.

Comment: Several commenters urged CMS to explicitly include cyberattacks as qualifying extraordinary circumstances under the ECE policy. Commenters emphasized that cyberattacks are increasingly frequent in the healthcare industry and can debilitate data systems for extended periods, disrupting hospitals' data collection and reporting. A few commenters highlighted the burden associated with reverting to manual documentation practices during cyberattacks and the challenges of later integrating this data into electronic systems. A commenter urged CMS to provide additional clarification on its process for approving ECE requests related to cyberattacks, including publicly posting any supplemental documentation that would aid in requesting an ECE.

Response: We thank commenters for their recommendations. We note that extraordinary circumstances are not limited to the examples provided in § 412.140(c)(2). We have received and accepted multiple ECE requests due to cyberattacks across reporting programs. We recommend that hospitals submit an ECE request anytime an event beyond the control of a hospital affects the ability of the hospital to comply with one or more reporting requirements with respect to a fiscal year, regardless of whether it was included in the examples provided in the CFR language. We note that QualityNet provides the ECE Request Form, ECE Information and Resources document, and ECE Quick Reference document, all of which are updated as necessary. We will continue to update these documents to provide updated information, resources, and references.[369]

[366] 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.*

[367] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

[368] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

[369] We refer readers to the Hospital IQR Program ECE web page, available at: *https://*

Comment: Several commenters, while supporting this proposal, cautioned CMS to avoid defaulting to extensions in cases where broader relief is warranted, and ensure reporting extensions are not disproportionately utilized in place of exceptions. Commenters also urged CMS to recognize that a mere extension is not always sufficient, as the reliability and integrity of data collected during extraordinary events may be compromised. A few commenters urged CMS to provide details on how the determination of an exception versus an extension will be made to ensure transparency. A commenter noted this transparency will allow hospitals to better prepare for response times and required resources based on whether they are likely to receive an exemption or an extension.

Response: We appreciate commenters' concerns regarding the use of extensions for ECE requests. We note that we do not intend to replace exemptions with extensions and acknowledge that extensions are not always appropriate or technically possible. The determination of an exception versus an extension will be approved on a case-by-case basis based on the specifics of the circumstance affecting the hospital.

Comment: A commenter supported the inclusion of the Severe Sepsis and Septic Shock Management Bundle (SEP–1) measure within the ECE process and recommended that newly mandated measures, such as the Hospital-Level Total Hip Arthroplasty/Total Knee Arthroplasty Patient-Reported Outcome-Based Performance measure (THA/TKA PRO–PM), be incorporated into the ECE policy annually.

Response: We note that this policy is inclusive of any measures within the program, regardless of when the measure was adopted.

Comment: Several commenters did not support the reduced timeframe for hospitals to request an ECE from the current 90-day period to 30 days following an extraordinary circumstance. Commenters stated that the proposed 30-day window is insufficient for hospitals to respond to a crisis, assess the impact on data collection and systems, and submit a request for an exception. Commenters highlighted examples, such as severe flooding and ransomware attacks, where hospitals were fully engaged in patient care and operational recovery, leaving little capacity to prioritize administrative tasks like ECE requests. A few commenters expressed concern that the reduced timeframe encourages hospitals to divert critical staff at a time they are needed most and would force them to prioritize paperwork over patient care, undermining the goals of the CMS quality reporting and value programs. A commenter requested that CMS review past ECE submissions to assess the feasibility for hospitals to meet a 30-day response deadline and disclose its justification for the readjustment.

Several commenters urged CMS to retain the current 90-day window, which they stated provides a more reasonable timeframe for hospitals to recover and assess the impact of extraordinary events. A commenter suggested a compromise of 60 days to provide hospitals with more flexibility while still encouraging timely notification to CMS. The commenter also urged CMS to retain discretion to accept late requests in extraordinary circumstances, such as if communication lines are down for an extended period, to ensure that hospitals are not unfairly punished for failing to report data during a crisis.

Response: We appreciate commenters' concern regarding the reduced timeframe for hospitals to submit an ECE request. We recognize that hospitals may not have the ability to assess the impact on quality data submissions and complete the necessary paperwork within 30 days of the extraordinary circumstance. Due to concerns regarding hospitals' ability to complete the ECE request within 30 days of the extraordinary circumstance, we are modifying the timeframe to allow for 60 days to submit an ECE request. We believe this timeframe will provide sufficient time for hospitals to assess the impact on quality reporting without disrupting operational and care needs.

After consideration of the public comments, we will finalize our ECE proposals as proposed, except for the proposed 30-day deadline. In lieu of the 30-day deadline, we will finalize an ECE deadline of 60 days following an extraordinary circumstance. We are making conforming amendments to our regulation text (at § 412.140(c)(2)(ii)(A)) to reflect this policy change.

D. 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. 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18344 through 18345), we proposed 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 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

qualitynet.cms.gov/inpatient/iqr/participation#tab3 for reference materials.

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.

We stated that if the proposed removal is finalized, any HCHE measure data received by CMS would not be used for public reporting purposes.

We invited public comments on our proposal to remove the HCHE measure from the PCHQR Program beginning with the CY 2024 reporting period/FY 2026 program year.

We received many general comments regarding our proposed removal of the HCHE measure. We focus here on comments specific to removing this measure from the PCHQR Program. For our responses to general comments, we refer readers to our responses in the Hospital IQR Program section of this final rule (section X.C.4.a.).

Comment: A commenter expressed concern regarding removal of the HCHE measure, stating that public reporting on hospital performance fosters transparency and helps patients make informed decisions about where to seek care, which is especially important for patients with complex conditions such as cancer.

Response: We thank the commenter for sharing this concern. We are removing these measures from the PCHQR Program to reduce the burden incurred by patients and providers for screening, data storage, and data reporting. We note that the other quality measures in the PCHQR Program continue to be publicly reported to allow patients to make informed decisions about their care.

Comment: A commenter recommended that CMS consider ways that health equity can be integrated into cancer-specific outcome, patient experience, or quality-of-life measures.

Response: We thank this commenter for this recommendation and will consider this input in future measure development. PCHs may use a range of strategies to ensure positive outcomes for their patients and we encourage PCHs to pursue strategies that support efficient and high-quality care for all patients.

After consideration of the public comments we received, we are finalizing the removal of the HCHE measure as proposed.

b. Removal of Two Social Drivers of Health Measures Beginning With CY 2024 Reporting Period/FY 2026 Program Year and for Subsequent Years

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18345), we proposed 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 proposed 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 (90 FR 18345). 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. As stated in section XIII.B.5.d of the proposed rule, removal of Screening for Social Drivers of Health measure would alleviate an estimated annual burden for hospitals and patients of 29 hours, at a cost of $773 for 6 PCHs for the FY 2026 program year and 103 hours, at a cost of $2,699, across all PCHs for the FY 2027 program year (90 FR 18411). Also, as stated in section XIII.B.5.e. of the proposed rule, removal of Screen Positive Rate for Social Drivers of Health measure would alleviate an estimated annual burden of 1 hour, at a cost of $55 for 6 PCHs for the FY 2026 program year and 2 hours, at a cost of $111, across all PCHs for the FY 2027 program year (90 FR 18411).[370] Further, we noted 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 (90 FR 18345). We stated that the costs of the use of these measures in the PCHQR Program outweigh the benefits to beneficiaries and providers at this time. 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.

We stated in the proposed rule (90 FR 18345), that, if finalized, any SDOH measure data received by CMS would not be used for public reporting purposes.

We invited public comment on our proposal to remove the SDOH measures from the PCHQR Program beginning with the CY 2024 reporting period/FY 2026 program year.

We received many general comments regarding our proposed removal of the SDOH measures. We focus here on comments specific to removing these measures from the PCHQR Program. For our responses to general comments we refer readers to our responses in the Hospital IQR Program section of this final rule (section X.C.4.c.).

Comment: A few commenters recommended that CMS consider how social risk factors can be integrated into future outcome, patient experience, or quality-of-life measures specific to cancer treatment. A commenter stated that patients with cancer are at increased risk for financial distress, which can impact their quality of life, mental health, and satisfaction with social activities and relationships. The commenter emphasized the importance of addressing social needs as part of broader efforts to improve health and well-being, particularly for vulnerable populations like cancer patients.

Response: We appreciate commenters' concerns regarding the role SDOH can have on patient outcomes and will consider this risk in development of future measures. We expect PCHQR Program participants to continue to provide appropriate, high-quality care to all their patients. We agree that

[370] We note that in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18345) we state that ''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).'' We have updated the burden in this final rule to more accurately reflect the estimated impact.

addressing social needs is an important effort in improving health and well-being for patients, particularly for vulnerable populations like patients with cancer, and that healthcare outcomes may be different for those experiencing financial distress. Hospitals may find ways to address these concerns in their workflow, including connecting patients with community resources that would address patients' needs and provide appropriate referrals, because they recognize the importance of these items. The removal of this requirement should not preclude hospitals from collecting and using this information. Hospitals will still be able to screen patients for SDOH related concerns, but they will not be required to report on these screenings or results.

After consideration of the public comments we received, we are finalizing the removal of the two SDOH measures as proposed.

c. Summary of Adopted PCHQR Program Measures for the CY 2026 Reporting Period/FY 2028 Program Year and Subsequent Years

Table X.D.–01 summarizes the finalized measures for the PCHQR Program measure set beginning with the CY 2026 reporting period/FY 2028 program year.

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TABLE X.D.-01: FINALIZED MEASURES FOR THE PCHQR PROGRAM MEASURE SET BEGINNING WITH THE CY 2026 REPORTING PERIOD/FY 2028 PROGRAM YEAR

Short Name	Consensus-Based Entity (CBE) Number	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
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

*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.

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: 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) • 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)	2019 and subsequent years
• 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) • CLABSI* (CBE #0139)	October 2022 and subsequent years
• 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) • 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)	July 2024 and subsequent years
• Surgical Treatment Complications for Localized Prostate Cancer Measure (PCH-37)	July 2024 and subsequent years
• 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

*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 final rule for more detailed discussion of technical updates to re-baseline CDC's NHSN Healthcare-Associated Infection measures for the HAC Reduction Program.

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b. Public Reporting of 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18347), we proposed 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 proposed 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 proposed 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 proposed corresponding changes to the regulation text at § 412.24(f) replacing references to ''Provider Data Catalog'' with ''CMS websites''.

We invited public comments on our proposal to publicly report PCHQR data on both the Provider Data Catalog and Compare tool or successor websites.

Comment: Several commenters supported the proposal to publicly report data from the PCHQR Program on the Compare tool in addition to the Provider Data Catalog. A few of these commenters noted that data displayed on the Compare website would be more user friendly, thus promoting interpretability and transparency. Additionally, a few commenters highlighted that presenting quality-of-care metrics in a more accessible format on the Compare website would empower patients, families, and referring providers to make well-informed decisions about where to seek intensive cancer care. A commenter noted that choosing a cancer care provider is a critical decision and patients should have easy access to quality-of-care data to support care decisions.

Response: We thank commenters for their support. We agree that publishing data on the Compare website will increase interpretability and transparency, which is critical for consumer engagement.

Comment: A commenter stated that PCHQR data should only be compared between hospitals in the PCHQR Program to maintain data validity and accuracy.

Response: We thank this commenter for their support and recommendation. We proposed to publish data on the Compare tool, in addition to the Provider Data Catalog, to allow consumers to more readily compare quality of care delivery among PCHs. We will consider how best to display the data so that consumers can readily understand and compare data between PCHs.

Comment: A commenter recommended that CMS re-engage stakeholders before making the PCHQR data using the updated 2022 NHSN rebaseline publicly available.

Response: We will consider this commenter's recommendation to re-engage stakeholders before making data using the updated 2022 NHSN baseline publicly available, however, we reiterate that PCHs have an opportunity to review their data prior to publication during a preview period via the Hospital Quality Reporting (HQR) system.

After consideration of the public comments received, we are finalizing our proposal to publicly report PCHQR data on both the Provider Data Catalog and the Compare tool or their successor websites.

4. Codification of 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.[371] 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.[372]

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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18347 through 18348), we proposed 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 requirement if CMS determines that this type of relief would be appropriate under the circumstances.

b. Update to the Extraordinary Circumstances Exception (ECE) Policy for the PCHQR Program

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18348), we proposed 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 § 412.24(e)(1), we proposed 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

[371] 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.*

[372] CMS QualityNet. Available at: *https://qualitynet.cms.gov/pch/pchqr/participation#tab2.*

applicable reporting requirements with respect to a fiscal year.

We proposed 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.[373] At § 412.24(e)(2)(i), we proposed 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 § 412.24(e)(2)(ii), we proposed 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 proposed that CMS may grant an ECE to one or more PCHs 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 § 412.24(e)(4), we proposed 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 proposed 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 invited public comment on our proposal to update the ECE policy for the PCHQR Program with corresponding updates to regulatory text at § 412.24(e).

We received many general comments regarding our ECE-related proposals. We did not receive any comments specific to these updates for the PCHQR Program. For our responses to general comments we refer readers to our responses in the Hospital IQR Program section of this final rule (section X.C.8.). As discussed in section X.C.8 of this final rule in response to commenter concerns, we recognize that hospitals may not have the ability to assess the impact on quality data submissions and complete the necessary paperwork within 30 days of the extraordinary circumstance. Due to concerns regarding PCHs' ability to complete the ECE request within 30 days of the extraordinary circumstance and a commenter suggestion to increase to a 60-day deadline, we are modifying the timeframe to allow for 60 days to submit an ECE request. We believe this timeframe will provide sufficient time for PCHs to assess the impact on quality reporting without disrupting operational and care needs.

After consideration of the public comments, we will finalize our ECE proposals as proposed, except for the proposed 30-day deadline. In lieu of the 30-day deadline, we will finalize an ECE deadline of 60 days following an extraordinary circumstance. We are making conforming amendments to our regulation text (at § 412.24(e)) to reflect this policy change.

E. 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) of the Act 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 final rule, we finalize our proposal 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 this final rule. We also finalize our proposal 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 finalize our proposal to amend our reconsideration policy and process as described in section X.E.4. of this final rule. Finally, we provide summaries of the public comments received in response to several requests for information (RFIs), specifically on: (1) future measure concepts for the LTCH QRP as described in section X.E.5 of this final rule; (2) revisions to the data submission deadlines for assessment data collected for the LTCH QRP as described in section X.E.6. of this final rule; and (3) advancing digital quality measurement (dQM) in the LTCH QRP as described in section X.E.7. of this final 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 did not propose to adopt any new measures for the LTCH QRP.

[373] *https://qualitynet.cms.gov/inpatient/iqr/participation#tab3.*

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).

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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 (CAUTI) 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)
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.

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3. 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.[374] They have specifically noted

[374] 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

Continued

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).[375] 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 proposed 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 proposed 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 proposed 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 invited 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. A summary of comments received and our responses follow.

Comment: Several commenters supported CMS's proposal to modify reporting requirements for the Patient/Resident COVID–19 Vaccine measure, citing support for reducing the administrative burden in the LTCH QRP. A few commenters agreed that it was challenging to obtain vaccination status after a patient expires, and the information was no longer actionable. Another commenter appreciated CMS's consideration of the burden associated with LCDS collection and support this proposal.

Response: We thank commenters for their support. CMS continually looks for opportunities to work with LTCHs in order to balance data collection requirements and quality care delivered to the patient.

Comment: A commenter supported the modification of reporting requirements and recommended that CMS implement this change sooner.

Response: We appreciate the commenter's support. We recognize that with regard to patients who expire in a LTCH, assessing for and collecting information on COVID–19 vaccination status is challenging and burdensome. We plan to remove this item from the expired LCDS assessment beginning on October 1, 2026, but since it is not technically feasible to remove this item earlier, we are making submission for data on Patient/Resident COVID–19 Vaccine item (O0350) for expired patients optional for discharges on or after October 1, 2025.

Comment: A commenter supported the removal of this measure from the LTCH QRP, citing the end of the public health emergency, high vaccination rates, and the diminishing relevance of the measure for LTCHs.

Response: We wish to clarify that we did not propose to remove the Patient/Resident COVID–19 Vaccine measure, but to modify reporting requirements to exclude patients who have expired in the LTCH.

After consideration of the public comments, we are finalizing 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. 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 from the LTCH CARE Data Set[376] (LCDS): 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 items 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 the proposed rule, we proposed to remove these four standardized patient assessment items under the SDOH category from the LCDS 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 for data collections regarding quality care and burden that such data collections may have on LTCH providers. One goal we have is 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 items being part of a low burden interoperable electronic system. The focus will turn towards how the data and associated recommendations can improve care coordination, efficiency, reduction in errors and improved patient experience. As health information technology (IT) 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) items using the LCDS beginning with patients discharged on or after October 1, 2026, removing the required collection and reporting of these items that we previously finalized. Under this proposal, these items would not be

December 15, 2023, *https://www.cms.gov/files/document/december-2023-pac-and-hospice-cross-setting-tep-summary-report.pdf-1*.

[375] 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*.

[376] The LTCH CARE Data Set is CMS's required assessment instrument used by LTCHs to collect certain data from patients upon their admission and discharge from the LTCH. See section 1899B of the Act, which requires LTCHs to use Post-Acute Care (PAC) assessment instruments for collecting and submitting to CMS certain standardized patient assessment data as part of PAC quality reporting programs, including the LTCH QRP.

necessary to meet LTCH QRP requirements to avoid a 2 percent payment reduction beginning with the FY 2028 LTCH QRP. In the proposed rule, we calculated that removing these items from the data collection for the FY 2028 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 (90 FR 18350). We refer readers to section XIII.B.6. of this final rule for more details on this estimated burden reduction.

We invited public comment on our proposal to remove these four standardized patient assessment data elements collected under the SDOH category from the LTCH QRP beginning with the FY 2028 LTCH QRP. A summary of comments received and our responses follow.

Comment: Several commenters supported our proposal, citing the burden of data collection. These commenters stated that the items can be time-consuming and detract from direct patient care. A few commenters state that removal of these items will help providers focus their resources on other areas of importance, address quality issues that matter most to patients, and allow LTCH staff to spend more time caring for patients. Two commenters acknowledged that CMS must work towards a balance of provider burden and data collection efforts for quality, ensuring data adds value to its program and advances health care. Another commenter stated support for the removal of the four SDOH items, stating that this will not impact quality of care in LTCHs while noting that the items overlap with existing assessments or other health initiatives.

Response: We thank commenters for their support for our proposal to remove these four SDOH items from the standardized patient assessment data elements collected and submitted using the LCDS. We continue to monitor the LTCH QRP data collection requirements to look for ways to reduce administrative burden, where appropriate, while maintaining a high standard of quality care. We agree that removing these items at this time will alleviate some of the burden on LTCH providers associated with LTCH QRP data collection and submission requirements. We intend to align the LTCH QRP more closely with CMS's overarching goal for improved health care delivery through health IT advances and low-burden interoperable electronic systems. As we stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18350), we plan to refocus efforts on how data elements can improve care coordination, efficiency, reduction in errors, and patient experience.

We appreciate commenters' recognition of having an appropriate balance of burden and value in quality measurement programs, such as the LTCH QRP. By streamlining the number of data elements required for reporting, LTCHs and their staff can focus efforts and resources to address the quality issues that matter most to their patients. As stated in section X.E.6 of this rule, we solicited comment on measurement concepts that address resident well-being while more appropriately reflecting factors that are within practitioners' and facilities' scope of care or where practitioners can provide actionable advice that will help reduce the prevalence of chronic diseases, including nutrition, increased adherence to expected daily thresholds for physical activity, minimization of chronic stressors, and improvements in mental health.

Comment: A commenter supported these items becoming voluntary beginning October 1, 2025, and phased out of the LTCH QRP altogether by FY 2028.

Response: We wish to clarify that these items were finalized to be collected beginning with patients discharged on or after October 1, 2026, and were never intended to be voluntary. They do not appear on the current version of the LTCH Care Data Set (LCDS, Version 5.1). We did not propose to modify these four SDOH items to be optional items on the LCDS that LTCHs could voluntarily report. Because we are finalizing our proposal to remove these items as proposed, they will not be added to the next version of the LCDS.

Comment: Many commenters were opposed to CMS's proposal to remove the four SDOH items from the LCDS and urged CMS to reconsider the proposal. These commenters stated that this data adds value to LTCHs, who serve some of the most vulnerable patients in the health care continuum. The commenters stated certain literature on how screening for SDOH improves health outcomes and how this information results in a more holistic approach to patient care and discharge planning which facilitates proactive approaches to reduce risks. A few of these commenters stated that removal of these items would leave remaining measures to focus too exclusively on diagnosed conditions at the expense of whole-person care. A few commenters stated these SDOH items were particularly important in caring for patients with complex or chronic conditions including geriatric patients. These commenters also stated that identification and subsequent support of patients' social needs decreased healthcare expenditures, readmissions, inpatient stays, and emergency department visits resulting in both health and financial benefits.

Response: We appreciate commenters' concerns and feedback regarding the importance of collecting these SDOH items from LTCH patients and acknowledge the value that commenters ascribe to the collection of this information for discharge planning and patient care, especially for the LTCH patient population. We also acknowledge feedback from commenters that healthcare outcomes may be different for those experiencing unstable housing, food insecurity or challenges paying utilities.

However, in reviewing the data collection and reporting requirements for the FY 2027 LTCH QRP, we determined that these SDOH items should be removed from the LCDS prior to the start of data collection and submission. We have re-evaluated the value of adding these SDOH items to the LCDS for the purposes of the LTCH QRP against their burden at this time. We considered that LTCHs have not yet begun to report these data, we do not currently have a use for these items in the LTCH QRP, and, these SDOH items are not clinical items related to direct patient care. We also have refocused our efforts on modernization of health care and health care systems. We continuously review and reassess the balance of data collection and LTCH provider burden for the LTCH QRP, and at this time, determined these SDOH items should be removed prior to implementation.

The objectives of the LTCH QRP continue to be the improvement of care and health outcomes for all patients through transparency and quality measurement, while balancing burden on LTCHs and their staff. As outlined in our request for information in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18353 and 18354), we are refocusing our efforts to advance the digital quality measurement transition to include ways for data elements, such as those related to SDOH, to be collected as part of a low-burden interoperable electronic system. Given these administrative goals and efforts to reduce burden for LTCHs, we do not believe that the collection of these SDOH items via the LCDS assessment outweighs the cost and burden of collecting them at this time.

At this time, we believe that halting the implementation of the four SDOH items prior to their being added to the LCDS on October 1, 2026 removes the

burden these data collection requirements and submission would impose on LTCHs before most training activities, data collection, reviews of the guidance manuals, and other implementation tasks have occurred.

Comment: A few commenters noted standardized items on the LCDS improve consistency and the exchangeability of information and further support LTCH providers in administering a comprehensive plan of care in accordance with CMS's regulation. A commenter urged CMS to retain the SDOH items until a more efficient electronic health record (EHR) data collection framework was in place. A few commenters stated that the cost and burden does not meaningfully outweigh the value of collecting this information, which includes being able to more accurately measure the quality of care in LTCHs by determining whether the influence of poor outcomes is through factors outside the influence of the facility. These commenters added that assessing SDOH for patients improves coordination between facilities and community care providers ensuring that Medicare dollars are spent efficiently and facilitating high quality care across settings.

Response: We acknowledge the value that commenters ascribe to the collection of this information for discharge planning and care coordination, and commenters' experiences with improving outcomes and facilitating high quality care through improved coordination between providers. We agree with the commenters that the exchangeability of information is important for a comprehensive plan of care. CMS intends to work towards the workflow and data exchange for items being part of a less burdensome interoperable electronic system. We appreciate the commenter's suggestion to retain the items until a more efficient health IT infrastructure and data collection framework is in place. However, all data collection requirements have inherent burden associated with collection and we strive to balance that burden with the value of measuring the quality of care that patients receive. Data collection for these four SDOH items would be burdensome on LTCHs and there is no current or planned use for the data in the LTCH QRP at this time. As we have stated, LTCHs can continue to collect this information to inform discharge planning but, for the purposes of the LTCH QRP, we are finalizing our proposal to remove these four items from the LCDS before implementation begins. This means that LTCHs would not need to submit this information to meet requirements of the LTCH QRP. With the alleviation of this data collection requirement, LTCHs could redistribute their resources toward efforts to improve or enhance clinical care, health IT, or other areas as determined by the LTCH.

Comment: A commenter stated CMS provided extensive support and rationale for adopting these four items in the FY 2025 IPPS/LTCH PPS final rule, developing a policy that was well-vetted and examined in detail. This commenter stated that CMS has not provided any reasoning or explanation in our proposal in the FY 2026 IPPS/LTCH PPS proposed rule as to why these are no longer important or how circumstances have changed to necessitate their removal.

Response: We reiterate that, in the proposed rule, we explained that the removal of these items is a result of CMS's focus on balancing the need for data collections regarding quality care and the burden of these data collection on LTCHs and their staff (90 FR 18350). We would also like to reiterate that LTCHs and their staff independently may determine to screen their patients for factors that may affect their clinical decision-making, even in the absence of a reporting requirement. We did not intend to suggest with our proposal to remove these items from LTCH QRP requirements that LTCHs should cease collecting this or similar information for other purposes, such as the LTCH's patient-specific assessment of needs in developing a discharge plan as required by 42 CFR 483.43. Rather, we are removing these four SDOH items from the LCDS to reduce the burden of data collection and submission for the LTCH QRP. Reducing the burden of LTCH QRP requirements would enable LTCHs and their staff to focus their efforts on clinical decision making by preserving clinicians' flexibility to address social risk factors in other ways that are tailored to the needs of and make the most sense for their patient populations.

We understand implementation efforts to collect and submit any data elements for the purposes of meeting LTCH QRP requirements is inherently burdensome for LTCHs and their staff, particularly adopting and implementing new data elements since they involve adjustments to health IT systems and EHRs, workflows, and staff trainings. We are always reviewing and reassessing this balance of data collection and LTCH provider burden for the LTCH QRP.

For these four SDOH items, we reconsidered the value of their collection and submission to CMS for the purposes of the LTCH QRP against their burden at this time. We specifically considered that these items are not clinical in nature. While they reflect certain aspects of a patient's health that may inform clinical decisions, they are not factors within the scope of care an LTCH and its staff provides. Furthermore, if maintained on the LCDS, there is currently no use for these items in risk adjustment models, reporting of LTCH measure results, or the development of new quality measures. We proposed removal of these four SDOH items from the LCDS because LTCHs have not started data collection for these items yet, we are not utilizing the information for any purpose at this time, and there is an agency-wide refocusing on modernization of health care and health care systems and on engaging LTCHs and their staff with these health IT efforts. We are working towards developing less burdensome data collection methods as we believe leveraging technological advances and data modernizations can streamline standardization of the LCDS in ways that support interoperable patient data and reduce time spent collecting this data by LTCHs and their staff. We strive to collaborate with LTCH providers in these efforts as exhibited in our request for information on advancing digital quality measurement (dQM) in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18353 and 18354). This collaboration includes reducing the burden of paperwork for participating in the LTCH QRP, where possible, to support LTCH providers in moving towards health data technology and interoperability that promotes spending more time with patients. LTCHs are welcome to continue collecting this information to inform care coordination and discharge planning.

Comment: Many commenters stated that the SDOH items provide important insights into housing, food, and utility insecurity, which affect patient outcomes and that removing these SDOH items is counter to national efforts aimed at improving health outcomes, including current CMS agency goals related to the development of patient nutrition, physical activity, and well-being measures. The commenters stated that the SDOH items could be utilized to support the Make America Healthy Again initiative's core mission of a more efficient, prevention-focused health care system through the treatment of expensive complications that could be prevented through early identification of risks.

A few commenters encouraged CMS to specifically retain the items related to nutrition. These commenters stated that

nutritional risk is often linked to readmissions and overall health outcomes, especially for patients in rural and underserved areas. They also felt addressing food insecurity can reduce preventable healthcare cost, adding an estimated $53 billion annually, and disproportionately affects individuals with or at risk for diet-related diseases, such as patients with diabetes.

Response: We disagree but understand why LTCH providers believe that removal of these items is counter to our national efforts aimed at improving health outcomes. In response to comments about the agency's goals related to nutrition and well-being, we do not believe these four SDOH items are the only foundational items needed for future measure development related to nutrition. As we finalized in the FY 2025 IPPS final rule (89 FR 69585 and 69586), the two Food items (R0320A and R0320B) assess one particular aspect of nutrition: food availability and food security. These items do not encompass other relevant, meaningful information to improve patients' health outcomes, including healthy nutrition, sleep, and physical activity levels. In addition, there are other existing data elements on the LCDS that could support the development of measure concepts we are considering in the future. For example, the LCDS includes other nutrition items in Section I and K. To reiterate, at this time, we are removing these SDOH items to refocus efforts and resources towards a less burdensome interoperable system for LTCHs participating in the LTCH QRP and existing LCDS items, such as the standardized patient assessment data elements in Section K that were finalized in the FY 2020 IPPS final rule (84 FR 42564 through 42568), provide a foundation for building out nutrition measures.

We would also like to note that CMS is currently considering other ways to measure nutrition in our RFI on potential future measures in the LTCH QRP. In the proposed rule (90 FR 18352 and 18353), we stated that preventable care, including assessment of an individual's nutritional status, 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. With regard to well-being, we are soliciting comment on ways to improve patient well-being across the Medicare programs and we remain committed to identifying the needs of patients and supporting LTCHs in addressing those risks in a way that best accounts for patients' clinical circumstances with minimal burden. We also remain committed to supporting LTCHs and their staff in addressing health risks and needs of at-risk populations such as those experiencing challenges with maintaining healthy nutrition and physical activity levels and managing or improving chronic stressors, mental health concerns, and chronic diseases.

Comment: A few commenters were concerned that many healthcare facilities across the country have already made substantial investments to incorporate the screening of these SDOH items into setting up systems, electronic health records, and workflows. These commenters stated that this would amount to more than ongoing implementation costs, and that hospitals and other settings expecting to report these items have already expended the necessary resources to set up their systems and referral programs. These commenters stated that removing these SDOH items does not reduce their prior investments and may result in additional resources to rework their systems. A few other commenters stated that many healthcare organizations have already invested in incorporating SDOH screening into their admissions processes and care coordination workflows.

Response: We acknowledge the commenters' concerns and understand the time and resources that LTCHs may have spent anticipating the requirement to collect these items as part of the LTCH QRP. Since the inception and initial development of the LTCH QRP, interested parties have requested we provide draft specifications for the upcoming release of the revised LCDS as early as possible. We have been responsive to this request and aim to provide as much information as possible when that information is available. However, we would like to emphasize that the information released consists of draft LCDS data specifications, not final specifications, and that the LCDS data specifications cannot be finalized until CMS policies are finalized after the final rule is released.

We also note that the time and resources spent to build technical infrastructure accounts for only a portion of the overall cost we considered, which also includes training activities, continuous data collection, reviews of the guidance manuals, and other implementation tasks. Collecting these SDOH items is not a one-time task but an ongoing requirement for every LTCH patient admitted to the facility. As a result, we believe removing these items before data collection begins will still save LTCHs and their staff time, money, and resources.

After consideration of the public comments, we are finalizing our proposal to remove four standardized patient assessment data elements collected under the SDOH category (one item for Living Situation (R0310); two items for Food (R0320A and R0320B); and one item for Utilities (R0330)) from the LTCH QRP beginning with the FY 2028 LTCH QRP without modification.

5. Proposals To Amend the Reconsideration Request Policy and Process

a. Background

In the 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 final 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 proposed to remove the term ''extenuating circumstances'' as used currently in our reconsideration policy and replace it with ''extraordinary circumstances.'' Specifically, we proposed 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 proposed to incorporate our prior explanation regarding the meaning of the term 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 proposed 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 proposed 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 proposed 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 proposed to codify this process at § 412.560(d)(4).

We further proposed 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 proposed 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 proposed to codify this process at § 412.560(d)(5).

We note that we proposed similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invited 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).

The following is a summary of the public comments received and our responses:

Comment: Several commenters supported the proposed revisions, particularly the efforts to address inconsistencies in the reconsideration policy. Several of these commenters appreciated CMS's recognition that extraordinary circumstances, such as disasters, can prevent timely filing of

reconsideration requests. A commenter encouraged CMS to consider adopting similar policies across its other quality and value-based programs.

Response: We thank commenters for their support.

Comment: A commenter supported CMS's proposal to allow an extension of time to submit a request for reconsideration but opposed shortening the timeframe for submitting an ECE request from 90 days to 30 days following an extraordinary event, stating that a 30-day window is simply too short for hospitals that are in the midst of responding to a disaster.

Response: We appreciate the commenter's concerns and recommendations, though we find aspects of the comments to be unclear. We interpret the commenter to mean that they believed our proposed 30-day deadline would apply to the exception and extension (ECE) process for data submission, rather than the ability to request an extension due to extraordinary circumstances during the reconsideration process following a determination of noncompliance.

We wish to clarify the proposed policies do not modify either the deadline for submitting an ECE request during the reporting period, or the deadline for submitting a reconsideration request, but specifically address an LTCH's ability to submit a request for an extension to submit the reconsideration request. This policy establishes that providers impacted by an extraordinary circumstance within the reconsideration time frame will have 30 days to request an extension to file their reconsideration request after receipt of the CMS initial notice of noncompliance for a given fiscal year annual payment update. LTCHs still have 90 days to submit an exception and extension request from the time of an extraordinary event, and 30 days from the initial notification of noncompliance to submit a request for reconsideration. Because our current policy does not specify a deadline for an LTCH to submit its request for such an extension (79 FR 50317) during the reconsideration period, we are providing a clear timeframe of 30 days for this process.

Comment: Several commenters opposed CMS's proposal to remove the ''extenuating circumstances'' standard from the LTCH QRP reconsideration policy. They stated that this standard was established in the FY 2015 IPPS/LTCH PPS Final Rule and has been upheld by federal courts (79 FR 50317). Commenters urged CMS to reaffirm and codify this standard in regulation as a valid and independent basis for reversing a payment penalty, separate from demonstrating full compliance. Another commenter emphasized that ''extenuating'' and ''extraordinary'' circumstances are not synonymous.

Response: We appreciate commenters' feedback and recognize the historical use of the term ''extenuating circumstances'' in prior rulemaking and administrative decisions. However, as noted in the proposed rule, CMS identified inconsistencies between regulatory text and preamble language and is using this rulemaking to clarify and align the LTCH QRP reconsideration policy with other post-acute care quality reporting programs. The intent of this clarification is to promote consistency, not to reduce flexibility. Moving forward, CMS will use the single term ''extraordinary circumstances,'' defined as circumstances beyond the LTCH's control, to standardize the basis for reconsideration. We believe this approach enhances transparency and improves alignment across quality reporting programs.

In response to the commenter who stated that ''extenuating'' and ''extraordinary'' circumstances are not synonymous, we agree with this distinction and proposed using ''extraordinary circumstances'' to establish a clear, program-wide definition that reflects events beyond a provider's control. This approach aligns with policies used in other CMS quality reporting programs. CMS remains committed to reviewing documentation requesting an extension to file a reconsideration request on a case-by-case basis and will continue to consider all relevant evidence demonstrating that circumstances outside of the LTCH's control impacted their ability to file a reconsideration request within the 30-day deadline.

After consideration of the public comments, we are finalizing our proposal 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 (d)(5).

c. Update to 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 proposed 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 proposed 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 noted that we considered proposing similar modifications across all post-acute care setting quality reporting programs to more closely align the reconsideration processes.

We invited 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).

The following is a summary of the public comments received and our responses:

Comment: Commenters requested that CMS continue to allow LTCHs to raise extraordinary circumstances during the reconsideration appeal process. These commenters also requested that CMS reverse a payment penalty during the reconsideration process if an LTCH provides evidence of extraordinary circumstances that prevented timely submission of data, even if the LTCH did not previously submit an exception request to CMS.

Response: We appreciate commenters' input on the reconsideration process. We clarify that LTCHs will be considered compliant if an exception or extension request (ECE) was submitted and approved under § 412.560(c). However, in order to be considered compliant, the ECE must have been both submitted and approved prior to the reconsideration request.

LTCHs may not submit an ECE as a basis for requesting reconsideration in response to a notice of noncompliance. The ECE process requires that requests be submitted within 90 calendar days of the extraordinary circumstance event, as outlined in the current policy. During the 30-day reconsideration period, providers may also request an extension to file the reconsideration if they experienced extraordinary circumstances that prevented timely submission of the reconsideration request.

Comment: Commenters had concerns about the change in terminology from ''extraordinary'' to ''extenuating'' and circumstances. They cited legal definitions to demonstrate that extenuating circumstances involve a reduction in culpability, whereas extraordinary circumstances imply highly unusual events. They expressed concern that removing ''extenuating circumstances'' narrows the scope of acceptable reasons for reconsideration and removes an avenue for more subjective, contextual review.

Response: We interpret these comments to mean that commenters are opposed to the use of ''extraordinary circumstances'' as a basis for reconsideration of a notice of noncompliance. We wish to clarify that we are proposing to permit LTCHs to request extensions to file reconsideration requests based on extraordinary circumstances in section E.5.b. We are also proposing in section E.5.c to update the bases by which we grant a reconsideration request. Specifically, we would only reverse an initial finding of non-compliance if CMS determines that the LTCH was in full compliance with the LTCH QRP requirements for the applicable program year. We would not consider an LTCH's assertion of ''extraordinary circumstances'' as a new basis for overturning a noncompliance finding during the reconsideration process. While full compliance with the LTCH QRP requirements may include CMS granting an exception or extension to LTCH QRP reporting requirements under our ECE policy at § 412.560(c), we wish to reiterate that the LTCH would need to comply with our ECE policy's requirements, including compliance with the specific scope of the exception or extension as granted by CMS. After consideration of the public comments, we are finalizing our proposal to amend the bases by which we grant a reconsideration request under the LTCH QRP reconsideration policy and to codify this proposed policy.

6. LTCH QRP Measure Concepts Under Consideration for Future Years—Request for Information (RFI): Interoperability, Well-Being, Nutrition & Delirium

In the proposed rule, we sought 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 2025 LTCH PPS proposed rule (89 FR 36350 through 36351), 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 2025 LTCH PPS final rule (89 FR 69594 and 69596) for a summary of the public comments we received in response to the RFI.

We sought input on four concepts for future measures for the LTCH QRP. We refer readers to the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18352 and 18353) for a description of each of the quality measure concepts under consideration for this RFI.

TABLE X.E.-02: FUTURE MEASURE CONCEPTS UNDER CONSIDERATION FOR THE LTCH QRP

Quality Measure Concepts
Interoperability
Well-being
Nutrition
Delirium

We received several public comments with feedback on these measure concepts. The following is a summary of the comments we received.

a. Interoperability

Comment: A few commenters supported the interoperability measure. A commenter recommended CMS to consider a phased approach with financial incentives. Another commenter stated that they would be supportive of the interoperability measure in the LTCH QRP if CMS provided funding for implementation upgrades that are needed to achieve interoperability.

A commenter opposed the measure, saying that LTCH staff responsible for quality reporting are not trained to evaluate the level of readiness for interoperable data exchange. The commenter also noted that CMS has not financially supported information technology systems.

b. Well-Being

Comment: Some commenters supported the measure concept of well-being. A commenter stated that the adoption of well-being would be beneficial in supporting patient care. A few commenters recommended CMS to work with nurses in quality reporting and the use of validated tools. Another commenter noted that well-being relates to SDOH and recommends CMS to consider and account for SDOH before implementing new measures.

Several commenters provided recommendations on assessing the concept of well-being. A few commenters noted that it will be difficult to define and measure the concept. The commenters also recommended that CMS consider a person-centered approach, a focus on supporting pathways in improving well-being, and mechanisms for auditing and transparency when considering well-being integration. Another commenter stated that well-being plays a key role in promoting health and recommends CMS to consider principles such as improving outcomes, meeting patient's needs and harmonized measures when considering new measures. A commenter recommended CMS to use malnutrition from the International Classification of Diseases, Tenth Revision, (ICD–10) coding, and available data on patient loneliness for consideration of the measure. The commenter also noted that CMS should consider mental and physical health of healthcare personnel. Another commenter offered a few recommendations on well-being including prioritizing patients and caregivers, focusing on outcomes important to patients, and allowing flexibility in measurement approaches. Another commenter recommended a technical expert panel to discuss the implementation of the well-being measure.

Some commenters were concerned about a well-being measure. A few noted that there is ambiguity in requirements and questioned how data for the measure will be used. A couple commenters noted that it was not clear how well-being would be assessed or how it is already captured under existing measures. Another commenter noted that the assessment of well-being would be better suited in community health outside of the hospital population. A commenter stated that well-being is a general concept and is difficult to assess without staff that are trained or have expertise in the concept.

c. Nutrition

Comment: Several commenters stressed the importance of nutrition while also providing recommendations for CMS to consider. A commenter recommended that the measure should be evidence-based, actionable, and patient-centered. Another commenter recommended CMS to utilize the Malnutrition Care Score Electronic Clinical Quality Measure (eCQM)for the nutrition measure. A commenter noted that a nutrition-focus measure should reflect the role of Registered Dietitian Nutritionists (RDNs) in preventing and managing chronic diseases. A few commenters recommended CMS to consider SDOH elements when considering the nutrition measure. Another commenter recommended the nutrition measure to include patient's input, goals, and stage of life or illness. A commenter recommends that nutrition should include a screening for food insecurity and elements of SDOH. A commenter recommended using malnutrition ICD–10 codes and existing data to create a framework for nutrition while another commenter recommended CMS to use existing data elements to assess nutrition to reduce provider burden.

A few commenters voiced their concerns of a nutrition measure saying that nutrition is collected in the LCDS, or other existing measure assessments and a new measure would be redundant with the current data collection.

d. Delirium

Comment: A few commenters voiced their support of the delirium measure, stating that the measure is a patient safety issue and impacts patients' health outcomes. A commenter noted that there are existing assessment items that can support the delirium measure such as the Confusion Assessment Method.

A few commenters opposed the measure, stating that the concept is captured in existing measures and protocol, potentially create additional provider burden.

e. Other Suggestions on Future Measure Concepts

Comment: In addition to comments received on the four measure concepts of interoperability, well-being, nutrition, and delirium, we also received comments on concerns and recommendations on future measure concepts in this RFI. A couple of commenters stated that LTCH QRP should consider reducing provider burden, eliminating unnecessary measures and collaborating with stakeholder. A commenter suggested Universal Foundation measures when considering streamlining new measures.

Response: We thank all the commenters for responding to this RFI. While we are not responding to specific comments in response to the RFI in this final rule, we will take this feedback into consideration for our future measure development efforts for the LTCH QRP.

7. Potential Revision of the Final Data Submission Deadline Period from 4.5 Months to 45 Days—Request for Information

In the proposed rule, we requested feedback on this potential future reduction of the LTCH QRP data submission deadline from 4.5 months to 45 days that is under consideration. We refer readers to the proposed rule for the full text of the RFI (90 FR 18353). Specifically, we requested 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.

The following is a summary of the comments we received.

Comments: A commenter supported reducing the data submission timeframe from 4.5 months to 45 days, stating that there is not an added burden by shortening the submission timeframe, as most LTCHs already submit within the 45-day window. A few commenters opposed reducing the data submission timeframe, citing risk for compromised quality of data and a decrease in the number of completed assessments. A commenter stated that this will be a risk in situations where reporting all required assessment information quickly is impossible (for example, emergency discharges and transfers). This commenter stated that the reduced timeframe could put providers at risk of failing to meet the minimum assessment data threshold, resulting in a 2 percent Annual Payment Update (APU) penalty. A commenter suggested that CMS conduct additional analyses and solicit further input from facilities on what timeframe would strike the best balance of feasibility and timeliness.

A few commenters cited special circumstances that could delay reporting, including system outages and changes of ownership (CHOW) where a new owner must obtain access and approvals to the internet Quality Improvement & Evaluation System (iQIES) for staff.

A commenter had concerns that current LTCH systems and workflows would not be able to sustain the change, especially with limited staffing and limited capacity of LTCH IT systems. This commenter noted that few LTCHs have fully automated, real-time reporting pipelines and urged CMS to take a more gradual approach to reducing the data submission timeline. A few commenters stated that CMS should not reduce the data submission timeframe to less than 90 days, stating that the change to 45 days is drastic in scope.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, 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, in the proposed rule, we issued an RFI to gather broad public input on the dQM transition in LTCHs. We also issued an RFI and sought input on the use of Health Level Seven® (HL7®) Fast Healthcare Interoperability Resources® (FHIR®) in certain CMS quality reporting and value-based purchasing programs. We refer readers to the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18354 and 18355).

a. Background

We are committed to improving healthcare quality through measurement, transparency, and public reporting of quality data, and to enhancing healthcare data exchange by promoting the adoption of interoperable health IT that enables information exchange using FHIR® standards. We refer readers to the FY 2026 IPPS/LTCH PPS (90 FR 18354 and 18355) for additional background on the dQM transition.

We also sought 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 this final rule for more information.

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 sought 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 applicable security and patient privacy laws, such as HIPAA and its implementing regulations (the HIPAA Privacy, Security, and Breach Notification Rules)?
- 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? [377]

- 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 invited any feedback, suggestions, best practices, or success stories related to the implementation of these technologies.

We invited 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. The following is a summary of the comments we received.

Comment: Several commenters were supportive of the transition to dQM for the LTCH QRP, stating that this will support more timely and actionable insights. A commenter stated that this transition will reduce the effort needed to develop measures and collect data as well as facilitate payers sharing with providers to inform care delivery in real time. A few of these commenters were supportive but encouraged a phased or ''glide path'' approach to implementation, along with pilot testing and technical assistance. Many commenters had concerns about barriers to dQM. A commenter was concerned that post-acute care (PAC) providers and vendors lack uniform technology capabilities and the IT workforce required for this transition. Another commenter recommended updates to CMS billing, CDC/NHSN and iQIES systems' technical capabilities to support consistency and direct transfer of data from providers. A few commenters recommended that CMS provide technical assistance and adequate timelines for LTCHs to transition. Another supported dQMs but suggested that national infrastructure should be developed first, so that EHRs contain all the necessary data elements specified in FHIR®.

Several commenters recommended that CMS provide funding for LTCHs to update and modernize their systems for FHIR®. A few commenters stated that LTCHs were not included in Meaningful Use funding through the Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009. A commenter stated that LTCHs have a lower level of IT maturity and may need considerable development resources to implement FHIR®-based APIs. This commenter cited costs related to program evaluation, technology development, and staffing, training, and certification costs, which are difficult for LTCHs with tight margins. Commenters recommended grants, direct funding, or incentive opportunities.

Response: We thank commenters for their feedback. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this information to inform future dQM transition work.

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. Modification of 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 this final rule, we proposed 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 proposed 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 proposed 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 invited 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.

We have summarized the comments we received about modifying reporting requirements for the Patient/Resident COVID–19 Vaccine measure in section X.E.3. of this final rule and provided responses. After consideration of the public comments, we are finalizing 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.

10. Policies Regarding Public Display of Measure Data for the LTCH QRP

We did not propose any new policies regarding the public display of measure data in this final 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. 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

[377] For more information about USCDI see *https://www.healthit.gov/isp/united-states-core-data-interoperability-uscdi.*

use of CEHRT for the applicable EHR reporting periods.

In addition to the policies discussed in this final rule, we also refer readers to the CY 2026 Physician Fee Schedule (PFS) proposed rule, where we have proposed to adopt a measure scoring suppression policy beginning with the EHR reporting period in CY 2026 and proposed to suppress the Electronic Case Reporting measure from scoring for the EHR reporting period in CY 2025 (90 FR 32732 through 32736). We invite public comment on those proposals through the CY 2026 PFS proposed rule.

2. EHR Reporting Period in CY 2026 and Subsequent Years

a. Definition of 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18355 to 18356), we proposed to maintain the EHR reporting period for CY 2026 and subsequent years as a minimum of any continuous 180-days. 180-days would be the minimum length, and eligible hospitals and CAHs are encouraged to use longer periods, up to and including the full calendar year. This provides consistency with the EHR reporting period established for CY 2025 and would 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. We proposed 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 to as ASTP/ONC),[378] we stated 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 invited public comment on the 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.

Comment: Many commenters supported our proposal to maintain a 180-day EHR reporting period in CY 2026 for eligible hospitals and CAHs. Several commenters emphasized the importance of flexibility for eligible hospitals and CAHs to manage system upgrades, address technical issues, coordinate with vendors, and implement changes effectively. Several commenters appreciated the stability provided by the 180-day reporting period, citing benefits such as reduced resource strain, effective system implementation, and consistency in reporting timelines. A few commenters supported the 180-day EHR reporting period as a manageable timeframe that allows eligible hospitals and CAHs to focus on improving EHR use without risking penalties due to shorter reporting windows. A commenter stated that the proposal enables better planning and execution for eligible hospitals, CAHs, and organizations.

Response: We thank commenters for their support. We agree that maintaining the 180-day EHR reporting period provides consistency with the prior years' EHR reporting periods and provides eligible hospitals and CAHs the flexibility and stability they may need to develop and update their system, and coordinate with their EHR vendors as necessary. Furthermore, we note that many commenters agreed that the 180-day reporting period is a manageable timeframe to plan, execute, and improve their certified EHR use.

Comment: A few commenters urged CMS to maintain the 180-day EHR reporting period beyond CY 2026, emphasizing the need for sufficient time to safely deploy and test EHR upgrades before the EHR reporting period begins. A commenter recommended that CMS provide an additional year for implementation if the EHR reporting period is further expanded, citing insufficient time to adapt to such changes.

Response: We thank commenters for their comments. We note we proposed to use a 180-day EHR reporting period in CY 2026 and subsequent years, which would continue to be our policy unless we propose a change through future rulemaking. Continuing to improve the interoperability of health information exchange by enabling patients and providers to have more comprehensive and reliable data are key goals of the Medicare Promoting Interoperability Program. We will continue to monitor technological advancements and strive to maintain the consistency, flexibility, and stability of our policies for the EHR reporting period, providing sufficient time for eligible hospitals and CAHs to safely deploy and test EHR upgrades before the EHR reporting period begins. Additionally, we appreciate the recommendations regarding future EHR reporting periods and may consider this for future rulemaking.

Comment: A commenter did not support the proposal stating that a 180-day EHR reporting period may hinder their ability to leverage timely data and optimize certified EHR use. This commenter instead recommended that CMS revert to the 90-day EHR reporting period in CY 2026 because it would preserve flexibility, support data driven decision making, and better align with the Medicare Promoting Interoperability Program's goal to demonstrate meaningful use of CEHRT.

Response: After finalizing the 180-day EHR reporting period for CY 2024 in the FY 2022 IPPS/LTCH PPS final rule (*86 FR 45460* through *45462*), and for CY 2025 in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59259 and 59260), eligible hospitals and CAHs have had more than 3 years of advance planning with their vendors to build upon and utilize investments already made within their infrastructure to meet site-specific needs for implementation. We also note that the EHR reporting period remained at 90-days from adoption for the EHR reporting period in CY 2011 through the EHR reporting period in CY 2023. When we adopted the 90-day EHR reporting period, we indicated that we did not believe a 90-day period would be appropriate in future years because potential delays in implementing CEHRT were limited to the initial implementation of CEHRT (75 FR 44320). Maintaining an EHR reporting period of 180-days for CY 2026 and subsequent years would not impact eligible hospitals' and CAHs' efforts to

[378] 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).

update, implement, and test EHR systems. Reporting data from a longer period provides eligible hospitals and CAHs the opportunity to continuously monitor their performance and identify areas that may require investigation and corrective action. Maintaining the 180-day EHR reporting period in CY 2026 and subsequent years supports the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers.

After consideration of the public comments we received, we are finalizing our 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 we are finalizing these proposed changes at 42 CFR 495.4.

3. Modifications to the Security Risk Analysis Measure

a. Background on the Security Risk Analysis Measure

The HIPAA Security Rule [379] (45 CFR part 160 and subparts A and C of part 164) contains administrative safeguards that covered entities and business associates (45 CFR 160.103) must implement, such as the standard and implementation specifications for security management processes. 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).

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 aspects of meaningful use. We also noted that impermissible disclosures of protected health information, whether unintended, unlawful, or both, could diminish individuals' confidence in EHRs and electronic health information exchange and that ensuring that health information is adequately protected and secured would assist in addressing the unique risks and challenges that may be presented.

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 included the Security Risk Analysis measure.

Prior to the FY 2026 IPPS/LTCH PPS final rule, the Security Risk Analysis measure required eligible hospitals and CAHs to attest ''yes'' or ''no'' as to whether they had conducted or reviewed a security risk analysis, as required by the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(A). Eligible hospitals and CAHs were required to attest ''yes'' to the measure to be considered a meaningful EHR user and avoid a downward payment adjustment. The measure was not scored and did not contribute any points to the total score for the Protect Patient Health Information objective. An attestation of ''no'' resulted in the eligible hospital or CAH not meeting the requirements of 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. Modification of the Security Risk Analysis Measure Beginning With the EHR Reporting Period in CY 2026

As of the EHR reporting period in CY 2025, the Security Risk Analysis measure does not 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 educational resources and information on conducting a HIPAA Security Rule risk analysis available in the U.S. Department of Health and Human Services (HHS) Office for Civil Rights' (OCR) cybersecurity newsletters,[380] OCR's website[381], and YouTube channel,[382] 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,*[383] and the HHS Administration for Strategic Preparedness and Response 405(d) Program and Task Group website.[384]

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18357 to 18359), we proposed to modify the Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required by the HIPAA Security Rule implementation specification for risk management. This proposed modification 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

[379] Under the Biden administration, the Department proposed to modify the HIPAA Security Rule to strengthen the cybersecurity of ePHI(90 FR 898). This proposed rule has not been finalized as of publication of this final rule.

[380] *See* generally *https://www.hhs.gov/hipaa/for-professionals/security/guidance/index.html.*

[381] Guidance on Risk Analysis available at *https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html.*

[382] *See https://www.youtube.com/user/USGovHHSOCR.*

[383] *See* NIST SP 800–66, rev. 2. *https://csrc.nist.gov/pubs/sp/800/66/r2/final.*

[384] *See* generally *https://405d.hhs.gov/resources.*

managing security risks to ePHI associated with the implementation and use of EHRs in accordance with 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 proposed 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.

We proposed the following text for the modified measure, with proposed revised text (as compared to the prior measure text) in italics:

Conduct or review a security risk analysis *and conduct security risk management activities,* in accordance with the requirements under 45 CFR 164.308(a)(1)*(ii)(A) and (B),* including addressing the security of data created or maintained by CEHRT (*to include encryption*), in accordance with 45 CFR 164.312(a)(2)(iv) and 45 CFR 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the *eligible hospital's or CAH's* risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

To meet the requirements of the modified measure, we proposed that eligible hospitals and CAHs would need to separately attest ''yes'' to both components of the 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 objective. 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 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 invited public comment on the 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 for eligible hospitals and CAHs to attest ''yes'' to having conducted or reviewed a security risk analysis as required by the HIPAA Security Rule. We also invited 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.

Comment: Many commenters supported our proposal. Several of these commenters emphasized that requiring eligible hospitals and CAHs to attest to having conducted security risk management activities in addition to security risk analysis aligns with the HIPAA Security Rule and strengthens cybersecurity preparedness. A commenter supported CMS' continued alignment of the Medicare Promoting Interoperability Program's interoperability objectives with national frameworks that advance trust, data integrity, and security. A few commenters agreed that requiring attestation to security risk management activities increases accountability for reducing risks and vulnerabilities to ePHI. They noted that many eligible hospitals and CAHs have already taken steps to prepare for and manage these risks with policies and procedures in place to address cybersecurity risks. They anticipate the additional requirement would help ensure ePHI is adequately protected in organizations that have not adopted such risk management practices. A few commenters noted that the proposal strikes an appropriate balance between safeguarding patient data and minimizing mandatory reporting requirements.

Response: We thank the commenters for their support. We agree that adding the security risk management attestation requirement to the Security Risk Analysis measure aligns with the HIPAA Security Rule and would assist eligible hospitals and CAHs to strengthen their cybersecurity preparedness. We also agree that the change to the Security Risk Analysis measure will increase accountability for reducing risks and vulnerabilities to ePHI while balancing the need to safeguard patient data with minimal reporting requirements. Eligible hospitals and CAHs are required to conduct security risk management activities by implementing security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with § 164.306(a), as covered entities and business associates under the HIPAA Security Rule. We refer readers to the educational resources that the Department has published on performing security risk analyses and other activities for managing security risks, such as OCR's cybersecurity newsletters,[385] OCR's website,[386] and YouTube videos [387] and other resources published by the HHS Administration for Strategic Preparedness and Response through the 405(d) Program and Task Group.[388]

Comment: Several commenters that supported the proposal offered recommendations for consideration. A commenter recommended a phased-in approach to implementation, that we offer technical assistance, and that we provide toolkits to support CAHs and rural hospitals. A few commenters recommended HHS issue guidance on performing security risk management activities. Another commenter recommended providing a voluntary reporting year to allow eligible hospitals and CAHs to integrate the new requirements into existing workflows.

Response: We thank the commenters for their support and feedback. We recognize that eligible hospitals and CAHs may sometimes need additional flexibility to work with external vendors to implement measure changes or to adjust their workload accordingly, however, we note that the HIPAA Security Rule required covered entities to assess and manage risks to ePHI beginning in CY 2003 (68 FR 8346 to 8348). When we adopted the Security Risk Analysis measure in the Stage 1 final rule (75 FR 44369), the HIPAA Security Rule already required risk management administrative safeguards under 45 CFR 164.308(a)(1) and had

[385] *See https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html.*

[386] Guidance on Risk Analysis,'' available at *https://www.hhs.gov/hipaa/for-professionals/security/guidance/guidance-risk-analysis/index.html.*

[387] *See https://www.youtube.com/user/USGovHHSOCR.*

[388] *See https://405d.hhs.gov/resources.*

done so for years. Therefore, we do not believe a phased-in approach, or a voluntary year of reporting are warranted for eligible hospitals and CAHs to attest to having conducted risk management activities that have been required activities since adoption of the HIPAA Security Rule.

Regarding the request for technical assistance, toolkits, and other guidance to support CAHs and rural hospitals, we refer readers to OCR's resources on performing security risk analyses and other related security risk management activities.[389] The guidance materials OCR makes available would best inform all eligible hospitals and CAHs on how to meet the requirements of the measure, since we intend the modified measure to be aligned with the HIPAA Security Rule requirements.

Comment: A commenter recommended specific refinements to the measure language to reduce ambiguity and enhance the focus on cybersecurity without unnecessarily increasing administrative burden. Another commenter recommended CMS provide guidance modeled after OCR's documentation expectations for demonstrating implementation of recognized security practice (RSP), to support consistent implementation.

Response: With respect to the recommendation to modify the measure language to reduce ambiguity, we appreciate the commenter's recommendations. To minimize any potential for confusion or ambiguity in the measure's requirements, we are providing technical and clarifying revisions to simplify the language of the proposed measure text as follows:

First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include 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). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the eligible hospital or CAH would adopt an equivalent alternative measure if it is reasonable and appropriate to do so. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

We note that the HIPAA Security Rule does not currently prescribe a specific methodology for conducting and documenting a risk analysis or managing risk, and we reiterate our proposal was not intended to exceed or extend beyond what is required under the HIPAA Security Rule. We have modified the measure text accordingly.

In addition, with respect to risk management documentation, we appreciate the recommendation to provide guidance modeled after OCR's documentation requirements for demonstrating implementation of RSPs; however, we note that 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)).

Comment: Many commenters did not support the security risk analysis measure modification for various reasons. Several commenters stated the proposed modification is duplicative because eligible hospitals and CAHs are already required by the HIPAA Security Rule to conduct regular security risk analyses and address identified vulnerabilities. A few commenters urged CMS to reconsider inclusion of the Security Risk Analysis measure altogether because they stated it is duplicative of the HIPAA Security Rule requirements and, therefore, believe removing the measure would reduce burden. A commenter stated the proposed modification would undermine established enforcement practices and place eligible hospitals and CAHs at an increased financial risk. Another commenter stated the Paperwork Reduction Act (PRA) prohibits duplicative federal information collections unless justified by clear, demonstrable benefit, and that requiring eligible hospitals and CAHs to re-attest to security risk management under the Medicare Promoting Interoperability Program may contradict the PRA's purpose.

A few commenters did not support the measure change and stated it creates an administrative burden without clear evidence of improved security outcomes. A few commenters expressed concern that the proposed modification to the Security Risk Analysis measure runs counter to the Administration's policy objective to reduce regulatory burden.

A few commenters did not support the proposal and stated it would create an additional compliance step for eligible hospitals and CAHs, raising concerns that compliance may be difficult to measure, and that implementing cybersecurity requirements can be financially challenging for some. A commenter recommended that CMS work with OCR to implement consistent requirements and provide funding, resources, guidance, and education for entities, particularly small, rural, and otherwise under-resourced eligible hospitals and CAHs.

Response: With respect to the relationship between the HIPAA Security Rule and the security risk analysis required by the Security Risk Analysis measure, we previously explained in the Stage 3 final rule (80 FR 62794), and discussed in greater detail in the Stage 3 proposed rule (80 FR 16746 to 16747), that our measure is narrower than what is required to satisfy the security risk analysis requirement under the HIPAA Security Rule at 45 CFR 164.308(a)(1). The security risk analysis required by the measure is limited to annually conducting or reviewing a security risk analysis to assess whether the technical, administrative, and physical safeguards and risk management strategies are sufficient to reduce the potential risks and vulnerabilities to the confidentiality, availability, and integrity of ePHI created by or maintained in CEHRT and to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306(a). In contrast, the security risk analysis and risk management requirements under 45 CFR 164.308(a)(1) require covered entities and business associates to assess the potential risks and vulnerabilities to the confidentiality, availability, and integrity of all ePHI that an organization creates, receives, maintains, or transmits, including ePHI in all forms of electronic media, and to implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level to comply with 45 CFR 164.306(a) for all ePHI held by the covered entity or business associate.

As covered entities and business associates, eligible hospitals and CAHs are required to conduct security risk management activities under the HIPAA Security Rule. Therefore, we do not agree that the requirement to attest ''yes'' to having conducted risk management activities creates an additional administrative or regulatory burden, introduces an additional compliance step other than attesting ''yes'' or ''no'' once a year to CMS, adds significant technical complexity, places eligible hospitals and CAHs at financial risk, or contradicts the PRA's purpose.

[389] *https://www.hhs.gov/hipaa/for-professionals/security/guidance/cybersecurity/index.html.*

The proposed security risk management attestation reflects an eligible hospital's or CAH's acknowledgment of having performed activities that also meet the requirements of the HIPAA Security Rule implementation specification for risk management at 45 CFR 164.308(a)(1)(ii)(B). Furthermore, non-compliance with the HIPAA Security Rule's requirements for security risk analysis and risk management could expose eligible hospitals and CAHs to greater financial and other risks in the event of a data breach.

We note that our intention with this attestation measure, including the new modification to require an affirmative attestation to having conducted security risk management as required under the HIPAA Security Rule implementation specification for risk management, is not to measure the level of HIPAA Security Rule compliance. Rather, we intend to augment our past efforts to incorporate security, including security risk analysis and risk management, as a fundamental structural component for the meaningful use of EHRs. Instead of being duplicative, we consider the modified Security Risk Analysis measure to be complementary to the HIPAA Security Rule. As we explained previously in the Stage 2 final rule (77 FR 54002 and 54003), we emphasize again that our discussion of the HIPAA Security Rule implementation specification for security risk analysis and 45 CFR 164.308(a)(1) is only relevant for purposes of the meaningful use requirements and is not intended to supersede what is separately required by the HIPAA Security Rule or other applicable laws.

We also explained in the Stage 3 final rule that OCR administers and enforces the HIPAA Rules, including the HIPAA Security Rule, to ensure the privacy and security of protected health information (PHI); however, we continue to believe it is important and necessary for eligible hospitals and CAHs to attest to certain actions required to protect ePHI created or maintained by CEHRT in order to meet the Medicare Promoting Interoperability Program requirements (80 FR 62830). The modification to the Security Risk Analysis measure demonstrates our continued commitment to ensuring that electronic health information created or maintained by CEHRT is protected and secured by eligible hospitals and CAHs given the unique risks and challenges that may be presented by EHRs, particularly at a time when cybersecurity threats are increasingly common and sophisticated.[390]

Comment: A commenter was concerned that imposing parallel but independently administered requirements increases the likelihood of conflicting interpretations and audit standards across Federal agencies that would introduce significant technical complexity and risk.

Response: We explained previously in the Stage 2 final rule (77 FR 54002 and 54003) that the Security Risk Analysis measure is only relevant for purposes of the meaningful use requirements and is not intended to supersede the HIPAA Security Rule or other applicable laws that address cybersecurity, nor is it intended to introduce additional technical requirements other than what is already required under HIPAA. As we explained in the Stage 3 final rule (80 FR 62794), and described in greater detail in the Stage 3 proposed rule (80 FR 16746 to 16747), the Security Risk Analysis measure is narrower than what is required by the HIPAA Security Rule at 45 CFR 164.308(a)(1) because it only applies to ePHI created or maintained by CEHRT and excludes other forms of electronic media, such as hard drives. These statements continue to apply after the modification we proposed to the Security Risk Analysis measure.

Comment: A commenter expressed concern that the proposed modification to the measure is procedurally flawed because the commenter stated that it relies on the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898) that has not been finalized.

Response: We disagree that the proposal to add a security risk management attestation requirement relies on OCR's HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule. The proposed Security Risk Analysis measure modification refers to current requirements of the HIPAA Security Rule that are codified at 45 CFR 164.308(a)(1)(ii)(A) and (B), 164.312(a)(2)(iv), and 164.306(d)(3). The cross-references we proposed do not rely on any other proposed policies or proposed modifications to these provisions. We acknowledge that if the HIPAA Security Rule to Strengthen the Cybersecurity of Electronic Protected Health Information proposed rule (90 FR 898) is finalized, we will consider whether we need to modify the Security Risk Analysis measure accordingly in future rulemaking.

Comment: A few commenters stated that the proposed measure modification would not prevent cyberattacks. A commenter recommended reevaluating existing metrics for the effects of the industry's move towards interoperability. A commenter recommended keeping the measure as-is and exploring other avenues to encourage risk mitigation. A few commenters expressed reservations around requiring ''yes'' attestations to receive full scoring credit.

Response: While we agree with commenters that an attestation by itself will not prevent cyberattacks, at this time it is important and necessary to use available levers to protect patients' health information, including the attestation of actions required to protect ePHI created or maintained by CEHRT to meet the Medicare Promoting Interoperability Program requirements. We note that we may consider re-evaluating existing metrics and other avenues to encourage risk mitigation in future rulemaking.

After consideration of the public comments we received, we are finalizing our proposal to modify the Security Risk Analysis measure, with modification, 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 by the HIPAA Security Rule, with clarification of the specified measure language as discussed previously so that the finalized measure reads as follows:

First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include 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). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the eligible hospital or CAH would adopt an equivalent alternative measure if it is reasonable and appropriate to do so. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.

[390] Healthcare and Public Health Sector Coordinating Council, Centers for Medicare and Medicaid Services, and U.S. Department of Health and Human Services. Hospital Cyber Resiliency Initiative Landscape Analysis. Washington, DC: April 17, 2023 at *https://405d.hhs.gov/Documents/405d-hospital-resiliency-analysis.pdf.*

4. Modifications to 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.[391] 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. Modification of the SAFER Guides Measure Beginning With the EHR Reporting Period in CY 2026

In January 2025, ASTP/ONC 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.[392] 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 titles of the 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 • Organizational Responsibilities	• High Priority Practices • Organizational Responsibilities
Infrastructure Guides	• Contingency Planning • System Configuration • System Interfaces	• Contingency Planning • System Management
Clinical Process Guides	• Patient Identification • Computerized Provider Order Entry with Decision Support • Test Results Reporting and Follow-Up • Clinician Communication	• Patient Identification • Computerized Provider Order Entry with Decision Support • Test Results Reporting and Follow-Up • Clinician Communication

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18358 to 18359), we proposed 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, beginning with the EHR reporting period in CY 2026. Some commenters who submitted comments on the FY 2024 IPPS/LTCH PPS proposed rule believed the 2016 SAFER Guides were outdated and recommended that ONC review and update them. 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 addresses these concerns and suggestions, 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.

We proposed the following text for the measure:

> 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 noted that our proposed modification of the measure to reference the 2025 SAFER Guides would only be effective beginning with EHR reporting periods in CY 2026. We further noted that during EHR reporting period in CY 2025, eligible hospitals and CAHs should continue to use the 2016 SAFER Guides to complete their self-assessment. 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 invited 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.

Comment: Many commenters expressed support for the proposal to

[391] ASTP SAFER Guides—*https://www.healthit.gov/topic/safety/safer-guides.*

[392] ASTP SAFER Guides—*https://www.healthit.gov/topic/safety/safer-guides*

modify the SAFER Guides measure. A few of these commenters cited the importance of updating the guides to reflect advancements in health IT, cybersecurity, and clinical safety practices. A few commenters expressed appreciation for the streamlined and consolidated nature of the 2025 SAFER Guides.

Response: We thank the commenters for their support. We agree that the 2025 SAFER Guides reflect advancements in health IT, cybersecurity, and clinical safety practices in a streamlined and consolidated format.

Comment: Many commenters expressed concern about the proposed requirement to attest to completing an annual self-assessment using all eight of the 2025 SAFER Guides beginning in CY 2026. A few of these commenters stated the requirement to review an updated set of SAFER Guides would introduce substantial administrative burden, particularly for rural, under-resourced, and safety-net hospitals. Several commenters expressed concern around the duplicative nature of the SAFER Guides measure with the Security Risk Analysis measure, the resource-intensive nature of completing a self-assessment using all eight guides, and ambiguity in several recommended practices. A commenter felt there was a lack of strong evidence linking utilization of the SAFER Guides to improved safety outcomes.

A few commenters urged CMS to reconsider requiring the measure entirely, citing claims of the burden it may impose on eligible hospitals and CAHs with limited health IT staff and its potential overlap with existing regulatory measures. A commenter requested that CMS work with stakeholders to assess the burden and effectiveness of the SAFER Guides measure and explore alternative tools for assessing EHR safety.

Response: We thank commenters for sharing this feedback. Regarding concerns around burden or resource constraints from completing the self-assessment, we reiterate that 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. We remind readers that the SAFER Guides measure only requires eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment using all eight SAFER Guides, at any point during the calendar year in which the EHR reporting period occurs. There are no requirements to meet a specific implementation status or implement any specific practices identified in the guides, and we defer to eligible hospitals and CAHs to evaluate the utility of adopting specific best practices contained within the SAFER Guides, on their own timeline. We therefore disagree that this measure update would introduce substantial administrative burden, particularly for rural, under-resourced, and safety-net hospitals, as there are fewer SAFER Guides to attest to, and much of the information between the 2016 and 2025 versions remains the same.

In response to concerns around the evidence base of the SAFER Guides, we note that the SAFER Guides are based on the best available evidence from literature and consensus expert opinion. Subject matter experts in patient safety, informatics, quality improvement, risk management, human factors engineering, and usability collaborated to update the guides. The SAFER Guides were reviewed by an external group of practicing clinicians, informaticians, and information technology professionals.[393] The SAFER Guides are a valuable resource for eligible hospitals and CAHs using EHRs, as they can help identify potential risks, prioritize safety concerns, and implement strategies to mitigate those risks. Most importantly, the 2025 SAFER Guides were published largely in response to stakeholder concerns that the 2016 SAFER Guides were outdated and no longer relevant (88 FR 59264 through 59265). Considering the rapid advancement of health IT, the information in the 2025 SAFER Guides reflects the current state of health IT, making the self-assessments more relevant. Therefore, we disagree that requiring the measure should be reconsidered altogether.

We acknowledge the concerns raised by commenters regarding the potential overlap between the SAFER Guides measure and the Security Risk Analysis measure. While both measures aim to assess and enhance areas such as patient safety and security, there are notable differences. The SAFER Guides are a set of tools and recommendations focused on optimizing the safety and safe use of EHRs that help eligible hospitals and CAHs identify and address potential risks by providing a distinct framework to proactively identify and mitigate those risks. The SAFER Guides include clinical process guides targeting recommendations focused on patient identification, computerized provider order entry with decision support, test results reporting and follow-up, and clinician communication, which are important patient safety topics not included in, nor are the focus of, security risk analysis. The SAFER Guides' foundational guide focuses on high priority practices and organizational responsibilities, and the infrastructure guide focuses on contingency planning and system management. These are useful and complementary to conducting a security risk analysis, but do not duplicate or replace it. The security risk analysis, consistent with the HIPAA Security Rule requirements, is a comprehensive assessment of all potential risks to the confidentiality, integrity, and availability of ePHI created or maintained by CEHRT. A self-assessment using the SAFER Guides would not constitute a complete security risk analysis, nor would a security risk analysis, lacking any guidance for appropriate approaches to clinical processes using EHRs, constitute a self-assessment using the complete set of SAFER Guides.

We appreciate the suggestion to work with stakeholders to assess the burden and effectiveness of the SAFER Guides and explore alternative tools for assessing EHR safety. We are committed to engaging with hospitals, health IT vendors, and other stakeholders to ensure the SAFER Guides are practical, effective, and aligned with industry needs.

Comment: Many commenters provided recommendations to address concerns about the SAFER Guides measure. These commenters suggested allowing hospitals to submit evidence of participation in recognized EHR safety programs or certifications as an alternative to attestation, phasing in the implementation of the 2025 SAFER Guides over multiple years or offering partial credit to reduce the burden on small or under-resourced hospitals, and providing flexibility for hospitals to choose between the 2016 and 2025 guides during CY 2025 to facilitate the transition.

Several commenters highlighted the importance of targeted education, streamlined tools, and technical assistance to help eligible hospitals and CAHs to complete the self-assessments more effectively. A few commenters recommended expanding access to technical assistance resources, exploring grant opportunities for resource-limited institutions, and collecting data on completion of self-assessments using the SAFER Guides, disaggregated by hospital size, location, and ownership types. A few commenters requested CMS clarify the timeline for transitioning from the 2016 to 2025

[393] *https://www.healthit.gov/sites/default/files/topiclanding/2025-01/4.%20High%20Priorities%20Final.pdf.*

SAFER Guides and suggested allowing eligible hospitals and CAHs to earn bonus points for early adoption of the updated guides.

A few commenters emphasized the need to balance safeguarding patient data with minimizing administrative burden, particularly for rural and resource-constrained hospitals.

Response: We appreciate the feedback and recommendations provided by commenters regarding the SAFER Guides measure. Based on our general understanding of recognized EHR safety programs and certifications, we believe the suggested approach to allow hospitals to submit evidence of participation in these programs as an alternative to attestation would not be as comprehensive as the topics covered in the SAFER Guides, nor would it be less burdensome to report the information to CMS. We recognize the importance of ensuring the SAFER Guides measure is both effective in promoting EHR safety and that it is feasible for eligible hospitals and CAHs across varying resource levels to meet measure requirements.

We reiterate that during the EHR reporting period in CY 2025, eligible hospitals and CAHs should continue to use the 2016 SAFER Guides for their self-assessment. Both the 2016 and the 2025 SAFER Guides are available on the ASTP website at: *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 appreciate commenters' eagerness to begin using the 2025 SAFER Guides earlier than the EHR reporting period in CY 2026, however, allowing one full year for the industry to review the updated guides will allow for uniform adoption beginning with the EHR reporting period in CY 2026 and subsequent years.

We acknowledge the importance of targeted education, streamlined tools, and technical assistance to help eligible hospitals and CAHs complete assessments effectively, as highlighted by several commenters. In response to prior feedback from the public, the 2025 version of the SAFER Guides has been updated and streamlined compared to the 2016 version. First, there was a reduction from nine guides to eight guides, with each guide organized into one of three broad categories focused on foundational best practices, infrastructure best practices, and clinical process best practices. Each of the eight individual guides includes an extensive set of references offering additional detailed information and evidence. There are also public resources available to eligible hospitals and CAHs that are completing the self-assessments.[394] We appreciate the emphasis placed by commenters on balancing the need to safeguard patient data with minimizing administrative burden, particularly for rural and resource-constrained hospitals. We remain committed to engaging with stakeholders and consider the feasibility of implementation strategies that address the concerns raised. We appreciate the continued collaboration and input from stakeholders.

After consideration of the public comments we received, we are finalizing our proposal to modify the SAFER Guides measure to require 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 in subsequent years.

5. Modification to 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 exchanging data 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

[394] One such source of information about the 2025 SAFER Guides is an academic paper titled, ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' written by the authors of the SAFER Guides. This paper is available to download or use at *https://jamanetwork.com/journals/jama/article-abstract/2788984.*

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.[395] 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/ONC 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 to be the primary mechanism of public health information exchange supported by entities that are part of TEFCA during CY 2026.

c. Adding an Optional Bonus Measure Under the Public Health and Clinical Data Exchange Objective Beginning with the EHR Reporting Period in CY 2026

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18359 through 18361), we proposed to add a third 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 proposed 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/ONC's website) [396]; (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 data with the PHA.

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 when 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.

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,[397] meaning either the Common Agreement or an agreement that includes the Participant/Sub-participant Terms of Participation,[398] and is not suspended under the respective agreement. 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. Finally, the eligible hospital or CAH must use the functions of CEHRT to engage in a data exchange with a PHA.

We believe there are numerous certified health IT capabilities that can support exchange with a PHA under a TEFCA Framework Agreement. For instance, eligible hospitals or CAHs may exchange information under TEFCA 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™ [399] (QHIN) using certified health IT in a variety of ways. This includes the other ONC health IT certification criteria 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.

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).[400] 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/ONC, 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.

[395] 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.*

[396] See Common Agreement for Nationwide Health Information Interoperability Version 2.1 November 2024 at: *https://www.healthit.gov/sites/default/files/2024-11/Common_Agreement_2.1.pdf.*

[397] 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.*

[398] Participant/Subparticipant Terms of Participation (Apr. 2024), *https://rce.sequoiaproject.org/wp-content/uploads/2024/05/Common-Agreement-v2.0-Exhibit-1_508.pdf.*

[399] 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.*

[400] For more information, see *https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf.*

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18359 through 18361), we proposed 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 can only earn a total of 5 bonus points even if the eligible hospital or CAH attests ''yes'' to multiple bonus measures. Because the Public Health Reporting Using TEFCA measure would be an optional bonus measure, we did not propose any exclusions. We also proposed 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 invited 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 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.

Comment: Many commenters supported our proposal to create an optional bonus measure for public health reporting using TEFCA. Many commenters supported the proposal because they stated it provides an appropriate incentive to encourage health information exchange between PHAs and health care systems, continues to invest in technical modernization, and improves the capacity for public health surveillance and interventions.

Response: We thank commenters for their responses. We agree that the goal of this bonus measure is to encourage public health information exchange, technical modernization, and improved public health capacity.

Comment: Several commenters supported the proposal and stated it would lead to benefits such as reduced workforce requirements, improved use of data exchange standards, reduced burden during public health crises, faster onboarding, improved data quality, and streamlined public health reporting workflows that would improve PHAs' ability to act upon timely and reliable data. Another commenter stated it would lead to less administrative burden from state agency specification changes and EHR vendor updates.

Response: We thank commenters for their responses. We anticipate that continued improvements in public health information exchange, such as methods relying upon TEFCA, will be beneficial for those eligible hospitals and CAHs that use them.

Comment: A few commenters supported the proposal and stated that the optional rather than required status of the measure would allow participants time and flexibility to engage in public health reporting using TEFCA as well as provide information as to its use for real world reporting. They stated that with the measure being optional, this will appropriately encourage adoption and crediting early adopters.

Response: We agree that an optional rather than required measure will allow eligible hospitals and CAHs more time and flexibility to adopt the measure and evaluate the utility of TEFCA for public health reporting purposes. While we do not require the measure currently, we encourage eligible hospitals and CAHs to consider the use of advanced protocols for public health data exchange.

Comment: A few commenters supported the proposal and recommended that CMS assess hospital and health system experiences with adopting the measure for future policymaking. A commenter recommended CMS treat the measure as informational or developmental in early years and ensure rural and community-based hospitals have clear, low-cost pathways to participate.

Response: We thank commenters for their responses and note we do consider the experiences of eligible hospitals and CAHs when considering all potential measures for the Medicare Promoting Interoperability Program. We are open to modifying or adjusting program measures if experiences of eligible hospitals and CAHs show this to be necessary. We will continue to work with the CDC and ASTP/ONC to find opportunities to lower barriers to participation among rural and community-based hospitals.

Comment: A few commenters supported the proposal but were concerned about the disproportionate burden the optional measure requirements may impose on small, rural, or under-resourced hospitals. These commenters were also concerned that smaller, under-resourced hospitals might not benefit from the optional measure due to the technical capabilities needed to support data exchange.

Response: One reason we proposed the Public Health Reporting Using TEFCA measure as an optional measure rather than a required one is because requiring the measure may have otherwise caused undue hardship for small, rural, or under-resourced eligible hospitals and CAHs. One goal of the optional bonus measure is to encourage the use of networks participating in nationwide exchange under TEFCA without unfairly penalizing eligible hospitals or CAHs that are not yet ready to participate in such networks and may need additional time and flexibility. Eligible hospitals and CAHs that are not ready to participate in exchange under TEFCA can still receive the 5 bonus points by reporting on either the Public Health Registry Reporting measure, the Clinical Data Registry Reporting measure, or both.

Comment: A commenter supported the proposal and recommended maintaining the existing options for exchange with PHAs.

Response: We thank the commenter for the support and recommendation to maintain existing options for exchange to PHAs. Our proposal to add an optional bonus measure for public health reporting using TEFCA is intended to complement, not replace, current exchange methods under the Public Health and Clinical Data Exchange objective. Eligible hospitals and CAHs will continue to have flexibility to use existing standards-based infrastructure and intermediaries to meet reporting requirements regardless of their direct or indirect participation in TEFCA. By establishing this optional measure, we aim to incentivize early adopters while ensuring that hospitals and CAHs can continue using their current arrangements for information exchange and reporting without disruption.

Comment: A commenter supported the proposal but recommended that the measure definition be refined to only count Level 2 exchange use cases within the TEFCA Public Health Exchange Purpose Implementation Standard

Operating Procedure because those have better defined standards.

Response: In the TEFCA Exchange Purpose Implementation Standard Operating Procedure, Level 2 use cases refer to more specific data exchange contexts with accompanying exchange standards.[401] Although we recognize the value of focusing on more mature and standardized use cases, such as the Level 2 exchange use cases, our proposal aims to provide flexibility for eligible hospitals and CAHs to engage in public health reporting using TEFCA across a variety of use cases. Limiting the measure to Level 2 use cases at this time could restrict participation and hinder measure adoption. However, we will monitor rates of adoption and consider proposing refinements to the measure in the future based on stakeholder feedback and real-world experience with TEFCA-supported exchanges.

Comment: A commenter supported the proposal and encouraged CMS to continue allowing flexibility in determining which certified health IT capabilities can be used to meet the specifications of this optional measure.

Response: We thank the commenter for their support. We agree that flexibility is necessary to accommodate the diverse technical environments and resources of eligible hospitals and CAHs. Our proposal is designed to allow eligible hospitals and CAHs to leverage various certified health IT capabilities to exchange data using TEFCA, ensuring they can choose the solutions that best fit their operational needs. We remain committed to supporting adaptable approaches that promote participation while minimizing burden, and we will continue to evaluate opportunities to enhance flexibility as TEFCA evolves.

Comment: Several commenters did not support the proposal to create an optional bonus measure for public health reporting using TEFCA. A few commenters did not support the proposal because they wanted CMS to allow a variety of options rather than one option using TEFCA. They recommended that including a variety of options would allow entities that are capable of public health reporting via TEFCA to pursue that path, while also allowing entities that have other standards-based and governance-supported infrastructures to continue to use what they have without re-architecting their infrastructure.

Response: We acknowledge commenters' concerns about ensuring flexibility in public health reporting options. Our proposal to create an optional bonus measure for public health reporting using TEFCA is intended to complement, not replace, existing pathways for meeting the Public Health and Clinical Data Exchange objective. Eligible hospitals and CAHs can continue using their current standards-based and governance-supported infrastructure to fulfill required measures, regardless of whether the intermediaries or other entities supporting current arrangements participate directly or indirectly in TEFCA. We recognize that many HIEs and other intermediaries across the country not yet participating in TEFCA continue to provide significant value to users reporting data to public health agencies. We remain committed to supporting diverse approaches to public health reporting that accommodate the varied capabilities and resources of stakeholders.

Comment: A few commenters did not support the proposal because they were concerned about a lack of clarity with respect to HIPAA protections and the use of the TEFCA. These commenters specifically raised concerns with respect to queries and exchanges without explicit patient permission, recent HIPAA protections of reproductive health, and the use of record locator services in TEFCA. The commenters were concerned that use of TEFCA may breach HIPAA protections by revealing through a record locator service without a patient's consent that they had sought certain medical services such as at a substance use clinic.

Response: TEFCA is designed to operate within the framework of existing privacy and security laws, including HIPAA, and does not override these protections.[402] Any exchange of health information using TEFCA must comply with applicable federal and state privacy laws, including those governing sensitive health information. The HIPAA Privacy Rule permits covered entities to use or disclose protected health information for treatment, payment, or health care operations without first obtaining an individual's authorization for such use or disclosure. We will continue to work closely with stakeholders to ensure that measures that reference TEFCA-supported exchange uphold high standards of privacy and security while enabling effective public health reporting. Additionally, we welcome ongoing feedback to address specific concerns and improve clarity around measures that reference the use of TEFCA.

Comment: A few commenters did not support the proposal because they believe there are flaws in TEFCA as a method of data exchange. Commenters stated that they believe TEFCA limits the digital enablement needed for the health care sector, that it is cumbersome and at odds with the technical underpinnings needed for digital applications, and that it is exclusionary because smaller hospitals and CAHs do not connect to QHINs for lack of financial and human resources.

Response: TEFCA is designed to create a standardized framework for secure, nationwide health information exchange, and we recognize that its expansion may require adjustments to address barriers for under-resourced entities. By making the Public Health Reporting Using TEFCA measure optional, we aim to encourage adoption of the measure without imposing undue burden on smaller hospitals and CAHs that may face financial or technical challenges. We remain committed to working with stakeholders to refine program measures to improve accessibility and ensure that they meet the needs of smaller and rural eligible hospitals and CAHs.

Comment: A commenter did not support the proposal and believes that all public health reporting should be done through Health Information Exchanges (HIEs) in states that have them. The commenter believes that CMS should provide strong incentives to form HIEs in states that lack them.

Response: We recognize the important role that HIEs play in facilitating public health reporting at the state level. Our proposal to introduce an optional bonus measure for public health reporting using TEFCA is intended to complement existing infrastructure, including HIEs, rather than replace or compete with them. TEFCA provides a standardized, nationwide framework that supports broader data exchange capabilities that can enhance interoperability across networks, including HIEs. We also note that we support the use of HIEs through the HIE Bi-Directional Exchange measure under the Health Information Exchange objective.

Comment: A commenter did not support the proposal, stating that HIEs are already connected to QHINs and already transmit public health data to

[401] For more information about Level 2 use cases, see the Exchange Purpose Implementation Standard Operating Procedure at: *https://rce.sequoiaproject.org/wp-content/uploads/2024/08/XP-Implementation-SOP-Public-Health-PH.pdf.*

[402] For details regarding compliance with the HIPAA Privacy Rule among signatories to the Common Agreement, see the Common Agreement at: *https://rce.sequoiaproject.org/wp-content/uploads/2024/11/Common-Agreement-2.1_ASTP–508.pdf.*

PHAs through TEFCA. The commenter recommended that CMS simplify the scored and bonus categories rather than adding a TEFCA-specific bonus measure.

Response: We acknowledge the commenter's perspective regarding potential redundancy with the proposed TEFCA-specific optional bonus measure. While some HIEs may already connect to QHINs and transmit public health data, some do not, and some may not effectively transfer public health information between networks. The optional bonus measure is intended to incentivize broader interoperability and electronic exchange of health information. We appreciate the recommendation to simplify scored and bonus categories and will continue to evaluate opportunities to streamline program measures in future rulemaking.

Comment: A commenter did not support the proposal because of a concern that TEFCA is not yet a viable national reporting mechanism. The commenter stated that readiness across hospitals, PHAs, and QHINs remains uneven.

Response: We acknowledge the concerns regarding the current readiness of hospitals, public health agencies, and QHINs to fully implement TEFCA as a national reporting mechanism. The Public Health Reporting Using TEFCA measure is intentionally designed as an optional bonus measure to encourage early adoption of this measure in order to foster the electronic exchange of health information and provide flexibility for eligible hospitals and CAHs while TEFCA continues to mature. This approach would allow stakeholders to explore the benefits of TEFCA without imposing requirements that could create challenges for entities not yet prepared to participate.

Comment: Several commenters recommended that CMS work with other HHS agencies to continue investing in public health reporting. The comments included recommendations that CMS continue to invest in TEFCA and in public health data systems' capabilities and that CMS explore mechanisms to encourage state and local PHAs to expand their engagement with TEFCA. Commenters also recommended that CMS work with CDC and ASTP/ONC to build upon and improve TEFCA. Another commenter added that TEFCA should continue to evolve over time to reflect advances in data exchange so that burden and cost are both reduced.

Response: We thank commenters for their recommendations and agree on the importance of continued collaboration with other HHS agencies to invest in public health reporting infrastructure. CMS is committed to working closely with the CDC, ASTP/ONC, and other stakeholders to enhance TEFCA and support the modernization of public health data systems. We also recognize the need to encourage state and local public health agencies to expand their engagement with TEFCA and to ensure its evolution reflects advances in data exchange, reducing both burden and cost for participants. We will continue to prioritize partnerships that strengthen public health reporting capabilities and improve interoperability across the health care and public health sectors.

Comment: A few commenters requested clarification on the proposal. A commenter requested clarification whether an eligible hospital or CAH that used TEFCA for electronic case reporting would attest ''yes'' to both the proposed optional bonus measure and the Electronic Case Reporting required measure. Another commenter asked for clarification on whether eligible hospitals and CAHs can attest to both the Enabling Exchange under TEFCA measure under the Health Information Exchange objective and the optional bonus measure or if they can only attest to one TEFCA measure.

Response: We thank commenters for their questions and appreciate the opportunity to provide clarification. An eligible hospital or CAH that uses TEFCA for electronic case reporting should attest ''yes'' to both the proposed Public Health Reporting Using TEFCA optional bonus measure and the required measure under the Public Health and Clinical Data Exchange objective if it used TEFCA to fulfill the measure's requirements, assuming it meets all of the measures' specifications. Additionally, eligible hospitals and CAHs may attest to both the Enabling Exchange under TEFCA measure under the Health Information Exchange objective and the Public Health Reporting Using TEFCA optional bonus measure, as these measures address use of TEFCA to meet different elements of the Medicare Promoting Interoperability Program. However, eligible hospitals and CAHs can only earn five bonus points, even if they report on multiple bonus measures.

Comment: A few commenters encouraged CMS to provide technical assistance resources and grant opportunities to help resource-limited institutions participate in TEFCA. Among these, a commenter recommended that CMS publish a TEFCA readiness framework that would include benchmarks for PHA onboarding, QHIN participation, and EHR vendor integration.

Response: We recognize the challenges faced by smaller and under-resourced eligible hospitals and CAHs and are committed to exploring ways to reduce barriers to participation. We appreciate the suggestion to publish a TEFCA readiness framework with benchmarks for public health agency onboarding, QHIN participation, and EHR vendor integration. We will continue to collaborate with other HHS agencies and stakeholders to identify opportunities for technical support and funding mechanisms that promote access to TEFCA and strengthen public health reporting capabilities.

Comment: A few commenters recommended that CMS collect and publish data on TEFCA enrollment and participation. A commenter requested data disaggregated by hospital size, location, and ownership type. Another commenter recommended the collection of patient-level data sources that they believe would improve the comprehensiveness of surveillance initiatives.

Response: We agree that transparency and data collection are useful for evaluating the adoption and impact of TEFCA and could provide valuable insights into participation trends. We will explore opportunities to collaborate with stakeholders and other HHS agencies to gather and share meaningful data that supports the advancement of TEFCA and public health reporting efforts. While patient-level data sources may enhance the comprehensiveness of surveillance initiatives, we remain committed to ensuring that any data collection aligns with privacy and security standards.

Comment: A commenter recommended including Option 1 of Active Engagement as fulfilling the measure because the commenter believes that TEFCA is still in early stages of adoption and implementation and limiting the measure to Option 2 will limit its applicability.

Response: While we recognize that TEFCA is still in its early stages, the intent of the measure is to incentivize the electronic exchange of health information, which we believe is best reflected by validated data production under Option 2, in which eligible hospitals and CAHs are actively exchanging production-level data with public health agencies. This approach aligns with the goal of promoting meaningful and actionable public health reporting. However, we understand the importance of supporting entities in earlier stages of engagement and will continue to monitor TEFCA's implementation to assess whether adjustments to the measure criteria are

warranted in the future to enhance its applicability and encourage broader participation.

Comment: A commenter recommended that measures related to TEFCA participation remain optional.

Response: We agree that flexibility is important, particularly as TEFCA is still in its early stages of adoption and implementation. By proposing the Public Health Reporting Using TEFCA measure as an optional bonus measure, we aim to avoid imposing undue burden on eligible hospitals and CAHs that may not yet have the resources or infrastructure to participate.

Comment: A commenter recommended making public health reporting with TEFCA mandatory but cautions that hospitals and PHAs would require sufficient time for adoption.

Response: We thank the commenter for the recommendation. We believe establishing the Public Health Reporting Using TEFCA measure as an optional bonus measure is the most appropriate approach at this time because it provides flexibility for eligible hospitals and CAHs while TEFCA continues to mature and expand its adoption. This optional status allows eligible hospitals and CAHs to explore TEFCA's benefits without imposing immediate requirements that could create challenges for entities still developing the necessary infrastructure.

Comment: A commenter was concerned that the 5 bonus points could dilute the incentive to report on multiple bonus measures. They recommended that CMS consider allowing eligible hospitals and CAHs to earn 5 points for each bonus measure they meet and report on.

Response: We designed the scoring structure to balance the opportunity for eligible hospitals and CAHs to earn bonus points while maintaining fairness and simplicity within the program. Allowing 5 points for each bonus measure could disproportionately shift the focus away from required measures and complicate the scoring methodology. The current approach encourages participation in bonus measures while ensuring the overall emphasis remains on fulfilling required objectives. However, we will continue to evaluate the effectiveness of the scoring methodology and may consider adjustments in future rulemaking based on stakeholder feedback and program outcomes.

Comment: A commenter was concerned about reporting the level of Active Engagement for measures in the Public Health and Clinical Data Exchange objective, including the proposed optional bonus measure. The commenter believed that eligible hospitals and CAHs are penalized if state agencies are not ready to promote hospitals to validated data production (Option 2). The commenter recommended that CMS add an exclusion to the effect that if the state or public health agency is unready or unable to move a hospital from pre-production to production reporting, the eligible hospital or CAH may be exempt from the measure.

Response: We recognize that some eligible hospitals and CAHs may face barriers to advancing from pre-production (Option 1) to validated data production (Option 2) if their state or PHA is not prepared to support production-level reporting. While the proposed Public Health Reporting Using TEFCA measure is an optional bonus measure and does not negatively impact scoring for eligible hospital and CAHs that do not participate, we understand the importance of ensuring fairness in reporting requirements.

For required measures, we remind eligible hospitals and CAHs that they may be able to claim an exclusion under the measure and therefore receive full credit. Specifically, any eligible hospital or CAH may be excluded from reporting on a Public Health and Clinical Data Exchange measure, such as Electronic Laboratory Reporting or Electronic Case Reporting if it operates in a jurisdiction for which no PHA is capable of receiving data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period. For those measures with a relevant exclusion in the Public Health and Clinical Data Exchange objective, CMS interprets ''capable of receiving data in the specific standards required'' in this exclusion to mean that the PHA in the eligible hospital's or CAH's jurisdiction has the ability to advance, and has advanced, an eligible hospital or CAH registered with the PHA to Active Engagement Option 2: Validated Data Production. Please also see section X.F.1. of the preamble of this final rule for additional discussion regarding this issue.

After consideration of the public comments we received, we are finalizing our proposal to add an optional bonus measure for Public Health Reporting Using TEFCA under the Public Health and Clinical Data Exchange objective, beginning with the EHR reporting period in CY 2026. Eligible hospitals and CAHs may earn a maximum of 5 bonus points under the Public Health and Clinical Data Exchange objective for reporting on any or all of the optional bonus measures.

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, in addition to the requirement to report on the objectives and measures of meaningful use, both under 42 CFR 495.24(e)(1), 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 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 final 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 newly finalized policies included in this final rule.

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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 finalized policy made in this FY 2026 IPPS/LTCH PPS final rule. For details on our adoption of the Public Health Reporting Under TEFCA measure, we refer readers to section X.F.5. of the preamble of this final 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.

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The maximum number of points available by measure in this final rule does not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We did not propose 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 final 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.

In addition to the policies discussed in Section X.F.1. in this final rule, we also refer readers to the CY 2026 PFS proposed rule where we have proposed to adopt a measure scoring suppression policy beginning with the EHR reporting period in CY 2026 and proposed to suppress the Electronic Case Reporting measure from scoring for the EHR reporting period in CY 2025 (90 FR 32732 through 32736). We invite public comment on those proposals through the CY 2026 PFS proposed rule.

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 finalized policies in this final 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. We also refer readers to section XI.*B* of this final rule for discussion of certain policies including certain certification criteria being finalized by ASTP.

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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.

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
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.

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)

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
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/ONC'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)

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
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.

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	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)

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)

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	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)

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	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)

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	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)

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	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)
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA 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/ONC'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)

Objective	Measure	Numerator	Denominator	Exclusion	Calculation considerations related to counting unique patients or actions for CY 2026 and subsequent years
Protect Patient Health Information	Security Risk Analysis* First, conduct or review a security risk analysis and second, conduct security risk management activities, in accordance with the requirements under 45 CFR 164.308(a)(1)(ii)(A) and (B). Security risk analysis and management activities include 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). The encryption implementation specified at 45 CFR 164.312(a)(2)(iv) must be implemented if it is reasonable and appropriate; if encryption is not reasonable and appropriate, then the eligible hospital or CAH would adopt an equivalent alternative measure if it is reasonable and appropriate to do so.. 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 measure change made in this FY 2026 IPPS/LTCH PPS final rule that applies to the EHR reporting period beginning 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.

* As discussed in section XI.*B*.4.b.(3) of this final rule, ASTP/ONC is not finalizing its proposal to include the "electronic prescribing" certification criterion and the criteria for electronic prior authorization in the Base EHR definition. However, this has no impact on the e-Prescribing measure, Query of PDMP measure, or the Electronic Prior Authorization measure in the Medicare Promoting Interoperability Program.

** Signifies a measure with a newly finalized policy made in this FY 2026 IPPS/LTCH PPS final 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

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 use CEHRT to report on clinical quality measures selected by the Secretary (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	Consensus-Based Entity (CBE) Number****
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 we inadvertently omitted indicating measures required for the CY 2027 reporting period in the FY 2026 IPPS/LTCH PPS proposed rule; however, this denotes policies finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69624).

*** Signifies a required measure added for the CY 2028 reporting period and subsequent years. We note that we inadvertently omitted indicating measures required for the CY 2028 reporting period in the FY 2026 IPPS/LTCH PPS proposed rule; however, this denotes policies finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69624).

**** 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.

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We did not propose, nor are we finalizing in this final rule, any changes to the eCQMs for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

9. Requests for Information (RFI)

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18371 through 18377), we solicited public comment on several areas involving the Medicare Promoting Interoperability Program. These areas included requests for information on changing the Query of PDMP measure from an attestation-based measure to a performance-based measure, modification of the Query of PDMP measure to include all Schedule II drugs, performance-based measures in the Public Health and Clinical Data Exchange objective and improving data quality.

We would like to thank commenters for the feedback, support, and responses we have received. We may consider this feedback in future rulemaking. Because we did not propose any policies in these RFIs, we have not summarized the comments we received in response to them.

XI. Other Provisions Included in This Final Rule

A. 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 final 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 final 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, in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18002) we proposed updates to TEAM that included 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.
- Broadening the Skilled Nursing Facility (SNF) 3-Day Rule Waiver.
- Removing the Decarbonization and Resilience Initiative.

We also solicited comment, but did not propose updates, in the following policy areas:

- Indian Health Service (IHS) hospital outpatient episodes.
- Low volume hospitals.
- Standardized prices and reconciliation amounts.
- Primary care services referral requirement.

The policies in the proposed rule, and this final rule reflect our commitment to ensuring TEAM's incentives help to drive beneficiary quality of care improvements and reductions in Medicare spending.

We continue to believe that this model will test ways to further our goals of reducing Medicare expenditures while preserving or enhancing the quality of care furnished to beneficiaries. We received meaningful public comment on our proposed policies and policy considerations and will be finalizing several provisions in this final rule. We note that some of the public comments were outside of the scope of the proposed rule. These out-of-scope public comments, including but not limited to comments about voluntary participation, episode categories and episode length, quality measures not proposed or considered, and target price components not proposed or considered are not addressed in this final rule. However, we will take into consideration these public comments as we implement the model and monitor TEAM participant performance, and if warranted, we would propose new policies or policy modifications in subsequent notice and comment rulemaking, as appropriate. We have summarized the public comments that are within the scope of the proposed rule and our responses to those public comments.

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.

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 3 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.[403] 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 3 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

[403] 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.

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 Final 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.

As stated in the proposed rule, 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).[404] Further, we recognize that there may be instances where a hospital no longer satisfies the definition of TEAM participant during the model performance period, such as a hospital joining the RCHD or a hospital converting to a CAH.

We also noted in the proposed rule 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 recognized 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 recognized 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 the proposed rule, we proposed 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 proposed that any new hospital, as identified by Medicare ID (CMS

[404] *https://www.cms.gov/priorities/innovation/innovation-models/rural-community-hospital.*

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 proposed 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 proposed 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). As noted in the proposed rule, we believed 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 noted in the proposed rule, 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 also proposed 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. As noted in the proposed rule, we believed it was 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 proposed 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 recognized in the proposed rule that this proposed policy may present an opportunity for hospitals to avoid mandatory participation in TEAM. However, we indicated in the proposed rule that we did 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.

In the proposed rule, 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 believed it would be 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 in the proposed rule 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, as noted in the proposed rule, we believed 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 recognized in the proposed rule 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 believed that such patient shifting would run counter to the goals of the model as discussed at 89 FR 69631. We anticipated 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 recognized in the proposed rule 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 proposed to monitor specifically for the potential shifting of patients with high anticipated episode spending from TEAM participants to non-participant hospitals. We also noted in the proposed rule that, based on experience with prior models, we anticipated the opening of new hospitals within selected mandatory CBSAs during the TEAM performance period to be a relatively rare occurrence. As a result, we anticipated that the proposed policy would not affect a large number of hospitals.

We considered, but did not propose, 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 in the proposed rule, we believed 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 did not propose, 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 6 months to prepare for model implementation in 2025, including receipt and analysis of baseline claims and preliminary target price data from CMS, we recognized in the proposed rule that these hospitals, especially those that open shortly before the cutoff date, could be disadvantaged relative to hospitals that have had at least 1 year to prepare for model implementation. We also recognized 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 did not propose 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 could have made 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 have disadvantaged hospitals if they started after the performance year begins.

We sought 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 sought 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 sought 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. Finally, we sought comment on our proposal 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.

The following is a summary of the public comments received on the proposed policy for a limited deferment period for hospitals that open in a mandatory CBSA or for hospitals located in a mandatory CBSA that begin to satisfy the definition of TEAM participant after December 31, 2024, and our responses to these comments:

Comment: Many commenters expressed support for the proposed limited deferment period for hospitals that open in a mandatory CBSA or for hospitals located in a mandatory CBSA that begin to satisfy the definition of a TEAM participant after December 31, 2024, indicating that the deferment period would allow new hospitals to prepare for the model. A few commenters stated that the deferment period would help hospitals maintain patient safety and access to care. A couple commenters noted that the deferment period would help to minimize financial risk for new hospitals under the model.

Response: We thank the commenters for their support. We agree that this limited deferment period will benefit hospitals by allowing time to prepare for model participation and permit a smooth transition of care redesign to support and improve patient care.

Comment: A couple commenters stated that the proposed limited deferment period is inadequate and recommended that hospitals that open or that begin to satisfy the definition of TEAM participant after December 31, 2024, be excluded from the model. These commenters indicated that new hospitals already face substantial challenges in recruiting staff, establishing workflows, and developing systems, along with inconsistent patient volume and revenue. The commenters stated that the financial risks to these hospitals would outweigh the benefits of participating for only part of the model's duration and could disincentivize the opening of new hospitals in areas that need them. A commenter stated that the proposed limited deferment period is inadequate and suggested that CMS extend the deferment period from 1 full performance year to 2 full performance years.

Response: We thank the commenters for their suggestions and recognize the challenges involved in establishing a new hospital. However, we disagree that the proposed limited deferment period of at least 1 full performance year is inadequate. We believe that new hospitals will be able to integrate TEAM preparation into their general preparatory activities and could benefit from establishing care processes with TEAM's focus on care coordination and efficiency in mind. We also note that many integral TEAM processes, including quality reporting, deliverables, and reconciliation, are designed to be simpler for participants compared to the requirements of voluntary models like BPCI Advanced. We recognize commenters' concerns that requiring new hospitals to participate in TEAM could disincentivize the opening of new hospitals in areas of need. However, we also note that the potential for financial gains, the receipt of claims data from CMS, and the incentive and support to

develop efficient care delivery processes under the model are potential benefits of TEAM participation for new hospitals. Therefore, we believe that it is unlikely that requiring new hospitals in TEAM mandatory CBSAs to participate in TEAM will have a strong and systematically negative effect on the opening of new hospitals. However, we emphasize the importance of beneficiary quality and access to care in TEAM, and we may monitor for anomalies in the rates of new hospital openings in TEAM mandatory CBSAs as well as any reports that TEAM is affecting the decision to open a particular hospital.

Comment: Some commenters recommended that newly established hospitals be allowed to participate in TEAM with no downside financial risk in their first performance year, which would mirror the Track 1 eligibility granted to all TEAM participants in PY1. These commenters stated that allowing new participants to participate with no downside financial risk in their first performance year would allow them to learn, adjust to the model, and optimize care without risking financial losses. The commenters also indicated that allowing new hospitals to participate with no downside financial risk in their first performance year would reduce the impact of the model on decisions of whether and when to open new hospitals.

Response: We thank the commenters for their recommendations and acknowledge that new hospitals and hospitals that newly satisfy the definition of TEAM participant after December 31, 2024, would not have the opportunity to participate in TEAM with no downside financial risk in their first performance year. However, we disagree that it is necessary to provide new hospitals and hospitals that newly satisfy the definition of TEAM participant after December 31, 2024, with the option to participate with no downside financial risk in their first performance year. As stated in the proposed rule and in comments summarized previously, the proposed limited deferment period provides an opportunity for new hospitals to prepare for the model and thus minimize financial risk. Additionally, hospitals that open or that begin to satisfy the definition of TEAM participant after December 31, 2024, will have a larger set of CMS-created model resources at their disposal compared to those available to participants at the time of publication of the initial TEAM participant list on September 5, 2024. We also note that hospitals newly joining the model in PY 2 or later would experience the financial incentives of the model for a shorter duration than hospitals that begin participation in PY 1. As a result, we believe that further limiting these participants' financial incentives by allowing them to participate without downside risk in their first performance year could dilute the intended impact of the model. However, we note that these new TEAM participants are not precluded from participating in Track 2, the participation track with lower financial risk and reward, if they meet the Track 2 eligibility parameters, as outlined in § 512. 520. Further, the model includes policies that help to protect TEAM participants from significant financial risk, including a high-cost outlier cap that limits high episode spending, as described in § 512.540(b)(4), in addition to a stop-loss policy that prevents extreme loss from a repayment amount, as described in § 512.550(e)(1).

As stated previously, we recognize commenters' concerns that requiring new hospitals to participate in TEAM could disincentivize the opening of new hospitals. However, we also note that the potential for financial gains, the receipt of claims data from CMS, and the incentive and support to develop efficient care delivery processes under the model are potential benefits of TEAM participation for new hospitals. Therefore, we believe that it is unlikely that requiring new hospitals in TEAM mandatory CBSAs to participate in TEAM will have a strong and systematically negative effect on the opening of new hospitals. However, we emphasize the importance of beneficiary quality and access to care in TEAM, and we may monitor for anomalies in the rates of new hospital openings in TEAM mandatory CBSAs as well as any reports that TEAM is affecting the decision to open a particular hospital.

Comment: Some commenters suggested that all TEAM participants be eligible for Track 1 throughout the model, indicating that hospitals would undergo learning and improvement activities throughout the duration of the model, not just in their first year. A commenter requested that all TEAM participants be eligible for Track 1 for 2 years in order to provide adequate time for hospitals to undergo practice transformation, assess risk management strategies, understand performance, and ensure all providers can participate in the model.

Response: We thank the commenters for their suggestions. However, we believe that extending Track 1 eligibility beyond PY 1 would not be sustainable for the model. The introduction of required downside financial risk in PY2 for hospitals that do not meet the definition of a safety net hospital is a critical incentive for efficiency in care delivery under the model and is necessary for the model to achieve its projected savings to Medicare, as indicated in section I.G.12. of the Appendix A of this final rule. We agree with commenters that learning, practice transformation, and care improvement activities are intended to be continuous under the model. However, we disagree that this necessitates an extension of the period without downside financial risk for TEAM participants, new or otherwise. The presence of financial risk provides an incentive for participants to engage in care transformation and performance improvement activities, while existing provisions—including lower-risk options for safety net and other special hospital types, stop-loss limits, and quality adjustments—help to protect against large financial losses.

Comment: A commenter requested that, in combination with the limited deferment period, CMS implement additional beneficiary protections to prevent inappropriate diversion from medically necessary SNF care. The commenter noted that current Medicare policy requires a beneficiary to be admitted to a SNF and receive care within 30 days of a qualifying hospital stay to retain eligibility for the SNF benefit, unless a ''Medical Appropriateness Exception'' applies. The commenter stated that the length of TEAM episodes, which extend for 30 days following discharge, could incentivize participants to delay or divert necessary SNF care to reduce episode spending. The commenter recommended that CMS expand the Medical Appropriateness Exception to include cases where TEAM hospitals delay or divert SNF placement, and in cases where diversion has occurred, reset the 30-day SNF eligibility clock to begin after the TEAM participant's accountability period ends. The commenter also suggested that CMS monitor for SNF-level diversion patterns, similar to the planned monitoring for shifting of high-cost patients to non-participant hospitals.

Response: We recognize that the financial incentives of the model could provide motivation for participants to delay necessary care until after the episode or shift care to a less appropriate setting to reduce costs. We agree that this possibility necessitates policy and monitoring protections to ensure that delays to and diversions from medically necessary care do not occur. We believe that the beneficiary protections and monitoring provisions in place will prevent delays to and diversions from medically necessary

care for TEAM beneficiaries. As established at § 512.582, beneficiary protections prohibit TEAM participants from restricting beneficiary choice or access to medically necessary covered services, require TEAM participants to notify beneficiaries of potential financial liability during discharge planning, and prohibit TEAM participants and their downstream participants from selecting for or against treating certain beneficiaries based on factors that would render the beneficiary an ''at-risk beneficiary'' as defined at § 425.20. We believe specifically that prohibiting TEAM participants from restricting beneficiary access to medically necessary covered services—which, in the case of SNF services, are expanded in TEAM by the 3-day SNF rule waiver—will protect beneficiary access to SNF care when their provider determines that SNF care is medically necessary. We believe that providers, in consultation with their patients, are in the best position to determine appropriate care destinations. Further, we expect that the financial incentive to avoid complications and readmissions will disincentivize participants from delaying or diverting medically necessary SNF care. As described in § 512.590, CMS may conduct monitoring activities to ensure compliance by the TEAM participant and each of its downstream participants with the terms of TEAM. CMS reserves the right to monitor data from the TEAM participant and its downstream participants, including claims data, medical records, beneficiary interviews, and quality outcomes. We plan to monitor for abnormal patterns in post-acute care destinations and utilization and may take remedial action in the event of noncompliance, pursuant to § 512.592. We believe that these combined elements of the model will provide comprehensive protection for beneficiaries, and we trust TEAM participants to appropriately pursue efficiencies in care delivery while maintaining care access and quality. We also plan to review monitoring findings across the model and may propose additional beneficiary protections in future notice-and-comment rulemaking if further provisions appear necessary.

Comment: A couple commenters requested that CMS provide hospitals in the proposed participation deferment period with monthly claims data to help them prepare for the model.

Response: We thank the commenters for their suggestion and recognize the value of claims data for participants in preparing for and managing episodes. As described in § 512.562, CMS will make beneficiary-identifiable claims data available to TEAM participants annually, at least 1 month prior to the performance year, for baseline period data. This provision will apply regardless of when a participant joins TEAM. Additionally, as we have done and continue to do in the year prior to PY 1, we will consider additional ways to provide data and support to late-joining TEAM participants prior to their participation.

Comment: A commenter expressed support for the proposal to discontinue a hospital's TEAM participation the day that the hospital no longer meets the definition of TEAM participant.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.508 for a limited deferment period for hospitals that open in a mandatory CBSA or for hospitals located in a mandatory CBSA that begin to satisfy the definition of TEAM participant after December 31, 2024. We are also finalizing without modification the proposal at § 512.508(d) to monitor specifically for the potential shifting of patients with high anticipated episode spending from TEAM participants to non-participant hospitals. Additionally, we are finalizing without modification the proposal at § 512.508(c)(2) to discontinue a hospital's TEAM participation the day that the hospital no longer meets the definition of TEAM participant.

(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 believed 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. We noted in the proposed rule that 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 associated policies in this rulemaking, we refer readers to section VI.E. of the preamble of this final rule. We also noted in the 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. We further noted in the proposed rule that 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, we stated that 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 or other designation, such as SCH or RRC.

In the proposed rule we recognized the end of the MDH program on September 30, 2025, affects Track 2 participation eligibility. However, we also acknowledged that, historically, Congress has extended the MDH program, and in some instances retroactively reinstated the program. Therefore, we proposed 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 noted 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.

In the proposed rule we believed 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 anticipated 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, a 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).

We noted in the proposed rule that 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,[405] 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, we stated in the proposed rule that 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.

We indicated in the proposed rule that 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 anticipated 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 did not propose, 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 did not believe that it would be appropriate for TEAM to maintain hospital designations that are no longer maintained in Medicare more broadly. We also noted in the proposed rule 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 did not believe that it would be appropriate for CMS to circumvent these established procedures for the purposes of TEAM. We also considered and are sought comment on, but did not propose, the potential for the CMS Innovation Center 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. We stated in the proposed rule that 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 recognized in the proposed rule 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 noted that provision of such assistance to TEAM participants could unfairly disadvantage non-participant hospitals that do not receive the same support from CMS.

[405] 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*.

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 sought 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 sought 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.

The following is a summary of the public comments received on the proposed policy to determine MDHs' eligibility for Track 2 participation in TEAM, and our responses to these comments:

Comment: Some commenters expressed support for the proposal to determine MDHs' eligibility for Track 2 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.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS treat a hospital's MDH designation preceding PY 1 as qualification for Track 2 participation in all PYs of TEAM. A couple commenters indicated that the financial constraints and community needs faced by these hospitals would still be present even if the MDH designation were to be removed. A commenter stated that the additional certainty afforded to a hospital by locking in its Track 2 eligibility for the duration of the model based on its MDH status prior to PY 1 would allow the hospital to make additional investments in the model. A couple commenters recommended that CMS treat a hospital as an MDH for a given performance year if it held such designation in the previous performance year.

Response: We thank the commenters for their suggestions and recognize the financial challenges and community needs faced by MDHs and other rural hospitals. However, we believe that conferring Track 2 eligibility to a hospital for the full duration of the model based on its MDH status in 2025, or conferring Track 2 eligibility to a hospital for a given performance year based on its MDH status at the beginning of the prior performance year, would not be appropriate. As stated in the proposed rule, § 412.108(b)(1) establishes that the Medicare Administrative Contractor (MAC) determines whether a hospital meets the criteria for MDH designation. We believe that it would not be appropriate for CMS to circumvent this procedure for the purposes of TEAM, nor for CMS to maintain hospital designations in TEAM that are not maintained within Medicare more broadly in the event that the MDH program is terminated. Additionally, we note that maintaining a hospital's eligibility for Track 2 in a given performance year based on its MDH status at a time other than the time of track selection for that performance year would unfairly disadvantage hospitals whose Track 2 eligibility determinations are made on the grounds of rural, SCH, or EACH status at the time of track selection. Finally, we remind commenters that rural hospital status in TEAM is determined by location in a rural area as defined under § 412.64 or location in a rural census tract defined under § 412.103(a)(1), regardless of whether the hospital has applied for and received rural reclassification from CMS under § 412.103. Therefore, we anticipate that, if the MDH program is terminated, a large majority of hospitals that would have been eligible for Track 2 based on their MDH status will continue to be eligible for Track 2 by meeting the definition of a rural hospital in TEAM without requiring additional effort from the hospital to achieve this classification.

Comment: A few commenters requested that CMS provide technical assistance to hospitals that may lose MDH status.

Response: We thank the commenters for their suggestions. While we project that the majority of TEAM participants currently designated as MDHs would already qualify for Track 2 by being a safety net hospital, rural hospital, SCH, or EACH, we are actively exploring forms of support we could provide to MDHs if the MDH program is discontinued. Potential forms of support under consideration include, but are not limited to the following:

- Targeted outreach to notify hospitals of changes in their MDH status.
- Determination and notification of rural hospital status as defined in TEAM, regardless of existing rural reclassification from CMS.
- Distribution of resources and interpretation of regulations related to qualification as a SCH or EACH.

We also welcome suggestions from TEAM participants on how we may best support them through potential changes in hospital classification and track eligibility.

After consideration of the public comments, we are finalizing without modification the proposal at § 512.520(b)(4)(i) to determine MDHs' eligibility for Track 2 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.

(4) Indian Health Services/Tribal Hospitals

As indicated earlier in section XI.A.2.a.(1). of the preamble of this final 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 indicated in the proposed rule that we 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 noted that IHS/Tribal hospitals are not paid under the OPPS, as described in § 419.20. We stated in the proposed rule that while the TEAM participant definition does not explicitly state a hospital needs to be paid under the OPPS to participate in the model, we recognized 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 final rule, 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. We noted in the proposed rule that 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). We indicated in the proposed rule that 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.[406] Therefore, it may be possible that IHS/Tribal hospital outpatient spending could be lower (or higher) compared to other hospitals in the same region. We further indicated in the proposed rule that 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 did not propose 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 hospitalizations. In the proposed rule we stated we believed this option would mitigate some of the concern with respect to regional prices being reasonable for IHS/Tribal hospitals. While we recognized 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 believed 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 we believed the existing monitoring requirements, as described in § 512.590, would have been 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 did not propose, 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 were 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 did not propose, excluding 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 stated in the proposed rule that we recognized this consideration may not have a significant impact on the model with respect to episode volume. That is because we were 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 were 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 did not propose, constructing IHS/Tribal hospital specific target prices for anchor procedures. We stated in the proposed rule that this would also help to ensure that IHS/Tribal hospitals have reasonable target prices for anchor procedures. However, we recognized 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

[406] *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.*

methodology and predict their episode spending.

Lastly, we also considered, but did not propose, including IHS/Tribal hospitals as a hospital type eligible for Track 2 participation. However, we stated in the proposed rule that we also believed many IHS/Tribal hospitals may already satisfy eligibility requirements for Track 2 due to being a safety net hospital or a rural hospital.

We sought comment on the alternatives we considered for IHS/Tribal hospitals. We also sought comment on alternatives that we may not have considered.

The following is a summary of the public comments received on the considerations for IHS/Tribal hospitals, and our responses to these comments:

Comment: Some commenters suggested the IHS/Tribal hospitals should be exempt from TEAM. A few commenters indicated that, because IHS/Tribal hospitals are not paid OPPS, it would not be possible to construct accurate target prices for them and fairly assess their performance for LEJR and spinal fusion episodes. A few of these commenters indicated that limiting IHS/Tribal hospitals in the LEJR and spinal fusion episode categories to inpatient-only episodes would result in adverse selection between inpatient and outpatient episodes and recommended that, were CMS to not fully exempt IHS/Tribal hospitals from TEAM, they should, at minimum, exclude all LEJR and spinal fusion episodes at IHS hospitals. These commenters also expressed concern that simply limiting the IHS/Tribal hospitals participation in team to inpatient episodes would significantly reduce episode volume for LEJR and spinal fusion—because these procedures are increasingly provided in outpatient settings—resulting in low episode volume for these episode categories that may prevent accurate assessment of a hospital's performance. In response to our alternative considerations, a commenter suggested that participation in Track 2 would not provide sufficient protection for IHS/Tribal hospitals and that they should be provided the same protections as Track 1 hospitals. The same commenter suggested that a robust low-volume policy was also necessary to protect rural hospitals, sole community hospitals, and IHS/Tribal hospitals. Another commenter suggested that finalizing any alternative approach to calculating target prices and reconciliation payments for IHS/Tribal hospitals would not give these hospitals adequate time to plan for TEAM.

Response: We agree with commenters that inclusion of inpatient episodes but not outpatient episodes for LEJR and spinal fusion presents an opportunity for adverse selection and patient shifting between care settings which may not be clinically appropriate, as we previously stated in the proposed rule. We also agree with commenters that omitting outpatient episodes, while continuing to include inpatient episodes in TEAM, may make it difficult to establish fair and accurate target prices for IHS/Tribal hospitals and that lower episode volume due to exclusion only of outpatient episodes for LEJR and spinal fusion would result in an incomplete picture of a participant's performance for these episode categories. We further agree that proposing and finalizing any new, alternative approach to calculating target prices for IHS/Tribal in this final rule would not give these hospitals adequate time to plan for TEAM.

Therefore, we are finalizing a policy to exclude IHS/Tribal hospitals from the model by updating the TEAM participant definition to state that a TEAM participant must be paid under IPPS and OPPS. Specifically, we are finalizing a modification to the TEAM participant definition at § 512.505 to define a TEAM participant as an acute care hospital that (1) initiates episodes and is paid under the IPPS and OPPS with a CMS Certification Number (CCN) primary address located in one of the mandatory CBSAs selected for participation in TEAM in accordance with § 512.515; or (2) Makes a voluntary opt-in participation election to participate in TEAM in accordance with § 512.510 and is accepted to participate in TEAM by CMS. We recognize that excluding IHS/Tribal hospitals from TEAM will reduce episode volume, thereby limiting the reach of the model. However, an internal analysis demonstrated that when using the first half of 2024 as a performance year, it was estimated that IHS/Tribal hospitals initiated only 158 (0.03%) episodes. Given the small episode footprint of IHS/Tribal hospitals, we believe excluding IHS/Tribal hospitals from TEAM will not have a significant impact on TEAM in terms of episode volume and beneficiary access to the model. Further, IHS/Tribal hospitals' exclusion from TEAM does not exclude them or their clinicians from other value-based care initiatives, such as the Quality Payment Program. Therefore, clinicians may still gain value-based care experience, and beneficiaries still have access to clinicians focused on value and quality of care.

After consideration of the public comments, we are finalizing the exclusion of IHS/Tribal hospitals from TEAM by making a modification to the TEAM participant definition at § 512.505 to state that a TEAM participant must be paid under the IPPS and OPPS. Lastly, we note that this policy applies to all IHS/Tribal hospitals without regard to episode volume. While we agree with commenters about the importance of a low-volume policy, which we are addressing in section XI.A.2.c.(8). of the preamble of this final rule, this low volume policy would not affect IHS/Tribal hospitals given their exclusion from TEAM.

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. As noted in the proposed rule, 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. We indicated in the proposed rule that 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 also stated in the proposed rule that 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 from the FY 2025 IPPS/LTCH PPS final rule 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 1-5	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 1-5	Lower Extremity Joint Replacement Episodes	Hospital-Level Total Hip and/or Knee Arthroplasty (THA/TKA) Patient Reported Outcome Based Measure (CMIT ID #1618)
Performance Year 2-5	All Episode Categories	Hospital Harm – Fall with Injury (CMIT ID #1518)
Performance Year 2-5	All Episode Categories	Hospital Harm -Postoperative Respiratory Failure (CMIT ID #1788)
Performance Year 2-5	All Episode Categories	Thirty-Day Risk – Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Compilations Mortality Rate)) (CMIT ID #134)

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 stated in the proposed rule that 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 in the FY 2025 IPPS/LTCH PPS final rule the 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).

We stated in the proposed rule that 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 in the proposed rule 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 final rule, we will finalize 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. We noted in the proposed rule that 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, we stated in the proposed rule that CMS has recognized public input regarding the difficulties in reporting the clinical data elements and is finalizing proposals in section X.C. of the preamble of this final 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 noted in the proposed rule that 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. We further stated in the proposed rule that 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 believed that TEAM participants will have sufficient time to prepare. Additionally, we believed 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 proposed 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 sought 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 sought 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.

The following is a summary of the public comments received on the proposed policy to align with the Hospital IQR Program on the Hybrid HWR measure, and our responses to these comments:

Comment: A few commenters supported the alignment of the Hybrid HWR measure with the IQR Program, stating this approach reduces participant burden and streamlines reporting.

Response: We thank the commenters for their support of the alignment of the Hybrid HWR measure with IQR Program and we agree that it is important to use measures in TEAM that minimize reporting burden so that TEAM participants can focus on making meaningful quality improvements.

Comment: Commenters expressed concerns about CMS' proposal to use the first mandatory reporting period of July 1, 2025, through June 30, 2026, as both the baseline and performance period for TEAM. This commenter noted that this timing creates problematic situations where hospitals will not have insight into national measure performance until January 2027, with hospital-specific reports unavailable until Spring 2026 and public data not available until Summer 2026. This commenter noted that hospitals will be in downside risk before knowing their performance on the measure.

Response: We acknowledge the commenter's concerns regarding the timing of using the first mandatory reporting period (July 1, 2025 through June 30, 2026) as both the baseline and performance period for TEAM. We thank the commenter for their input, and, as noted later in this section, we are opting to maintain the policy we finalized in the FY 2025 IPPS/LTCH PPS Final Rule that instead uses two separate periods for the PY1 CQS baseline period and PY1 measure performance period. That is to say for the Hybrid HWR measure in PY1, the CQS baseline period will be CY 2025 and the measure performance period is July 1, 2024, through June 30, 2025. We recognize that this measure performance period does not require hospitals to report the core clinical data elements and linking variables under the Hospital IQR Program. Therefore, for PY1, only the claims-based portion of the Hybrid HWR will be used in the CQS calculation. By focusing on the claims-based portion of the measure, we believe this will remove any influence the voluntary core clinical data elements portion of the measure will have on quality measure performance in TEAM. Further, we believe this approach maintains consistency and alignment with Hospital IQR Program's reporting periods for this measure, while allowing TEAM participants to establish benchmarks and build familiarity with reporting. However, we will continue to assess our quality measure approach, and if warranted, will make modifications in future notice and comment rulemaking.

Comment: Multiple commenters highlighted data collection and reporting challenges encountered during voluntary reporting of this measure that raise questions about the measure's readiness for implementation. Commenters reported difficulties with Electronic Health Record (EHR) derived data collection, concerns about data completeness, accuracy issues with vital signs and laboratory values, problems with linking variables, and complications with the patient matching process between EHR data and Medicare claims. A commenter made the recommendation to monitor hospitals' ability to collect and report on the Hybrid HWR measure due to existing concerns over the completeness of EHR data. A commenter also noted that patients may have been inappropriately included or excluded from measure calculations, indicating the methodology requires additional refinement. A commenter suggests to CMS to oversee hospitals' capability to report on this measure and to continue to refine the measure to better align with clinical workflows to ensure reliable and valid scores are produced. Commenters supported CMS's proposed reduction of data completeness thresholds from 95 percent to 70 percent but questioned whether modified reporting thresholds would apply to TEAM hospitals and expressed concerns about measure feasibility even with reduced thresholds.

Response: We understand the challenges related to accurate data and electronic health records that hospitals face when implementing quality measures. CMS heard feedback related to reporting burden and has made corresponding alterations in the Hospital IQR Program to extend voluntary reporting of the clinical data elements for the Hybrid HWR measure. For TEAM quality measurement, we believe alignment with existing CMS quality reporting requirements will reduce burden and enhance clarity for TEAM's quality measure approach. We will continue to listen to the public and hospital feedback and if adjustments are made to existing CMS quality reporting requirements, we would aim to adopt those changes in TEAM, where possible, and in future notice and comment rulemaking.

Comment: A commenter noted the inclusion of the Hybrid HWR measure in TEAM is duplicative since readmission costs are already embedded in episode spending. This commenter provided analysis showing that 81.3 percent of hospital readmissions are driven by non-surgical admissions while TEAM episodes are initiated by surgical procedures, and that only 7 percent of inpatient discharges correspond to MS–DRGs that would initiate a TEAM episode, meaning 93 percent of the measure denominator is unrelated to TEAM. This commenter deems the Hybrid HWR measure an unrelated quality performance measure to determine financial penalties in TEAM.

Response: We thank the commenter for their concerns regarding the appropriateness of including the Hybrid HWR measure in TEAM. While we understand the commenter's concern, we disagree that the measure is duplicative given the incentive structure and quality calculations in TEAM differs from other CMS quality reporting programs. Further, we believe this measure aims to drive positive change, not just for TEAM beneficiaries, but encourages hospitals to improve care delivery and reduce re-admissions for all inpatient beneficiaries. Therefore, using the same measure as other CMS quality reporting programs has the benefit of capitalizing on a measure that the hospital is already reporting, while also encouraging hospitals to implement protocols that reduce re-admissions for all inpatient beneficiaries, not just for those who have initiated a TEAM episode.

Comment: Commenters made various recommendations including delaying implementation by at least 1 year, using only claims-based elements initially during PY1 to reduce reporting burden, removing the measure entirely from the composite quality score (CQS), using the first mandatory reporting year as baseline rather than performance period, or implementing the legacy Hospital-Wide Readmission measure until the hybrid version is operational. A commenter raised equity concerns about safety net providers facing structural challenges in data collection due to patient demographics, health literacy, and language barriers, which, they stated, could result in unfair penalties based on patient population characteristics rather than care quality.

Response: We thank and recognize commenters vast recommendations that reflect genuine concerns around hospitals' readiness and capacity to implement the Hybrid HWR measure effectively. We acknowledge the thoughtful feedback regarding implementation timelines, data collection challenges, and the need for operational flexibility as hospitals navigate the transition to hybrid reporting methodologies. We are attentive to the concerns raised about safety net providers, recognizing that structural challenges related to patient demographics, health literacy, and language barriers could inadvertently result in penalties that reflect patient population characteristics rather than actual care quality. CMS remains committed to ongoing monitoring of measure feasibility and will continue to engage with stakeholders to ensure that quality measures accurately reflect quality of care rather than penalizing providers who serve vulnerable populations with complex healthcare needs.

After consideration of the public comments, we are not finalizing a change to the Hybrid HWR measure as proposed, but instead, will maintain the policy as finalized in the FY 2025 IPPS/LTCH PPS final rule. This finalized policy will utilize CY 2025 for the PY1 CQS baseline period and use July 1, 2024–June 30, 2025 as the measure performance period for the Hybrid HWR measure. Additionally, TEAM is maintaining alignment with the Hospital IQR Program. Given that CMS has extended the voluntary reporting of the core clinical data elements and linking variables for the Hybrid HWR measure through June 30, 2025, this means that for PY1, we will use the claims-only portion of the Hybrid HWR measure in the CQS calculation. In subsequent TEAM performance years, the complete Hybrid HWR Measure—incorporating both claims data and core clinical data elements—may be utilized once the core clinical data elements transition from voluntary to required reporting. Any changes or modifications, including modifications to the data used to construct the measure or the CQS baseline period, will be implemented through future notice and comment rulemaking.

(3) Information Transfer Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM)

We stated in the proposed rule that the existing quality measures finalized in the FY 2025 IPPS/LTCH PPS final rule for 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 continue to 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 indicated in the proposed rule that 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 stated in the proposed rule that 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 stated in the proposed rule that 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 stated in the proposed rule that we did 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 did not consider it beneficial to propose this measure for use in TEAM. Of the remaining two measures, we recognized the value of the Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery; however, this focuses on hospital readmissions and did not provide the patient viewpoint afforded by PRO–PMs that we are prioritizing capturing in the model. As such, we proposed the addition of the Information Transfer PRO–PM for all episode categories initiated in the HOPD in TEAM. We stated in the proposed rule that 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, we stated that this measure captures patient viewpoint afforded by PRO–PMs.

To ensure alignment with the Hospital OQR Program, we proposed 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*. We indicated in the proposed rule that 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. We stated in the proposed rule that the goal of this measure is to enhance recovery outcomes by standardizing information transfer. We also proposed including 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: 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 believed 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. We stated in the proposed rule that 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 emphasized 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 believed 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, we stated in the proposed rule that 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 sought comment on our proposal to include the Information Transfer PRO–PM in TEAM starting in PY 3. We also sought 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.

The following is a summary of the public comments received on the proposed policy to include the Information Transfer PRO–PM in TEAM in PY3, and our responses to these comments:

Comment: Many commenters provided support for the inclusion of PRO–PM based measures, highlighting their importance in capturing the patient's voice in assessing healthcare quality, as well as provider-patient communication and the patient's understanding of their role in recovery and outcomes. Additionally, these commenters emphasized their appreciation that these PRO–PMs align with existing reporting requirements and therefore do not increase participant reporting burden.

Response: We thank the commenters for their feedback and support regarding the inclusion of the Information Transfer PRO–PM. We agree this quality measure emphasizes the importance of the ongoing collaborative relationship between the provider and patient, the need for clear and effective discharge instructions, and improving recovery outcomes. We also agree with the importance of aligning with existing reporting requirements so as not to increase participant reporting burden.

Comment: A couple of commenters stated their support in the inclusion of this quality measure in TEAM, highlighting the relevance of the Information Transfer PRO–PM in outpatient settings where clear post-discharge instructions and medication adherence are crucial. A commenter raised concerns for accurate information transfer assessment and patient understanding influenced by factors like health literacy and language barriers, especially among older, complex patients. A couple of commenters made suggestions for operationalizing this measure, including the availability of technical guidance, standardized tools and learning collaboratives, especially if this measure is expanded to other settings outside of the hospital outpatient setting.

Response: We thank the commenters for their support of the Information Transfer PRO–PM in the hospital outpatient setting. We agree that the elements this measure incorporates are indeed crucial for patient care, specifically the importance of clear post-discharge instructions and medication adherence, as these commenters highlighted. We also appreciate the suggestions for technical

guidance, standardized tools, and learning collaboratives to assist in the successful implementation of this measure, including how to address measurement challenges related to health literacy, language barriers and older, complex patients. We refer the commenters to the CY 2026 OPPS/ASC final rule (89 FR 94408) for measure specifications. We recognize the potential need for additional technical assistance and guidance as the model progresses and will consider this in the development of materials specifically for the inclusion in the TEAM model.

Comment: A few commenters supported the inclusion of the Information Transfer PRO–PM and suggested the inclusion of additional PRO–PM quality measures. A commenter encouraged CMS to include measures related to musculoskeletal episode categories and to work with subject matter experts to find the most appropriate for TEAM. Another commenter emphasized the need to include more robust functional outcome measures, such as the Patient-Reported Outcomes Measurement Information System (PROMIS) Global–10 (PROMIS–10), to improve the evaluation of patient functional outcomes and the current wide use in orthopedic and rehabilitation cases. A commenter suggested incorporating the CollaboRATE Shared Decision-Making Tool for Outpatient or Ambulatory Surgery Patients into quality programs and future performance years of TEAM.

Response: We appreciate the commenters' support for the inclusion of the Information Transfer PRO–PM in outpatient settings. During model development, we did consider, but decided against, using the Patient-Reported Outcomes Measurement Information System (PROMIS) Global–10 generic PRO survey given the current episodes in TEAM and the concern of increasing participant and patient burden for generic PRO data. We will continue to assess the evolving inventory of measures and refine measures based on public comments, changes to payment methodologies, recommendations from TEAM participants and their collaborators, and new CMS episode measure development activities. While the CollaboRATE Shared Decision-Making Tool for Outpatient or Ambulatory Surgery Patients tool is not currently mandatory for CMS quality reporting, CMS encourages participants to use tools they find useful and helpful in gaining insight into shared decision making and improving quality and patient outcomes. We will continue to assess TEAM quality measures and refine as the model moves forward.

Comment: A commenter appreciated CMS's inclusion of the Information Transfer PRO–PM in TEAM. They stated that, in addition to the Hybrid Hospital-Wide Readmission (HWR) Measure, the Information Transfer PRO–PM was an important step toward evaluating care transitions and patient safety. However, the commenter encouraged CMS to expand the quality measurement framework to better reflect the full scope of recovery following surgery. They emphasized the critical role of post-acute care providers in helping beneficiaries regain mobility, self-care abilities, and independence and recommended CMS consider additional functional outcome measures across all episodes to recognize the contributions of post-acute care in supporting recovery and return to the community. They also highlighted the importance of cognitive health as a key determinant of recovery, particularly for older adults. They suggested CMS explore the inclusion of cognitive function measures or include cognitive function as an outcomes measure risk adjuster. The commenter encouraged TEAM to align with the IMPACT Act domains. The commenter stated there is an opportunity to further strengthen TEAM by facilitating post-acute care provider health information exchange interoperability capacity and CMS should focus on supporting and including incentives to improve bidirectional data exchange.

Response: We thank the commenter for their feedback and support of the inclusion of the Information Transfer PRO–PM and the Hybrid Hospital-Wide Readmission (HWR) Measure in TEAM, recognizing these measures as important steps toward evaluating care transitions and improving patient outcomes. We will continue to evaluate the need for additional patient-reported outcome measures, cognitive function measures or risk-adjustments for cognitive function in TEAM to capture the role of post-acute care in supporting recovery. We appreciate the feedback including suggestions to improve bidirectional data exchange, especially for post-acute care providers. We will continue to assess the need to expand quality measures in TEAM and how these measures provide continued support in improving numerous facets of overall care.

Comment: Many commenters expressed concerns about the new Information Transfer PRO–PM measure and the lack of reporting data and feedback on the measure prior to its inclusion in TEAM. A couple of commenters suggested quality measures included in the model should undergo mandatory reporting for at least 1 or 2 years before implementation in the model and quality scoring methodology. A couple of commenters recommended delaying its adoption until 2029 (TEAM PY4) to allow hospitals to understand their performance relative to others, while some other commenters requested this measure be excluded from the model.

Response: CMS's inclusion of the Information Transfer PRO–PM starting in PY3 (CY 2028) allows TEAM participants time for voluntary reporting and 1 year of mandatory reporting experience before the measure is incorporated into TEAM. We disagree with extending the timeframe further, as the current plan does not increase reporting burden by incorporating it into TEAM, as we are aligning with the mandatory reporting of the Hospital OQR program. As finalized later in this section, the Information Transfer PRO–PM will remain in TEAM beginning in PY3.

Comment: A few commenters requested CMS evaluate the fairness of the PRO–PM measure for safety net hospitals, specifically highlighting the need for risk adjustment and concerns of participants being penalized for low volume of responses.

Response: CMS will continue to evaluate the need to make modifications for safety net hospitals due to low volume responses. Any updates or changes made will be incorporated into future notice-and-comment rulemaking. Additionally, we refer the commenters to the CY 2026 OPPS/ASC final rule (89 FR 94408) for measure specifications.

Comment: Many commenters have expressed their disagreement with the inclusion of the Information Transfer PRO–PM, citing several issues. They believe its implementation increases the administrative burden on staff, and increases the need to build infrastructure, provide training, and adds costs, such as paying external vendors or hiring internal staff. Additionally, the commenters mention survey fatigue, selection bias, access issues, and electronic and language barriers among patients. Many of these commenters suggested the need for technical assistance with implementation and had questions regarding operationalizing the PRO–PM. They raised concerns about eligibility determination, survey anonymity and tracking, lack of EHR integration across providers, validation of the measure, data handling protocols, risk adjustment for those with reduction in cognitive function, and survey overlap. Many

commenters shared concerns regarding the reporting threshold and a commenter suggested reducing the survey volume to 35 percent for 2 additional years or allowing documentation of two failed attempts to collect follow-up data as a pass to help participants manage data capture without significant penalties and give patients time to become familiar with the measures. A commenter noted how participants with low volume may receive a neutral quality score with no path to improvement. Many commenters shared concerns including the measure's applicability to a broad patient population and not specific to TEAM episodes, increased burden on hospitals and patients, and operational challenges when surveying patients pre- and post-surgical events. Some commenters also noted the complexity and cost of administering PRO–PMs, the lack of comparative benchmarks, and the resource demands and technical difficulties associated with the measure.

Response: We acknowledge the concerns related to the operational challenges associated with implementing the Information Transfer PRO–PM. We believe the voluntary reporting period, followed by 1 year of mandatory reporting prior to its integration into TEAM, will provide participants with the opportunity to address these challenges. We refer the commenters to the CY 2026 OPPS/ASC final rule (89 FR 94408) for data sources and measure specifications. We recognize the potential need for additional technical assistance and guidance as the model progresses and will consider this in the development of materials specifically for the inclusion in TEAM. The broad scope of the Information Transfer PRO–PM was intentionally chosen to encompass all TEAM episodes and any future episodes added to the model.

Comment: Some commenters emphasized the need for episode-specific quality measures rather than general measures and did not support the inclusion of the Information Transfer PRO–PM. A commenter noted that the PRO–PM provides little insight into the quality of care for spinal fusion procedures since it is not specific to these procedures. A few commenters suggested using specialty society clinical data registries relevant to each specific episode included under the model. Another commenter noted that PRO–PMs do not provide timely feedback to make improvements in patient care. A commenter suggested only including the current THA/TKA PRO–PM instead of adding another PRO–PM. Another commenter recommended developing new quality measures specifically designed for TEAM. Additionally, a commenter encouraged the use of the 3-Item Care Transition Measure (CTM–3) as an alternative measure and a commenter proposed the THA/TKA PRO–PM that will be available in the OQR in 2028.

Response: We appreciate the feedback provided by the commenters. We acknowledge the preference for episode-specific measures among TEAM participants and we will consider incorporating such measures, including registries, where applicable in future rulemaking. The inclusion of general measures serves multiple goals of TEAM, including providing an indicator of overall quality of care at the hospital level. Additionally, the current measures are part of the hospital-required reporting program, which prevents duplicative reporting by participants. We will move forward with the inclusion of the Information Transfer PRO–PM as this measure encompasses a 9-question survey spanning across the three domains of applicability, medications, and daily activities, as opposed to the three questions in the CTM–31. Additionally, regarding the THA/TKA PRO–PM for outpatient reporting, this would only apply to our outpatient LEJR episodes. The Information Transfer PRO–PM applies to all outpatient episodes, and we believe it is important to use a measure that can capture quality in the outpatient setting for all episode categories rather than limiting it to a single episode category. Further, if we add other outpatient episode categories to the model through notice and comment rulemaking, we would not have to expand TEAM's quality measure set because the Information Transfer PRO–PM could be applied to future outpatient episode categories.

Comment: A couple of commenters discussed that the current quality measures capture all hospital patients, not just those specific to the episode being analyzed under TEAM. They expressed concerns that these measures do not provide a true picture of quality for TEAM episodes and a very small number of clinical episodes make-up the quality measure. A commenter discussed the concern that participants would not receive penalties for low-quality care with the current model structure. A commenter requested clarification on how volume constraints will be addressed in the measure calculation.

Response: Previous episode-based payment models, including the BPCI Advanced model, have utilized similar hospital-level quality measures to assess participant quality performance. Therefore, we believe this approach is consistent with other CMS models. We acknowledge TEAM participants' preference for episode-specific measures. We will consider incorporating episode-specific measures where applicable and may propose them in future notice and comment rulemaking. We disagree with the commenter that the Information Transfer PRO–PM does not assess quality, as it captures key information regarding the patient's understanding of discharge instructions, which benefits many aspects of their care and progress toward recovery. This measure allows hospitals to identify their strong areas of communication and where overall improvements can be made, which is vital to improving outcomes and reducing harm. We also recognize that participants may need clarification regarding measure calculation, including specifics related to low volume. As we continue to move forward with TEAM, this information will be considered as we develop informational materials to best support the needs of participants throughout the model period. Additionally, we refer the commenters to the CY 2026 OPPS/ASC final rule (89 FR 94408) for data sources and measure specifications.

Comment: A commenter noted that the measure does not accurately assess quality because it evaluates the patient's understanding of the information rather than the quality of the information provided. They also pointed out that the study CMS cited in support of the measure based its conclusions on documentation review rather than patient responses.

Response: We appreciate the feedback provided by the commenter. We disagree with the commenter that the Information Transfer PRO–PM does not accurately assess quality. The survey results provide hospitals with valuable patient-reported outcome (PRO) data designed to evaluate communication efforts. This data enables hospitals to mitigate the risk of patient harm that may occur if patients do not fully understand their recovery information. Patient responses are crucial for making overall improvements in the path to recovery. For more information, we refer the commenter to the Hospital OQR Specifications Manual, Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (PRO–PM) Measure ID #: OP–46.

Comment: A commenter discussed the current alignment of the Information

Transfer PRO–PM eligibility with the criteria used for the Outpatient and Ambulatory Surgery CAHPS (OAS CAHPS) survey. The commenter stated this alignment narrows the original eligibility for the measure and requested a Current Procedural Terminology (CPT) crosswalk between TEAM episodes to ensure all of those who qualify for the Information Transfer PRO–PM are included in the data.

Response: We appreciate the commenter's suggestion and will consider it during the development of supporting documents for the model that align with the policies finalized in this rule.

Comment: A commenter requested CMS clarify who should administer the survey associated with the Information Transfer PRO–PM. The commenter also requested clarification on how the measure will be used and if there will be implications if beneficiaries do not submit the survey.

Response: We thank the commenter for their comment. We note that, in the CY 2025 OPPS/ASC Final Rule, the Information Transfer PRO–PM was adopted into the CMS Hospital Outpatient Quality Reporting (OQR) Program as a voluntary measure for the CY 2026 reporting period followed by mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination (89 FR 99406). The measure will also be used in TEAM, starting in performance year 3 (CY 2028), to assess quality performance via the composite quality score (CQS) for episodes initiated in the hospital outpatient department. We refer the commenter to the FY 2025 IPPS/LTCH PPS final rule for the methodology on how the CQS will be constructed (89 FR 69774) and the CY 2026 OPPS/ASC final rule (89 FR 94408) for data sources and measure specifications. CMS finalized that the survey should be administered 2 to 7 days post-procedure and that survey administrators should allow a 65-day window for patient response. Additionally, only fully completed surveys are included in the measure calculation. We note there is a 300 minimum random sample size of completed surveys. Hospitals that are unable to collect 300 completed surveys will not be able to perform random sampling, and would instead be required to submit data on all survey responses. While the hospital is accountable for ensuring the electronic survey is offered to all patients meeting the measure's denominator specifications, and may administer it through their own internal means, a hospital is not precluded from using a third-party vendor to administer the survey electronically. For further information on the Information Transfer PRO–PM, we refer the commenter to the following resources: *https://qualitynet.cms.gov/files/6830be4d662c6b68b52ddd2d?filename=1z_OP46MIF_v19.0.pdf* and *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf*

After consideration of the public comments, we are finalizing without modification our proposals at § 512.547(a)(3)(vi) for inclusion of the Information Transfer PRO–PM for all TEAM outpatient episodes beginning in PY3 with a CY 2027 CQS baseline period. We will continue to monitor the need for revisions, with any future updates incorporated into a subsequent notice and comment rulemaking. Given our inclusion of the Information Transfer PRO–PM in TEAM, Table XI.A.-04 represents all TEAM quality measures by performance year.

TABLE XI.A.-04: TEAM QUALITY MEASURES BY PERFORMANCE YEAR

Performance Year	Episode Category	Quality Measure
Performance Year 1-5	All Inpatient Episode Categories	Hybrid Hospital-Wide All-Cause Readmission measure (CMIT ID #356)
Performance Year 1	All Inpatient Episode Categories	CMS Patient Safety and Adverse Events Composite (CMIT ID #135)
Performance Year 1-5	Inpatient Lower Extremity Joint Replacement Episodes	Hospital-Level Total Hip and/or Knee Arthroplasty (THA/TKA) Patient Reported Outcome Based Measure (CMIT ID #1618)
Performance Year 2-5	All Inpatient Episode Categories	Hospital Harm – Fall with Injury (CMIT ID #1518)
Performance Year 2-5	All Inpatient Episode Categories	Hospital Harm -Postoperative Respiratory Failure (CMIT ID #1788)
Performance Year 2-5	All Inpatient Episode Categories	Thirty-Day Risk – Standardized Death Rate among Surgical Inpatients with Complications (Inpatient Surgical Compilations Mortality Rate)) (CMIT ID #134)
Performance Year 3-5	All Outpatient Episode Categories	Information Transfer Patient Reported Outcome Based Measure (CMIT ID #1797)

(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. We stated in the proposed rule that 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 recognized it was possible that some TEAM participants may not have a complete measure set during the performance period in which to measure their quality against. For example, in the proposed rule we stated that 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 rely on quality measure performance periods starting on July 1, 2023, or 2024, through June 30, 2025. Additionally, we recognized 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, we noted in the proposed rule that it is 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 stated in the proposed rule that we still believe it is 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. We explained in the proposed rule that 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 indicated in the proposed rule that 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 proposed 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 believed 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 did not propose 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.

We noted in the proposed rule that 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 proposed to utilize this approach.

We considered, but did not propose, 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 believed this approach may result in a reasonable scaled quality measure score, we had concerns that a TEAM participant's scaled quality measure score is influenced by how well other TEAM participants perform in quality. Therefore, we believed our proposed approach of assigning a scaled quality measure score of 50 would be unbiased and easier to compute.

We sought 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.

The following is a summary of the public comments received on the proposed policy to assign a scaled quality measure score of 50 when the TEAM participant had no or an incomplete raw quality measure score for a given quality measure, and our responses to these comments:

Comment: Several commenters supported our proposal to assign a neutral scaled quality measure score of 50 when a TEAM participant has insufficient quality data for a given quality measure.

Response: We thank the commenters for their support of this proposed policy.

Comment: A few commenters supported the proposed policy, stating they appreciated the alignment and consistency with the CJR policy.

Response: We thank the commenters for their support and agree that aligning the neutral quality measure policy with that used in CJR allows for a consistent approach.

Comment: A few commenters expressed support for the proposed policy, specifically noting this would be helpful for participants with low episode volume. Commenters cited examples of rural hospitals and small hospitals, where low episode case counts may be prevalent.

Response: We thank the commenters for their support and feedback. We agree this policy will be valuable for TEAM participants with low episode counts, such as rural and small hospitals.

Comment: A few commenters expressed their appreciation for the proposed policy, noting that it does not add to reporting burden. A commenter specifically appreciated that the policy aims to ensure a fair assessment of all TEAM participants without increasing the reporting burden. This commenter also suggested that future model quality metrics should align with the hospital IQR program to maintain consistency throughout the model's duration. Another commenter appreciated the selection of quality measures that are already required, as this reduces the need for duplicate measures. Additionally, this commenter valued the movement toward universal quality measures.

Response: We thank the commenters for their support and input. We agree that TEAM's alignment with existing reporting requirements will not increase reporting burden or create duplicative reporting.

Comment: A commenter supported the proposed policy as a solution to avoid penalizing providers who deliver high-quality care but lack reportable data. They discussed the challenges hospitals face in reporting quality data, especially for new facilities and those with prior voluntary participation in IQR reporting. However, the commenter

suggested that CMS differentiate the causes of missing data in order to distinguish between hospitals unable to report due to structural factors and those that choose not to report. The commenter proposed a tiered scoring approach and encouraged transparency by publicly reporting whether a neutral score result was due to insufficient volume, new status, or non-reporting. Additionally, they suggested allowing voluntary submission of supplemental data to justify using a neutral quality score. This commenter also requested that CMS consider the impact on the CQS in areas where specialists do not have control over missing PRO or hybrid measure data, noting it should not disproportionally affect the CQS in ways clinicians cannot reasonably influence. Another commenter agreed that a neutral quality score for measures with insufficient data is important for those available for self-selection in the IQR program, as facilities might choose not to report on those particular measures and should not be penalized for lack of sufficient data due to the self-selection process.

Response: We thank the commenters for their thoughtful feedback. We agree that the proposed policy aims to fairly address hospitals providing high quality care but lacking sufficient quality data. We agree with the commenter that this policy does not remove a hospital's ability to self-select measures in the Hospital IQR program. TEAM participants that do not self-select eligible measures that are also used in TEAM and have insufficient data will receive a neutral scaled quality score of 50 for that measure. We also value the suggestions for the tiered approach, public reporting and voluntary supplemental data, and will take these into consideration, and if warranted, would propose in future notice and comment rulemaking.

Comment: A commenter stated the proposed policy may unfairly penalize hospitals for reasons unrelated to quality performance, such as their option to report on other voluntary measures. The commenter states this defeats the purpose of applying a standardized quality measure and urges CMS to make this model voluntary.

Response: We thank the commenter for their feedback. We did consider that the Hospital IQR allows for self-selection of quality measures and considered how to approach where TEAM quality measures are included in this self-selected set. We considered requiring TEAM participants report on all TEAM quality measures, but this would remove the flexibility for their Hospital IQR self-selection. We ultimately determined that in order to stay aligned with CMS quality reporting programs, we would continue to allow hospitals the option of self-selection, understanding that if they choose not to report on a quality measure used in TEAM, and there is insufficient data, they will receive a neutral scaled quality measure score of 50. We thank the commenter for their considerations and will monitor the impact of this policy. Any changes to TEAM's quality measure approach will occur through future notice and comment rulemaking.

Comment: Several commenters did not support the proposed policy and suggested alternative approaches for quality measures in cases where participants have insufficient data. Suggested alternatives included allowing supplemental quality data submissions, temporary exemptions or exclusion instead of a neutral score, setting the weight of these measures to zero, and using historical performance instead of a neutral value. Commenters expressed that these alternatives would avoid unfair penalties for participants facing data collection challenges while still reflecting actual performance.

Response: We thank the commenter for their insight and suggestions. We did consider other approaches for when a TEAM participant has insufficient quality data for a given quality measure. However, alternative approaches go against our effort to align with existing reporting requirements and to not increase participant reporting burden. We hear the commenters concern that alternative policies would better capture quality performance. We will monitor the impacts of this policy through the first performance year and, if needed, make adjustments through future notice and comment rulemaking.

Comment: A commenter expressed concerns related to the Hospital IQR Program reporting thresholds for the THA/TKA PRO–PM being difficult to achieve, stating this affects both large and small hospitals, with smaller facilities lacking resources to carry out the PRO–PM and larger ones unable to meet reporting percentages. Further, this commenter states that the neutral quality score could unfairly reduce reconciliation payments for hospitals lacking sufficient quality data, despite already having incentives to report under the Hospital IQR Program.

Response: We thank the commenter for their helpful insights. Though we understand the concerns related to achieving reporting thresholds, the strategic alignment of TEAM with established quality reporting programs minimizes participant administrative burden through the utilization of quality measures with which providers are already familiar. We will continue to monitor these requirements to determine whether this alignment continues to be most beneficial for TEAM participants. Additionally, we appreciate the commenters feedback related to the neutral quality score unfairly reducing reconciliation payments. In the case of insufficient data, CMS will be unable to determine if quality performance is high or low, therefore believes the approach that is most fair is to apply a neutral score.

Comment: A commenter stated that, though they appreciate the intent of this proposed policy, they are concerned it will lessen the role quality has in the model. The commenter stated that applying a neutral quality score lessens accountability and reduces the ability to apply comparisons between model participants. This commenter urged CMS to reconsider its quality strategy to better align with specific episodes and overall quality of care.

Response: We appreciate the commenter's feedback and share their desire for accountability and peer comparison. However, we disagree this approach lessens the role of quality in TEAM. We believe applying a neutral quality score will encourage TEAM participants with insufficient quality measure data to be more engaged in quality measure reporting, ultimately spurring them to improve beneficiary quality of care and allowing them to have sufficient quality measure data that results in a more accurate scaled quality measure score.

After consideration of the public comments, we are finalizing without modification 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. We will continue to monitor the need for updates or changes, and any future updates will be incorporated into a subsequent notice and comment rulemaking.

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.

We stated in the proposed rule that 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.

We stated in the proposed rule that 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 finalized in the FY 2025 IPPS/LTCH PPS final rule 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.

We also stated in the proposed rule that 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.-05 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.-05: 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, we indicated in the proposed rule that 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.-06 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.-06: 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

As noted in the proposed rule, 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 FY 2025 IPPS/LTCH PPS 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 final 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. We stated in the proposed rule that failing to incorporate MS–DRG or HCPCS changes that arise between the baseline period and the performance year may lead to a significant drop in episode volume during the performance year and limit the number of beneficiaries exposed to the potential benefits of the model.

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. We stated in the proposed rule that 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. We noted in the proposed rule that 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 proposed 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 proposed 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.-07.

TABLE XI.A.-07: 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 proposed 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 proposed to construct episodes using the remapped MS–DRG or HCPCS/triggers. We proposed 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 proposed 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 proposed 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 proposed to use a scaling factor, which we proposed to define at § 512.505 to mean the ratio of the re-mapped MS–DRG or HCPCS/APC relative weight in the performance year, as applicable to the original MS–DRG or HCPCS/APC relative weight in the baseline period. We stated in the proposed rule that 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.–08 provides an example of the scaling factor calculation for each of the three possible MS–DRG groups.

TABLE XI.A.-08: 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 proposed 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.–09 demonstrates application of the scaling factor for anchor hospitalizations while Table XI.A.–10 demonstrates application of the scaling factor for anchor procedures.

TABLE XI.A.-09: 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.-10: 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

As stated in the proposed rule, we believed 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, we indicated that 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 stated in the proposed rule that we believed 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. We noted in the proposed rule that 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. We explained in the proposed rule that 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 sought comment on these alternatives.

We noted in the proposed rule 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. We also noted that 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 did not propose, 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 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. We stated in the proposed rule that 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 sought 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 sought 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.

The following is a summary of the public comments received on the proposed policies to define scaling and to account for MS–DRG and HCPCS/APC changes between the baseline period and the performance year, and our responses to these comments:

Comment: Many commenters expressed support for the three-step methodology to account for coding changes that occur during the course of the model.

Response: We thank the commenters for sharing their support regarding the methodology to account for future changes to MS–DRGs and HCPCS.

Comment: A commenter recommended CMS add a scaling factor for the post-discharge period portion of the benchmark price to account for spending variations in the post-discharge period for MS–DRGs with new mappings. A commenter suggested CMS apply setting-specific update factors in response to MS–DRG coding changes, as was done in BPCI Advanced.

Response: We thank the commenters for recommending additional scaling factors representing costs incurred during the post-discharge period and the inclusion of setting-specific update factors. We would like to clarify that if the MS–DRG or HCPCS in the post-discharge period is a TEAM-eligible trigger code, the scaling factor will still be applied to the inpatient stay or outpatient procedure. We believe creating post-discharge period specific scaling factors and including setting-specific update factors would add considerable operational complexity to the implementation of TEAM. However, we will continue to monitor the necessity of these changes for MS–DRGs and HCPCS affected by updated mappings and, if warranted, would make any methodological changes in future notice and comment rulemaking.

Comment: A commenter requested CMS exclude any TEAM clinical episodes which are subject to MS–DRG coding changes.

Response: We thank the commenter for their suggestion but believe that the exclusion of TEAM episodes subject to MS–DRG coding changes will unnecessarily reduce participation in TEAM and the number of patients covered by value-based care arrangements. Furthermore, we believe that excluding specific MS–DRGs may create new opportunities for gaming by providers.

Comment: Some commenters suggested that CMS update preliminary target prices during the performance year when changes are made to MS–DRG or HCPCS fee-for-service (FFS) rates specific to those included in TEAM. A couple commenters opposed the process of updating preliminary target prices when changes are made to MS–DRG or HCPCS FFS rates as constructing two levels of target pricing for 1 performance year is undesirable and would increase program complexity.

Response: We thank the commenters for their suggestions regarding when updates to TEAM target prices should be made to incorporate changes to MS–DRGs. We believe that updating preliminary target prices during the performance year would add considerable complexity for TEAM participants. We plan to update the list of TEAM-eligible MS–DRGs and HCPCS for each performance year based on finalized coding changes. Inpatient hospitalizations and outpatient procedures will only be included if the updated performance year MS–DRGs and HCPCS are included in the list of TEAM-eligible trigger codes. We plan to release preliminary target prices during the last calendar year quarter preceding the upcoming performance year and calculate final target prices during reconciliation, which occurs after the completion of the performance year. We note that we intend to perform reconciliation after 6 months of claims runout, as noted in § 512.550(b).

Comment: A couple commenters requested that CMS provide more details of the proposed mapping methodology that will occur for new or re-mapped MS–DRGs and HCPCS. One of these commenters noted concerns that the mapping strategy lacks transparency and invites mispricing. This commenter requested that CMS provide the public with an opportunity to review and provide feedback on the proposed mapping logic.

Response: We acknowledge the commenters requesting additional details and examples regarding the mapping and scaling methodology for MS–DRGs and HCPCS affected by coding changes. We intend to release additional materials ahead of the release of the performance year 1 preliminary target prices, tentatively scheduled to be released in the fourth quarter of 2025, so TEAM participants will be well-informed about the process.

Comment: A few commenters shared concerns regarding the MS–DRGs selected in TEAM for specific episode types and the downstream effect on target price construction. A commenter noted concerns for CABG MS–DRGs 231–236 which differ from each other with respect to patient acuity and the resource utilization needed to treat patients. The commenter requested that CMS clarify whether the target price paid to cover all costs associated with the episode of care for a qualifying CABG procedure will reflect the specific MS–DRG to which the patient is assigned, or whether that target price will be uniform across cases that fall under MS–DRGs 231–236. Another commenter noted concerns for Spinal Fusion MS–DRGs and HCPCS which represent a wide range of spinal fusion procedures, from simple to complex. This commenter noted that TEAM-specific components should not occur across blended categories of 2–7 level fusions, as the complexity of these procedures can vary substantially.

Response: We thank the commenters for their clarification questions and can confirm target prices will be constructed at the MS–DRG level. For example, there will be six different target prices constructed for MS–DRGs 231–236 for each TEAM participant, as applicable. Similarly, there will be separate target prices for each of the Spinal Fusion MS–DRGs, along with the MS–DRGs applicable to the remaining TEAM episode types. We agree that constructing target prices for each MS–DRG ensures the complexity and the resource utilization needed to treat patients is specific to the assigned MS–DRG.

After consideration of the public comments, we are finalizing without modification the definition of scaling factor at § 512.505. We are also finalizing the proposed methodology at § 512.540(a)(2)(i) through (iii) to account for future changes to MS–DRGs and HCPCS using the three-step mapping and scaling approach without modification.

(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 proposed to revise the definition for region at § 512.505 to more clearly reflect this policy. Therefore, we proposed 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 proposed 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 stated in the proposed rule that we believed 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, we indicated in the proposed rule that 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 did not propose grouping hospitals in a U.S. territory into a separate group not based on Census Division but believed that doing so would create unnecessary complexity and reduce uniformity in how target prices are constructed in TEAM.

We sought comment on our proposal at proposed § 512.505 to include U.S. territories in Census Division 9.

We did not receive any comments on the proposed policy to include U.S. territories in Census Division 9 and are finalizing the proposal without modification at § 512.505.

(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 stated in the proposed rule that 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. We stated in the proposed rule that 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 in the FY 2025 IPPS/LTCH PPS final rule that 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.

To ensure consistency in our approach to calculating the prospective normalization factor(s) and the final normalization factor(s), we proposed 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 proposed 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 similarly proposed revising 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. We stated in the proposed rule that 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. The proposed policy would ensure consistency in the construction of the prospective and final normalization factors. We sought 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 proposed to calculate normalization factors at the MS–DRG/HCPCS region level. We proposed 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. We stated in the proposed rule that 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 believed 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 sought 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.–11 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

TABLE XI.A.-11: 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

We also stated in the proposed rule that we wished 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 normalization 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 the proposed rule, we proposed 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 believed 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 sought comment on our proposal at § 512.540(b)(8) to communicate and share preliminary target prices that are region specific and TEAM participant specific.

The following is a summary of the public comments received on the proposed policies to construct and apply the normalization factors, and our responses to these comments:

Comment: A few commenters expressed support for the proposed changes to the normalization factor. The commenters expressed support for these methodological changes that intend to increase the accuracy of the target prices, intend to make hospital spending more comparable both across and within markets, and intend to avoid unintended financial burden on providers.

Response: We thank commenters for their support of the proposed changes to the normalization factor, and we agree that the changes would improve target price accuracy and lead to better assessment of TEAM participants' performance in the model.

After consideration of the public comments, we are finalizing without modification the definition of the prospective normalization factor to be calculated using benchmark prices rather than preliminary target prices at § 512.505. We are also finalizing without modification the proposal at §§ 512.540(b)(6) and 512.545(e)(1)(i) for the calculation of the prospective and final normalization factors at the MS–DRG/HCPCS episode type and region level rather than at the national level. Lastly, we are finalizing without modification 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. We stated in the proposed rule that 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 so that it is transparent for 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 MS–DRG 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, as stated in the proposed rule, 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, we noted in the proposed rule that 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 proposed updating 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 proposed 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 proposed 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. We explained in the proposed rule that 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 1-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. We clarify in this final rule that to convert the coefficient into a trend factor by which to multiply benchmark prices, we would exponentiate the coefficient estimate. For example, a coefficient estimate of 0.03 would be exponentiated as: $e^{0.03} = \sim 1.03$. We stated in the proposed rule that 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: $1.03^2 = \sim 1.061$, 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 $0.97^2 = \sim 0.941$, 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 proposed using 2 additional years of episode spending data in our calculation of the prospective trend factor. We proposed these 2 years be the 2 years immediately prior to the 3-year baseline period. Therefore, we proposed 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 believed 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 proposed the use of trend years to only be applicable to construction of the prospective trend factor used in preliminary target price calculations. We stated in the proposed rule that 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 proposed that trend years would roll forward on an annual basis in the same manner as the 3-year baseline period. We believed 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 proposed 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). We stated in the proposed rule that 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 proposed 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 proposed 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). We stated in the proposed rule that 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 proposed 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 the calculation of the benchmark price, we proposed 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 proposed 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 believed this approach would improve the accuracy of our benchmark prices and trend factors and, ultimately, of target prices.

We stated in the proposed rule that 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 indicated in the proposed rule that we intended 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 note the findings from this analysis in our comment responses in this section of the final rule. In the proposed rule we requested 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 requested 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 stated in the proposed rule that we intended to conduct further analysis on whether alternative weights would provide better estimates of real FFS spending.

We noted in the proposed rule that 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 believed 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 sought 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.

The following is a summary of the public comments received on the proposed policy to calculate the prospective trend factor, and our responses to these comments:

Comment: Some commenters supported the proposed changes to the prospective trend methodology. They noted that including 2 additional years and using a log-linear regression to produce the prospective trend factor would result in a more reliable and accurate prospective trend factor, reducing uncertainty and large retrospective adjustments.

Response: We thank the commenters for their support of the proposed changes to the prospective trend factor methodology.

Comment: A commenter expressed concerns that capping the retrospective trend at 3 percent of the prospective trend factor would penalize participants and would lead to a 3 percent lower target price.

Response: We disagree with the commenter who expressed concerns about the 3% cap on the retrospective trend penalizing participants and reducing their target prices significantly. Preliminary target prices contain a prospective trend factor to project baseline episode spending forward to the performance year (PY). This prospective trend factor, along with the prospective normalization factor and the risk adjustment multiplier, is updated during reconciliation. The retrospective trend is calculated as the average capped PY episode spending at the MS–DRG/HCPCS episode type and region level divided by the capped mean baseline episode spending in BY3 dollars at the MS–DRG/HCPCS episode type and region level. The retrospective trend factor is capped at +/- 3 percent of the prospective trend factor to make target price adjustment more predictable and prevent extreme, unexpected losses for both participants and CMS. As an example, if the prospective trend factor is 1.05 and the retrospective trend factor is 0.98, the capped retrospective trend factor will be 1.02 (3 points lower than the prospective trend factor as opposed to 7 points lower).

Comment: A couple of commenters expressed concerns that the 2 additional years (CYs 2020 and 2021) proposed to be used to calculate the prospective trend factor were significantly impacted by the COVID–19 public health emergency and are not representative of general patterns of care. These commenters urged CMS to revert back to the prospective trend factor calculation finalized in the FY2025 IPPS rule.

Response: We thank the commenters who raised their concerns with adding data from CYs 2020 and 2021 to the prospective trend calculation. While these CYs have been significantly impacted by the COVID–19 PHE, the prospective trend factor approach finalized in the FY 2025 IPPS final rule would be more sensitive to COVID–19 and the changes in spending, as it only uses data from 2 calendar years (for TEAM PY1 it would use CY 2022 and CY 2024 data). The approach proposed in the current rule mitigates the year-to-year fluctuations by using a longer time period to establish the trends.

We also conducted analysis of the proposed approach and alternative approaches to calculating the prospective trend factor, as described in the preamble of this rule. That analysis demonstrated the proposed approach to use 5 years of data was more accurate at predicting performance year spending than alternative approaches when years most affected by the COVID–19 PHE (CYs 2020 and 2021) were included in the 5-year baseline and trend period. Therefore, we anticipate this approach to not only be more accurate over the long term but also more robust to potential short-term disruptions that may affect care patterns and provider spending.

Comment: A commenter requested CMS to provide more detail on the log-linear regression model, including restatements of historical trend factors using this approach.

Response: The log-linear regression will be run on 5 years of trend data at the MS–DRG and region level. The dependent variable will be the natural logarithm of the episode spending. The primary dependent variable will be the calendar year of the clinical episode based on episode end date. We intend to provide detailed methodology documents ahead of the release of the performance year 1 preliminary target prices in Fall 2025. For PY1 of TEAM the baseline period will include CYs 2022 through 2024 and CYs 2020 and 2021 will be used as additional trend years to produce the prospective trend factor. The baseline and trend years will roll forward with each PY.

Comment: A few commenters expressed concerns about the ratcheting effect. A commenter suggested to avoid rebasing the benchmark each year to minimize the ratcheting effect and another commenter expressed concerns that weighing the more recent baseline years more heavily would lead to difficulties in creating financial savings.

Response: We thank commenters for expressing their concerns about the ratcheting effect. In the FY 2025 IPPS/LTCH PPS final rule (89 FR 69750), we finalized a 3-year baseline period that is rebased annually. We believe that calculating target prices at the MS–DRG/HCPCS episode type and region level mitigates issues related to the provider-level ratcheting effect. Our analyses showed that the proportion of hospitals participating in similar models such as BPCI–A and CJR is low among all participants in a region, so any regional-level ratcheting effect is also minimized. We also believe that a longer baseline and trend period for calculating the prospective trend factor, with all years weighted equally, may mitigate the ratcheting effect compared to a shorter baseline period or more heavily weighting more recent years. Therefore, we are not making any change to our policy to roll the baseline period forward each performance year and will mimic this policy for the 2 trend years. However, we will take into consideration these comments as we implement and monitor TEAM participant performance, and if warranted, would propose new policies or policy modifications in subsequent notice and comment rulemaking, as appropriate.

Comment: A commenter supported the inclusion of the national trend in the prospective trend factor but recommended to use a different weighting approach where the weight on the national trend is proportional to the share of episodes a hospital contributes within its region for a given MS–DRG.

Response: We thank the commenter for supporting the inclusion of national trends and for providing their thoughts on alternative techniques to weighing national trends. We believe that having a different set of weights for each participant would increase administrative burden and increase the complexity of the model. We will monitor how the currently specified national trend performs in projecting target prices and may consider alternative weighing approaches in the future.

Comment: A commenter requested detailed examples of the preliminary target pricing and trend factor methodology to allow participants to validate and track their targets.

Response: We thank the commenter for submitting their public comment. We will provide technical assistance to TEAM participants throughout the duration of the model to allow TEAM participants to track their performance in TEAM. These materials will include fact sheets, FAQs, and specification documents. Many of these documents will be made publicly available on the TEAM website. Additionally, all TEAM participants will receive a target price summary report that details each component of the target price methodology including the prospective trend factor to help participants easily validate and track their targets.

Comment: A commenter supported applying the high-cost outlier cap to episodes in the trend years.

Response: We thank the commenter for their support.

After consideration of the public comments, we are finalizing without modification our proposal at § 512.540(b)(7) to calculate the regional trend factor using 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 and the 2 additional trend years immediately preceding the baseline years. We are also finalizing without modification at § 512.540(b)(7) the calculation of the prospective trend factor as the average (arithmetic mean) of the regional trend factor 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 finalizing the definition of trend year and high-cost outlier cap at § 512.505 and finalizing without modification our proposal at § 512.540(b)(4) to apply the high-cost outlier cap to episodes in the trend years in addition to 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.

We stated in the proposed rule that 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. We indicated in the proposed rule that 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 included 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. We stated in the proposed rule that 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, we noted in the proposed rule that ACO REACH has modified the 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 of 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. The primary purpose of standardization in the ADI is to prevent any single indicator from dominating the composite score due to differences in measurement scales. Without standardization, variables with larger numerical values or greater variance would disproportionately influence the final deprivation score. We stated in the proposed rule that given the extensive work the ACO REACH model has conducted to standardize the ADI, we believed 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 proposed a few changes to the construction of the social need risk adjustment factor for beneficiary-level risk adjustment in TEAM.

First, we proposed renaming 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 proposed using 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 proposed 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 proposed 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 believed the updated variable name better represents what the variable is risk adjusting for. We also believed 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 proposed using 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. In the proposed rule, we stated that 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 believed 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 believed 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 use of the state-level rankings. We further believed 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. In the proposed rule, 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 continued 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 did not propose the SVI as a potential risk adjustor in TEAM.

We sought comment on our proposal at § 512.545(a) to rename the risk adjustment variable. We also sought 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 did not propose 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. We stated in the proposed rule that 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. We indicated that 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 did not propose any change at this time to the inclusion of the dual eligibility variable in our construction of the economic risk adjustment factor, we sought comment on whether the removal of this variable to streamline construction of the economic risk adjustment factor would be preferable.

The following is a summary of the public comments received on the proposed policies to rename the social needs risk adjustment factor and to replace ADI with CDI, and our responses to these comments:

Comment: Many commenters supported the proposal to replace the ADI with the CDI for the purposes of constructing the beneficiary economic risk adjustment variable. Some commenters stated that the CDI would improve on the ADI by standardizing the variables used to construct the index or by correcting the weighting of the home value and income variables, which is the result of this standardization. Some commenters noted that CDI would be better at measuring deprivation in urban, high cost, or underserved areas. Another commenter noted that the ADI had been demonstrated to mask disparities in certain areas.

Response: We thank the commenters for their support and agree that the fact that the CDI standardizes the variables used to construct the ADI will prevent variables with high nominal values such as income and home values from masking the other variables included in the index. As discussed in section XI.A.2.c.(6). of the preamble of this final rule and in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69798), we have been tracking stakeholder concerns about the ADI's lack of standardization and monitoring ways to improve the index's ability to measure deprivation in urban areas. We believe that replacing the ADI with the CDI in the construction of the beneficiary economic risk adjustment variable will allow TEAM to better identify deprivation in areas with high cost of living and more accurately adjust TEAM target prices to account for beneficiary economic risk.

Comment: A commenter appreciated that the proposal would bring TEAM into alignment with ACO REACH.

Response: We thank the commenter for their support. ACO REACH used the ADI as part of its risk adjustment in the 2023 and 2024 performance year which has provided insight into the advantages and disadvantages of the index. We believe that incorporating the improvements made to ACO REACH through the replacement of the ADI with the CDI will not only increase the accuracy of risk adjustment in TEAM, but it will also increase alignment across CMS models.

Comment: A commenter questioned whether the proposal would be sufficient to properly capture economic risk, particularly for safety net hospitals. The commenter noted lack of transportation and inability to afford medications as social needs that were not properly accounted for under TEAM.

Response: We thank the commenter for their concern regarding properly accounting for beneficiary economic risk. We disagree that the binary economic risk variable will not sufficiently capture this risk, or that risk adjustment could be improved by adding additional economic risk variables such as lack of transportation and inability to afford medications. The binary economic risk variable was designed to capture multiple markers of beneficiary economic risk. The inability to afford medications is a measure of income, which is already captured in the variable through eligibility for the LIS and full Medicare/Medicaid dual eligibility status. The inability to access transportation is also related to income, and the percentage of households within a census block group that do not have access to a motor vehicle is one of the 18 variables used to construct the CDI, which is included in the binary economic risk variable. We are concerned that adding additional economic risk variables would overcomplicate risk adjustment. Additionally, adding more variables that captured economic risk would prevent CMS from enforcing sign restrictions on the binary economic risk variable. We believe that it is important for the variable to only impact preliminary or reconciliation target prices if its coefficient is positive. Furthermore, all safety net hospitals will have a provider-level safety net status risk adjuster included in the risk adjustment model to improve target price accuracy for the episode expenditure variation experienced by safety net providers.

Comment: A few commenters recommended that, should this proposal be finalized, CMS monitor the impact of the CDI given how new the index is. Several of these commenters stated that CMS should specifically monitor the impact of the CDI in rural areas, with one of these commenters adding that the impact of the change on these areas must be more thoroughly examined. Another commenter requested bias testing on the measure to ensure that it did not inadvertently disadvantage high-risk patient populations or under-resourced hospitals.

Response: We thank the commenters for their input. We agree that it is critical to ensure that TEAM's risk adjustment does not disadvantage high-risk patient populations or under-resourced hospitals, such as rural hospitals. While the CDI is a new index, as discussed previously, the refinement of the ADI has been taking place for years in ACO REACH. We will continue to monitor the impact that this index has on risk adjustment in TEAM to

ensure that it accurately captures risk across all areas and populations. We would also like to reiterate that the beneficiary economic risk variable will only be used to adjust target prices if the coefficient on this variable is positive and will not be used to lower target prices for any TEAM participants.

Comment: A few commenters requested additional clarity on the CDI, including the detailed methodology of how the CDI is calculated and further explanation of the 18 variables included in the index.

Response: We refer readers to Appendix C of the ACO REACH model PY2025 Financial Operating Guide (*https://www.cms.gov/files/document/aco-reach-py25-fin-op-ovw.pdf*) for additional information on the CDI methodology used for ACO REACH including the 18 variables used in the construction of the index. We also plan to release TEAM-specific technical guidance addressing the CDI's methodology subsequent to the publication of this final rule.

Comment: A commenter supported replacing the ADI but questioned why the CDI was chosen as the replacement and suggested that CMS work with stakeholders to identify the best index to measure economic risk at the geographic level. The commenter questioned whether the CDI was validated across a wide range of geographic areas, such as rural areas. The commenter suggested that CMS consider other indices, including the Vizient® Vulnerability Index™.

Response: We thank the commenter for their suggestions. We finalized the use of the ADI for the purposes of economic risk adjustment in the FY 2025 IPPS/LTCH PPS final rule. While we stated in that rule that we would assess the use of standardization in calculating the ADI, we had no intentions of utilizing an entirely new index. CMS is familiar with the strengths and weaknesses of the ADI, and accordingly, the updated CDI, through the use of the index in other value-based programs such as ACO REACH. We believe that refining this index, as opposed to a larger overhaul of economic risk adjustment, will both provide more accurate risk adjustment and minimize changes to the model.

Comment: A few commenters supported keeping dual eligibility in the economic risk variable, noting that this variable is consistent, accessible, and easy for hospitals to understand.

Response: We appreciate the commenters pointing out the value of the familiarity hospitals have with this variable. We will not be finalizing any changes to the use of dual eligibility in the economic risk adjustment variable.

After consideration of the public comments, we are finalizing without modification our proposal at § 512.545(a)(3)(i) to use the CDI and remove a measurement of deprivation at the state level without modification. We did not receive any comments on our proposal to rename the social risk adjustment variable the beneficiary economic risk adjustment factor, which we are finalizing without modification at § 512.545(a).

(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.

We stated in the proposed rule that 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 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 proposed in the proposed rule to conduct a 180-day lookback for each beneficiary, beginning with the day prior to the anchor hospitalization or anchor procedure. We proposed 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 proposed that the TEAM beneficiary would need to meet beneficiary inclusion criteria, as described in § 512.535, during the entire 180-day lookback period. We stated in the proposed rule that 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. We noted in the proposed rule that 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. We further state that 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 stated in the proposed rule that 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 believed 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.

In the proposed rule we stated that 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 did not propose, a 90-day, 120-day, 270-day, or 365-day lookback period to determine which HCC flags the beneficiary is assigned. We did not consider lookback periods longer than 1 year as we believed 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 did not propose this alternative, we sought comment on whether these alternative lookback periods would be appropriate for TEAM or if there are other lookback period options we should consider.

We sought 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.

The following is a summary of the public comments received on the proposed policy to use a 180-day lookback period to determine which HCC flags the beneficiary is assigned, and our responses to these comments:

Comment: A few commenters supported the 180-day lookback period, noting this would lead to improved data collection, quality improvement and a more comprehensive assessment of patient risk. A couple commenters also supported the proposal since this would align with the lookback period implemented in BPCI Advanced.

Response: We thank the commenters for their support.

Comment: A few commenters opposed the proposed lookback period. These commenters also noted that 180 days is not sufficient to document patient risk. A few commenters noted that a lookback period of only 180 days would create burden for providers to capture all risk factors during pre-operation visits within this period. Commenters were concerned that this may be especially challenging for unplanned surgical episodes and may unintentionally drive additional utilization if providers are concerned patient acuity may not otherwise be captured.

Response: We appreciate the commenters' concerns with the 180-day lookback period. We disagree that the 180-day lookback period would create additional reporting burden for providers. We believe that 180 days will significantly reduce any burden put on providers to capture risk factors during pre-operation visits relative to the 90-day lookback period, or even in-episode HCC risk adjustment. Additionally, the 180-day lookback period was used in BPCI Advanced. In that model, we believe there were minimal concerns on reporting burden put on providers with respect to the lookback period. We believe the issue with additional utilization may be more of a concern in the 90-day lookback period, and that a 180-day lookback period will mitigate this concern. We believe 180 days is long enough to capture relevant patient risk information without increasing reporting burden for providers. Based on internal analyses, there were insignificant differences in the risk-adjusted benchmark prices across the different lookback periods assessed (90, 180, 270, and 365 days). Specifically, only 2 out of 29 MS–DRG/HCPCS episode type risk-adjusted benchmark prices changed by more than 2 percent when extending the lookback period from 180 to 365 days. Thus, we believe 180 days is sufficient to document risk, since extending the lookback period beyond that did not significantly affect risk adjustment's impact on these benchmark prices. We acknowledge that it may be possible for less data to be captured in the lookback period for unplanned episodes compared to planned procedures. However, based on the results of the internal analyses, extending the lookback longer than 180 days did not capture data significant enough to change the risk-adjusted benchmark prices.

Comment: A commenter was concerned that a 180-day lookback period may disadvantage smaller, rural providers or those treating underserved populations, since they may not be able to capture as much clinical data in the 180-day lookback. Additionally, FFS hospitals may not have been previously incentivized to record diagnoses and may be disadvantaged by this lookback compared to providers who participated in the CJR model.

Response: We acknowledge the commenter's concern for smaller, rural providers, those treating underserved populations, and those who have not previously participated in CJR or other programs. We believe our risk adjustment model is robust enough to capture spending accurately, even for these provider types. Specifically, we include provider-specific risk adjusters, such as safety net status, bed size, and a beneficiary economic index variable to appropriately capture risk for these provider types. Further, we believe that extending the lookback period longer than 180 days will decrease episode volume since the lookback period will also apply to relevant episode-level exclusions, which could negatively impact the reach of the model, particularly for smaller providers.

Comment: Many commenters suggested a one-year lookback period for TEAM since it will capture more annual visits, and thus, more diagnoses recorded in the annual visits, compared to the 180-day lookback period. A few commenters proposed that a 365-day lookback would lead to better predictions in spending and a more comprehensive picture of patient health. Many commenters also noted that a 365-day lookback period also aligns with Medicare Advantage risk adjustment methodology and other CMS programs, such as the CJR model.

Response: We acknowledge the commenter's concerns that it is possible for fewer annual wellness visits to be captured in the 180-day lookback period relative to a 365-day lookback period. However, as stated in the proposed rule and in the previous responses, we do not believe that extending the lookback period from 180 days to 365 days would provide significantly more patient risk information or significantly impact pricing. As stated previously, only 2 of

29 risk-adjusted benchmark prices changed by more than 2 percent when extending the lookback period from 180 to 365 days. On the other hand, in these same analyses, extending the lookback decreased the episode volume by about 100,000 among all episode types across a 3-year baseline period. Since the lookback period for episode-level exclusions and risk adjustment must be consistent, we believe extending the lookback to a full year will decrease episode volume and negatively impact the reach of the model. Additionally, we thank the commenters for acknowledging that a 365-day lookback period would align with Medicare Advantage and the CJR model. We believe our risk adjustment model and list of specific risk adjusters is more robust, especially compared to CJR. Thus, we do not believe we need to align the lookback period with that of other models or programs if the risk adjusters included in TEAM risk adjustment methodology is not consistent with those other programs.

Comment: A few commenters suggested to extend the lookback period to also include in-episode HCCs, since not including them may have a negative effect for unplanned procedures, which have fewer pre-episode visits.

Response: We appreciate the commenters' suggestion to include HCCs on the claims incurred during the anchor hospital encounter or during the episode. However, as stated in the proposed rule, we believe that using Medicare FFS claims from the lookback period, as opposed to the anchoring claim, is beneficial since it will reduce the incentive for increased coding intensity at the time of the initiating procedure or elsewhere in the episode window. We are only including HCC risk adjustment data prior to the anchor hospitalization or procedure.

After consideration of the public comments, we are finalizing without modification our proposal at § 512.545(a)(1) to use a 180-day lookback period to determine which HCC flags the beneficiary is assigned. The 180-day lookback period will also be applicable to episode-level exclusions which are dependent on the lookback period.

(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 stated in the proposed rule that 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 believed it was 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.

We stated in the proposed rule that 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. We noted in the proposed rule that 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. We also noted in the proposed rule that 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 proposed to use HCC v28 to identify the episode category specific HCC risk adjusters used in TEAM's risk adjustment methodology. Specifically, we proposed replacing 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. − 12.

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TABLE XI.A.-12: 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

Episode Category	Finalized HCC v22 Risk Adjusters	Proposed HCC v28 Risk Adjusters
		• 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 • HCC 463: Artificial Openings for Feeding or Elimination
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 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

Episode Category	Finalized HCC v22 Risk Adjusters	Proposed HCC v28 Risk Adjusters
		• 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

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We recognized in the proposed rule 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 believed this increase in HCCs is comparable given the HCC volume increased from v28 to v22. We also believed 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 noted in the proposed rule 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 did not propose replacing the non-HCC episode category specific risk adjusters. Nor did we propose 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 proposed to update the social need risk adjustment factor, as described in section XI.A.2.c.(6). of the preamble of this final rule.

We sought 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.

The following is a summary of the public comments received on the proposed policy to use HCC v28 to construct episode category-specific HCC risk adjusters, and our responses to these comments:

Comment: Some commenters expressed support for our proposed changes to the HCC version used to construct episode category specific HCC risk adjusters. A commenter noted that HCC version 28 includes more detailed data on patient information and that it would be useful to assess year-over-year changes. Another commenter cited that using HCC version 28 would also be consistent with other CMS models.

Response: We thank the commenters for sharing their support for HCC version 28.

Comment: A commenter expressed support for the proposed list of HCC risk adjusters, noting it would make TEAM more sensitive to patient complexity.

Response: We thank the commenter for their support.

Comment: A few commenters did not believe the proposed risk adjustment methodology would sufficiently adjust target prices to reflect or adjust for patient complexity or social determinants, despite the inclusion of the Community Deprivation index.

Response: We appreciate the commenters' concerns. We disagree that the proposed methodology is not sufficient to accurately risk adjust target prices. We believe that the list of risk adjusters is robust enough to accurately capture spending, while maintaining a simpler risk adjustment methodology. We also note that there are additional risk adjusters beyond the HCCs noted in the proposed rule. The comprehensive list of risk adjusters is summarized later in this section.

Comment: A commenter suggested CMS make the risk adjustment methodology specific to each episode category.

Response: We appreciate the commenter's suggestion. The list of risk adjusters is specific to each episode type/category in TEAM. We refer the reader to the comprehensive list of risk adjusters in TEAM summarized within this section.

Comment: A few commenters expressed concern on the usage of HCCs in general. These commenters suggested other risk adjustment methodologies, such as the inferred risk model, the Society of Thoracic Surgeons risk models, the American College of Surgeons National Surgical Quality Improvement Program, using socioeconomic status and dual eligibility factors, and surgical complexity not captured in HCCs.

Response: We appreciate the commenters' recommendations on different risk adjustment methodologies. We note that we did not propose and are not considering other risk adjustment models instead of HCCs at this time. However, we will take into consideration these public comments as we implement the model and monitor TEAM's risk adjustment methodology.

Comment: Some commenters requested transparency on the list of risk adjusters used in TEAM.

Response: To provide clarity, we are listing the comprehensive list of patient and provider-level risk adjusters for TEAM by episode type. This includes both the HCCs listed in the proposed rule, as well as the other non-HCC risk adjusters which were finalized per the FY 2025 IPPS/LTCH PPS final rule (89 FR 69773).

For CABG episodes, the following 28 risk adjustment variables are included: age bracket variable, HCC count variable, prior post-acute care use variable, beneficiary economic risk adjustment variable, hospital bed size variable (which is based on four categories: 250 beds or fewer, 251–500 beds, 501–850 beds, and 850 beds or more), safety net hospital status variable, and the following 22 HCCs:

- 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

For Surgical Hip/Femur Fracture Treatment (SHFFT) episodes, the following 30 risk adjustment variables are included: age bracket variable, HCC count variable, beneficiary economic risk adjustment variable, hospital bed size variable, safety net hospital status variable, and the following 25 HCCs:

- 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

For Major Bowel Procedure episodes, the following 30 risk adjustment variables are included: age bracket variable, HCC count variable, beneficiary economic risk adjustment variable, long-term institutional care use variable, hospital bed size variable, safety net hospital status variable, and the following 24 HCCs:

- 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
- HCC 463: Artificial Openings for Feeding or Elimination

For LEJR episodes, the following 29 risk adjustment variables are included: age bracket variable, HCC count variable, procedure-related variable (ankle procedure or reattachment, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty), variable for disability as the original reason for Medicare enrollment, beneficiary economic risk adjustment variable, prior post-acute care use variable, hospital bed size variable, safety net hospital status variable, and the following 21 HCCs:

- 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
- HCC 402: Hip Fracture/Dislocation

For Spinal fusion episodes, the following 31 risk adjustment variables are included in the TEAM risk adjustment methodology: age bracket variable, HCC count variable, prior post-acute care use variable, beneficiary economic risk adjustment variable, hospital bed size variable, safety net hospital status variable, and the following 25 HCCs:

- 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

Comment: Some commenters urged CMS to include additional risk adjusters in TEAM. A couple commenters suggested risk adjusters to stratify by elective status to ensure target prices are equitable for hospitals more likely to provide non-elective procedures. A few commenters urged CMS to include more risk adjusters to account for clinical complexity within episode categories, such as inpatient versus outpatient setting, frailty and procedure-specific factors. A commenter recommended CMS include a risk adjuster for swing bed utilization, limited to rural participants or specific participation tracks. A couple commenters suggested to use the disability risk adjustment factor across all episode types.

Response: As stated in the proposed rule, we did not propose or consider changes to the non-HCC episode category risk adjusters. However, we will take into consideration these public comments as we implement the model and monitor TEAM's risk adjustment methodology. With respect to emergent versus elective procedures, as noted in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69769), we believe that grouping emergent and elective procedures together, rather than stratifying them, reduces the incentive for increasing coding intensity. Similarly, we believe that setting separate target prices for inpatient versus outpatient settings may create incentives for adverse selection and gaming. We believe that the risk adjustment model, which includes clinical risk adjusters, should be sufficient in accounting for pricing differences and clinical complexities among emergent procedures.

Comment: Some comments requested hospital-specific risk adjusters in TEAM. Another couple commenters recommended HCC weights and HCC counts. A few commenters urged CMS to include more risk adjusters to account for clinical complexity within episode categories, such as fracture versus non-fracture, as well as demographic-specific factors.

Response: We thank the commenters for their recommendations. Hospital-specific (bed size and safety net status) and demographic-specific risk adjusters, as well as those for HCC counts are already included in TEAM. SHFFT and LEJR episode types also include a risk adjuster specific to Hip Fracture/Dislocation (HCC 402) and LEJR procedure-specific factors (for example, ankle procedures or reattachments, partial hip procedure, partial knee arthroplasty, total hip arthroplasty or hip resurfacing procedure, and total knee arthroplasty). We refer the readers to the comprehensive list of risk adjusters included in TEAM summarized within this section.

After consideration of the public comments, we are finalizing without modification our proposal to use HCC version 28 to construct our episode category specific HCC risk adjusters in TEAM. We are also finalizing our proposal without modification at § 512.545(a)(6)(i) through (v) to use the updated list of HCC risk adjusters for each episode as a result of using HCC version 28.

(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 the proposed rule for TEAM, we stated that 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).

We stated in the proposed rule that 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 the proposed rule, rather than offering a specific proposal, we proposed 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 sought comment on several potential policies to address prior commenters' concerns about low volume providers participating in TEAM.

First, we considered, but did not propose, 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. We stated in the proposed rule that 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 noted that the baseline period for a given performance year in TEAM rolls forward each year. Therefore, we acknowledged in the proposed rule that 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 stated in the proposed rule that we did 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.

We noted in the proposed rule that this considered policy may address 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. We stated in the proposed rule that 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 were concerned that waiving downside risk for low volume hospitals may affect potential TEAM savings for CMS. Additionally, we stated in the proposed rule that 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 did not propose, different low volume thresholds for the previously considered policy in the baseline period for a given episode category, including 91, 61, 51, 41, 21, and 11 episodes. In the proposed rule we stated that 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. We noted that 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 considered 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 did not propose, 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 were 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. We stated in the proposed rule that 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. We stated that 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 did not propose, 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 not be eligible to earn any reconciliation payment amount or repayment amount for that given episode category during the performance year. However, we stated in the proposed rule that we were 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. We noted in the proposed rule that 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.–13 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.-13: 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		$16,666.67
SHFFT	N	30	$50,000	$33,333.33

Table XI.A. – 14 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.- 14: 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	
SHFFT	N	20%	$33,333.33	$200,000	$40,000	N	$33,333.33	$38,333.33

However, as demonstrated by Tables XI.A.–13 and XI.A.–14, we were concerned that this approach adds complexity to the reconciliation calculations by adding additional steps. Further, we stated that we were 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 indicated in the proposed rule that we were concerned that including minimum episode volume thresholds during the performance year may introduce program integrity issues.

We sought comment on our considered policies. We also sought comment on low volume policy alternatives we have not considered.

The following is a summary of the public comments received on the considerations for low volume hospitals, and our responses to these comments:

Comment: Many commenters expressed concerns about the lack of a low volume policy in TEAM and urged CMS to establish one. Many commenters stated that a low volume policy was necessary to protect hospitals with low volumes from the volatility caused by small sample sizes. This volatility could result in hospitals facing large losses due to random variation over a small number of episodes. A couple of commenters also noted that, because of this variation,

performance on low volume procedures does not accurately reflect hospital performance. A few commenters stated that surgical excellence depended significantly on volume and repetition.

Response: CMS thanks the commenters for sharing their concerns regarding the lack of a low volume policy in TEAM. We acknowledge that low volume hospitals face barriers to success, as they may not have the procedure volume necessary to create efficiencies in a given episode category. We also acknowledge that evaluating these hospitals in episode categories where they display low volumes of episodes makes them vulnerable to losses from high-cost outlier cases that may be outside of their control. While TEAM will cap episodes at the 99th percentile of spending at the MS–DRG/HCPCS episode type and region level for each baseline year, we understand that this may not be sufficient to protect low volume hospitals who are more at risk for hitting the high-cost outlier cap. We do not want low volume hospitals to be exposed to unnecessary financial risk and want to provide low volume hospitals with the protection they need to succeed in TEAM.

Therefore, after consideration of comments received, we are convinced that TEAM needs a low volume policy to protect TEAM participants from undue financial harm and are finalizing a low volume policy in this final rule. We are finalizing one of the options we considered in the proposed rule that received a majority of public support, specifically the policy that if a TEAM participant does not meet a low volume threshold of at least 31 episodes in an episode category during the 3-year baseline period, CMS will still reconcile their episodes in the corresponding performance year, but the TEAM participant will not face downside risk in that category. In other words, if the TEAM participant's episode spending exceeds the final target prices in an episode category where they were classified as low volume in the baseline period, they will not owe any money to CMS in that episode category. However, they will still be held accountable for their performance in any episode category in which they were not classified as low volume in the baseline period per the participation tracks applicable to the hospital. Please note that all performance year episodes which are eligible for reconciliation will still be included in determining the CQS and stop-loss/stop-gain thresholds even if downside risk has been waived for those episodes. We believe this low volume policy not only financially protects low volume hospitals, but it allows these hospitals to continue participating in the model with a positive incentive to try and reduce spending.

Comment: Many commenters supported a low volume policy that would apply to specific episode categories. A few commenters added that under a low volume policy that applied across all episode categories, hospitals could reach the low volume threshold through high episode counts in one or two episode categories and face reconciliation in other categories in which they had very few episodes. For example, a hospital could have 30 episodes in the LEJR category, and one episode in each of the other categories. This would result in that hospital facing reconciliation for categories in which they did not have a significant number of episodes.

Response: We thank the commenters for their suggestions. We agree that the low volume policy should apply to specific episode categories, as opposed to across all episode categories. The low volume threshold previously considered and finalized in this rule will be applied at the episode category level. This will prevent hospitals with imbalanced episode volumes from facing reconciliation for episodes categories in which they had low episode volume. We recognize that systematic care redesigns made for one episode category will not always translate to other episode categories. Setting the threshold at the episode category level will ensure that hospitals only face risk for those categories in which they have a high enough volume of cases to meaningfully evaluate these redesigns. We believe that an additional threshold accounting for hospitals with a low total number of episodes would be redundant.

Comment: Many commenters stated that participants that do not meet the low volume threshold for a given episode category should not face downside risk in that episode category for the performance year. A commenter suggested that low volume hospitals be allowed to opt-in to participation in TEAM for episode categories in which they were below the threshold, or if forced to participate, be allowed to select Track 1 for the first 3 performance years of the model and Track 2 for the remaining years of the model for that episode category. A commenter stated that participants that do not meet the low volume threshold for a given episode category should be granted an exemption from participation in that episode category.

Response: We thank the commenters for their suggestions. While not holding TEAM participants who failed to reach the low volume threshold for a given episode category accountable for their performance in that category may result in higher savings for CMS, we are finalizing that these hospitals would still be able to receive reconciliation payment amounts because it both mitigates financial concerns for low volume hospitals and maintains an incentive for these hospitals to reduce spending and provide quality care for low volume procedures. This will have roughly the same impact as allowing hospitals to be placed in Track 1 for a given episode category. However, hospitals would retain the stop-gain limits for the participation track they had selected for that performance year. For example, if a Track 2 and a Track 3 hospital both fell below the low volume threshold for a given episode category in PY 2, and earned a reconciliation payment from CMS for that episode category, they would face stop gain limits of 5 percent and 20 percent, respectively.

Comment: A couple of commenters stated that participants that do not meet the low volume threshold for a given episode category should either be excluded from the model or be placed in Track 1 for the duration of the model, adding that anything less would provide insufficient protection for low volume hospitals.

Response: We disagree that TEAM participants that do not meet the low volume threshold for a given episode category for one performance year should be excluded from the model or protected under the low volume policy for the duration of the model. The combination of a 3-year baseline period and the fact that procedure volumes tend to remain consistent across years mean that it is likely that a hospital's status as low volume will remain constant for a given episode category across the duration of the model. However, if a hospital were to exceed the low volume threshold for a given baseline period, we believe that it would be inappropriate to continue to treat them as low volume.

Comment: Many commenters wrote in favor of specific low volume thresholds that would be appropriate in fairly assessing participant's performance. These suggestions included thresholds of 25, 30, 31, 40, 50, 72, 91, and even 200 episodes per episode category across a 3-year baseline period. A commenter also suggested an MS–DRG specific low-volume threshold of 50 episodes.

Response: We thank the commenters for their suggestions. When selecting the low volume threshold, we considered the need to minimize the financial risks

placed on low volume hospitals, the need to fairly evaluate participants, the goal of maximizing participants' incentives to invest in health care infrastructure, redesigned care processes, and provide higher value care, and potential savings to Medicare. We believe that a threshold of 31 episodes per episode category over three baseline years sufficiently protects low volume hospitals and provides a high enough volume for CMS to fairly assess their performance and for TEAM participants to fairly assess care transformation efforts made in these episode categories.

When assessing what protections should be provided to hospitals that fell below the low volume threshold, we determined that, in order to maximize incentives to transform care, it was important to continue to reconcile episodes for low volume hospitals who earn reconciliation payments from CMS. This approach, which exposes CMS to downside risk on low volume episodes, reduces savings for CMS, and that savings reduction increases as the low volume threshold rises.

Regarding the suggestion to set the low volume threshold at the MS–DRG level, while we recognize that pricing is done at this level, we believe that setting this granular of a low volume threshold would make the low volume threshold susceptible to increased coding intensity. While costs across MS–DRGs within an episode category may be different, we believe that care transformation efforts made within these categories will be largely transferable. Finally, we believe that annual thresholds, if assessed during the performance year, would also create gaming opportunities.

Comment: A few of commenters supported a threshold of 41 episodes per episode category across a 4-year baseline period, similar to BPCI Advanced.

Response: We thank the commenters for their suggestion. While we recognize that BPCI Advanced utilized a 4-year baseline period, TEAM has a 3-year baseline period. A threshold of 31-episode over 3 baseline years is the same per baseline year threshold as 41 episodes over 4 baseline years.

Comment: A commenter suggested that CMS adopt a tiered threshold or set a low volume threshold that is based on the percentage of total episodes within a category to account for the fact that some episode categories inherently have higher volumes than others.

Response: We thank the commenter for their suggestion. While we recognize that episode counts are inherently different across different episode categories, we believe that varying the low volume threshold by episode category would add unnecessary complexity to the model at this time.

Comment: A commenter expressed concern that Track 1 being optional in PY 1 meant that this track did not guarantee protection against financial vulnerability for low volume hospitals.

Response: We would like to clarify that, while Track 1 is optional for participants in PY 1, participants will be assigned this track unless they notify CMS that they would like to participate in Track 3. Therefore, the only TEAM participants that face downside risk under TEAM in PY 1 will be those that voluntarily elect to do so. We believe that this does guarantee protection against financial vulnerability for TEAM participants in PY 1.

Comment: A couple of commenters urged CMS to finalize a low volume policy prior to PY 1, stating that participants must know the key elements of TEAM prior to the start of the model for planning purposes. The commenters also noted that CMS should minimize mid-model changes. Another commenter stated that a low volume policy was one of several key features of TEAM that had not been determined, and that CMS should delay the model until these features were finalized so that hospitals had time to prepare for participation.

Response: We thank the commenters for their concerns regarding hospitals' ability to plan for TEAM and the importance of minimizing mid-model changes. We disagree that TEAM participants do not have adequate time to prepare for the model. There are approximately 17 months between the start date of TEAM and when hospitals were notified of their participation through the 2025 IPPS/LTCH PPS proposed rule. TEAM participants that elect to participate in Track 1 will have 12 additional months to prepare before they take on downside risk in PY 2, and TEAM participants that qualify as safety net will have up to 24 additional months to prepare before taking on downside risk in PY 4. We understand that the low volume policy is an important aspect of the model, and TEAM participants will have approximately 17 months between the low volume policy being finalized in this rule and when they are exposed to downside risk in PY 2. Furthermore, all TEAM participants will be notified whether or not they qualify as low volume in a given episode category based on the baseline period of that performance year ahead of the due dates for participation track selection for that performance year. TEAM participants will have the necessary information to decide what level of financial risk/reward they want to opt-into for a given performance year.

We recognize the importance of minimizing mid-model changes and will take the instability caused by such changes into account in future notice and comment rulemaking. However, we also recognize the importance of being responsive to TEAM participants. We will continue to monitor the low volume policy throughout the model test and may propose changes through future notice and comment rulemaking if we identify an approach that is more responsive to TEAM participants and spurs care improvements for beneficiaries at low volume hospitals.

Comment: A commenter expressed concerns that low volume providers would struggle to establish pre- and post-acute partnerships, causing them to struggle in TEAM.

Response: We thank the commenter for their feedback. We agree that these partnerships could significantly impact hospitals' ability to succeed in TEAM. We also recognize that factors outside of a hospital's control, such as geographic location and market dynamics, will impact their ability to form these partnerships. We believe that the low volume policy finalized in this rule, as well as other policies included in TEAM, such as the ability for rural hospitals to participate in Track 2, will help protect the TEAM participants most likely to struggle to form partnerships with providers for reasons outside of their control.

Comment: Some commenters noted that, for low volume providers, the upfront costs of participation in the model, such as updating analytics infrastructure or staffing, would outweigh the benefits of participating in the model, or that investing in care delivery improvements for specific episode categories would not be financially viable if hospitals performed low volumes of those procedures. A commenter added that low volume providers are not incentivized to make meaningful changes in care delivery under the model. A few commenters expressed concerns about the level of financial investment in infrastructure, analytics, and system redesigns hospitals would need to succeed under the model and some stated that the low volume threshold should be high enough that hospitals that met the threshold accrued enough episodes to determine if care delivery changes had a meaningful impact.

Response: We thank the commenters for their concern regarding low volume hospitals' ability to afford the upfront

costs needed to make meaningful changes in care delivery, their incentives to make these changes, and their ability to evaluate the impact of these changes. TEAM is intended to incentivize investments and changes in care processes that improve both the quality and efficiency of care. We understand that many of these improvements include fixed costs, and that it may be difficult for hospitals to justify these costs in areas where they have low volume of cases, as the hospital could provide greater quality and efficiency improvements by investing resources elsewhere. We acknowledge that it is difficult to justify major care changes without a high enough case volume to accurately measure the impact of these changes. We believe that the finalized low volume threshold of 31 episodes per episode category in a given baseline period represents a high enough volume for hospitals to evaluate the impact of changes made while participating in TEAM. Additionally, we believe that this policy will prevent hospitals from owing repayment amounts for episode categories in which they lack the incentive to invest in care transformation efforts.

Comment: Some commenters stated that the lack of a low volume policy would hurt rural, small, or safety net providers. A few commenters stated that safety net hospitals, which display low margins and depend on public payors, could not afford to invest in care teams for low volume procedures.

Response: We thank the commenters for their concerns for rural and safety net hospitals. While we are finalizing a low volume policy, we want to emphasize that TEAM provides significant protection for these hospitals outside of a low volume policy. Safety net hospitals, as defined at § 512.505, will be able to participate in Track 1 with no downside risk for the first 3 performance years of the model. Additionally, we will incorporate a variable in the TEAM risk adjustment model that accounts for safety net status when calculating target prices, providing more accurate targets for hospitals whose spending may exceed the averages in their region for reasons outside of their control. Both safety net hospitals and rural hospitals, as defined at § 512.505, will be able to participate in Track 2 for performance years 2 through 5 of the model with a 5 percent stop-gain and stop-loss limit. We believe that these protections, in conjunction with the low volume policy finalized in this rule, will allow rural and safety net hospitals the opportunity to succeed in TEAM.

Comment: Some commenters stated that CMS should apply the low volume threshold to all hospitals, as opposed to just rural and safety net hospitals.

Response: We thank the commenters for their suggestion. We agree that the difficulties that low volume hospitals face are not specific to rural and safety net hospitals. The low volume policy finalized in this rule will apply to all TEAM participants regardless of their status as rural or safety net hospitals.

Comment: Some commenters suggested that CMS maintain data sharing with hospitals that fell below the low volume threshold, as this data could help them prepare for future performance years in which they might exceed the threshold.

Response: We thank the commenters for their suggestion. Falling below the low volume threshold will have no impact on data sharing for TEAM participants. We agree with the commenters that continuing to share data with hospitals that fall below the low volume threshold is critical, as these hospitals are still TEAM participants and could exceed the threshold for future performance years. Given that hospitals who fall below the threshold for a given episode category will still have their episodes reconciled, just without facing downside risk, it would not make sense to withhold data from these hospitals.

Comment: A commenter stated that the low volume threshold should also apply to benchmarking calculations.

Response: We thank the commenter for their suggestion. While we recognize that low volume hospitals may generate outlier episodes, we believe that our current benchmarking methodology fairly accounts for those outliers. Additionally, because preliminary target prices are at the MS–DRG/HCPCS-region level, a regional low-volume policy would not be practical to implement as CMS will need to create target prices for all MS–DRG/HCPCS in all regions.

After consideration of the public comments, we are finalizing at § 512.550(c)(1) through (7) a low volume threshold policy that received the majority of public comment support in TEAM such that if a TEAM participant did not meet the 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.

(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 proposed to modify our approach to attribution of episodes to baseline years for the purpose of calculating preliminary target prices. Specifically, we proposed adopting the same approach that we finalized for attribution of performance year episodes, as described previously. Therefore, we proposed 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). We stated in the proposed rule that this modification does not make any change to the methodology for attribution of episodes to the performance year. We believed 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 recognized 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.–15 demonstrates how episodes starting in a one performance year and ending in a subsequent performance year are reconciled.

TABLE XI.A.-15: 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 proposed to reconcile an episode based on the episode's anchor hospitalization or anchor procedure discharge date. We believed this approach would simplify tracking episodes and their reconciliation timing for TEAM participants. Additionally, we stated in the proposed rule that 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.–16 demonstrates the proposed approach to reconciling episodes based on anchor hospitalization or anchor procedure discharge date.

TABLE XI.A.-16: 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 sought comment on our proposal at § 512.540(b)(2)(i) through (v) to construct baseline year episodes based on the anchor hospitalization or anchor procedure discharge date. We also sought comment on our proposal at § 512.540(a)(3) to reconcile episodes based on anchor hospitalization or anchor procedure discharge date.

The following is a summary of the public comments received on the proposed policies to construct baseline year episodes and to reconcile episodes based on the anchor hospitalization or anchor procedure discharge date, and our responses to these comments:

Comment: A few commenters expressed support for our proposal to assign baseline year episodes to corresponding baseline years based on the anchor hospitalization or anchor procedure discharge date and also to reconcile episodes based on anchor hospitalization or anchor procedure discharge date.

Response: We thank the commenters for sharing their support.

Comment: Some commenters expressed concerns that the proposed change would delay reconciliation.

Response: We disagree that the proposed change would delay reconciliation. Rather, the policy has been proposed to avoid delays in reconciliation. For example, per the policy finalized in the FY2025 IPPS/LTCH final rule, an episode in PY1 that has an anchor hospitalization or anchor procedure discharge date in 2026 and an episode end date in 2026 will be reconciled in Fall 2027 whereas a PY1 episode with anchor hospitalization or anchor procedure discharge date in 2026 but an episode end date in 2027 will be reconciled in Fall 2028. Even though both episodes fall in the same performance year and have the same final target price applicable to them, they would be reconciled in different time periods due to the end dates falling in different calendar years. As noted in the proposed rule, this may unnecessarily increase operational burden and delay the timely delivery of reconciliation reports. Therefore, we had proposed to reconcile episodes based on anchor hospitalization or

anchor procedure discharge date and not the episode end date such that all episodes belonging to a given performance year are reconciled together. In the previous example, both episodes would be reconciled at the same time in Fall 2027 and TEAM participants will not have to wait until Fall 2028 to find the outcomes of some performance year 2026 episodes. We refer readers to tables XI.A.–15 and XI.A.–16 which illustrate when episodes would be reconciled based on episode end dates compared to anchor hospitalization or procedure discharge date.

Comment: Some commenters stated that TEAM should be consistent with past models and use episode end dates to determine attribution of both baseline and performance year episodes.

Response: While the proposed policy differs from BPCI Advanced where episodes are reconciled based on episode end dates, it aligns with the approach used in CJR model. The approach used in BPCI Advanced has increased operational burden for both CMS and BPCI Advanced participants as a fraction of episodes belonging to a given performance year are reconciled at a much later date relative to other episodes in the same performance year.

After consideration of the public comments, we are finalizing without modification our proposal at § 512.540(b)(2)(i) through (v) to construct baseline year episodes based on the anchor hospitalization or anchor procedure discharge date. We are also finalizing our proposal at § 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. We indicated in the proposed rule that 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. We noted in the proposed rule that 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. In the proposed rule, we stated that 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 believed 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, in the proposed rule we acknowledged 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 stated in the proposed rule that 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 stated in the proposed rule that 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 noted in the proposed rule that 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, we stated 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, we stated that 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 did not propose any methodology for converting standardized target prices and reconciliation amounts to real dollars at this time. Instead, we kept 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.

We sought comment on whether and how to convert target prices and reconciliation amounts from standardized dollars to real dollars in a consistent manner.

The following is a summary of the public comments received on the considerations for converting target prices and reconciliation amounts to real dollars, and our responses to these comments:

Comment: A few commenters suggested CMS should convert standardized dollars to real dollars for both target prices and reconciliation amounts. A couple commenters urged CMS to establish a methodology to convert standardized dollars to real dollars to issue performance-based payments and recoupments from participating TEAM hospitals only during the reconciliation calculation for each performance year. Among commenters suggesting converting standardized dollars to real dollars for either the reconciliation amounts only or for both target prices and reconciliation amounts, a few commenters requested that CMS consider the wage factor conversion method used in the CJR model to best account for differences in hospitals' episode expenditures in relation to the target price. A commenter suggested reconciliation amounts should have a real-to-standardized dollar ratio applied, similar to the calculation in BPCI Advanced. However, this commenter suggested to exclude inpatient indirect medical education (IME) payments and disproportionate share hospital (DSH) payments. A couple commenters supported keeping target prices and reconciliation amounts in standardized dollars since it will better allow peer participants to compare themselves to a fixed reference point.

Response: We believe that keeping the reconciliation amounts in standardized dollars minimizes the risk of creating unfair rewards/penalties for hospitals. Specifically, we believe it may negatively impact participants, who receive additional payments like IME and DSH payments leading to higher real to standardized ratio causing an amplification of TEAM repayment amounts. On the other hand, hospitals that receive deductions through various hospital programs may lead to lower rewards through lower real to standardized ratio.

Comment: A commenter noted that the conversion methodologies used in BPCI Advanced and CJR are imperfect and suggested a six-step conversion methodology which applied different wage factors based on the payment system (that is, IPPS, OPPS, Physician Fee Schedule) used in each of the clinical episodes.

Response: We appreciate the detailed six-step methodology outlined by the commenter but have concerns regarding the complexity and feasibility of such an approach. Given the multiple payment systems throughout the various anchor and post-discharge period claim settings, the ability to calculate wage factors and apply them to target prices which are established using baseline data adds considerably to the operational complexity of the model.

Comment: A commenter stated that the use of standardized dollars removes any elements that would make one provider's Medicare payment different from another provider's payment for the same claim.

Response: We disagree that the use of standardized dollars removes the ability to distinguish the cost of care between two claims. Standardized dollars allow fair comparisons by removing the impact of geographical factor like wage index for the same services between two different providers. Cost differences based on variations in practice patterns and health care delivery choices continue to exist and are avenues for potential additional savings.

We did not propose, and after consideration of public comments, we are not convinced that we should make any changes to the calculation of target prices and reconciliation amounts. Therefore, the calculation of target prices and reconciliation amounts will remain in standardized dollars. We believe the standardized dollar payments will continue to remove differences in wage indexes and hospital-level payment adjustments across target prices and reconciliation amounts for TEAM participants.

(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.

In the proposed rule, we stated that we recognize it is important to remain consistent across our calculations when converting to real dollars. Therefore, we also sought comment on whether and how to convert the post-episode spending amounts from standardized dollars to real dollars. Specifically, we requested 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, we stated in the proposed rule that 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 sought comment on our consideration to determine post-episode spending amounts at the MS–DRG-hospital level rather than an episode level. We also sought comment on whether and how to convert post-episode spending amounts from standardized dollars to real dollars in a consistent manner.

The following is a summary of the public comments received on the considerations for post-episode spending amounts at the hospital rather than episode level and to convert post-episode spending amounts to real dollars, and our responses to these comments:

Comment: A commenter noted that CMS should carefully evaluate whether post-episode spending should be converted to real dollars as the conversion may improve transparency but could also introduce unintended financial risks for hospitals. This commenter requested that CMS further engage with stakeholders to determine whether real-dollar conversions would enhance financial predictability or create additional burdens for hospitals. Another commenter supported the use of real-dollar conversion for post-episode spending calculations as they believe the conversion will provide more meaningful insight into actual costs.

Response: We thank the commenters for sharing their thoughts regarding the conversion of post-episode spending amounts from standardized dollars to real dollars. We agree that hospitals in high wage index may incur high penalty amounts compared to low wage index areas, however it is not the primary factor of consideration for keeping the penalty amounts in standardized amounts since Medicare payments received by the providers are reflective of these wage-indexes. CMS believes provider-specific add-on payments like IME and DSH payments may lead to higher real to standardized ratio which in turn may unduly penalize the TEAM participants.

We did not propose, and after consideration of the public comments, we are not convinced that any changes should be made to the calculation of post-episode spending amounts. Therefore, the calculation of post-episode spending amounts will remain in standardized dollars and at the episode level.

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 stated in the proposed rule that 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 recognized the need to remove the voluntary health equity plan and the health-related social needs data to reduce burden on TEAM participants. We noted in the proposed rule that we recognized 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 believed 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 proposed to completely remove the health equity plan and health related social needs data policies from TEAM, including all references to health equity plans. We stated in the proposed rule that 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. We noted in the proposed rule that 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 proposed to remove the ''Health equity reporting'' title to § 512.563 and replace it with ''Health data reporting''. Lastly, we also proposed 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 proposed removing the voluntary collection of health-related social needs screening and reporting. This included 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 at § 512.563(b).

In the proposed rule we stated that we also continue to believe voluntarily collecting demographic data is important to better understand TEAM beneficiaries. Therefore, we did not propose any changes to this element. We noted 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 clarified in the proposed rule 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 proposed 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.[407] Specifically, we

[407] Executive Order No. 14168 of January 20, 2025, Defending Women from Gender Ideology

proposed 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 sought 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 sought 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 sought comment on our proposal at § 512.562(c)(3) to rename the ''gender'' variable to ''sex''.

The following is a summary of the public comments received on the proposed policies to remove health equity terms, remove the health equity plan and health related social needs data elements, and rename the gender variable, and our responses to these comments:

Comment: Some commenters supported CMS's decision to remove health equity plans from TEAM.

Response: We thank these commenters for their support.

Comment: A number of commenters did not support CMS's proposal to remove health equity plans from TEAM. These commenters recognized the plans were voluntary components of TEAM but noted environmental and social factors are important to understanding the context and health of patients fully. These commenters noted that this additional data on patients allows them to better understand and care for vulnerable patients.

Response: We thank these commenters for their feedback. We believe it is important for TEAM participants to have the autonomy and flexibility to determine how they can best meet the needs of their patient population. TEAM participants are permitted to collect additional information on their patients in the model, while remaining compliant with relevant laws and regulations, in order to improve quality of care and reduce Medicare spending. We anticipate that TEAM participants may work toward independently identifying and producing their own data, through electronic health records, health information exchanges, or other means that they believe are necessary to best evaluate the health needs of their patients, improve health outcomes, and produce efficiencies in the provision and use of services. Therefore, we support TEAM participants collecting additional information for their own use that could be beneficial to the health and wellbeing of their patients. We believe that removing health equity plans from the model does not prevent TEAM participants from collecting data that could give greater context to the care of patients. CMS is focused on reducing or not inflicting additional levels of administrative burden on TEAM participants. While we recognize health equity plans were voluntary, we believe removing health equity plans from TEAM will allow TEAM participants to direct their resources and attention to model requirements and achieving the goals of the model. We also believe removing health equity plans from TEAM will allow TEAM participants to make their own decisions on what data is the most useful to collect to provide the best care to patients.

Comment: A commenter noted voluntary submission of health equity plans would help CMS and participants identify where potential care and health disparities exist, tailor care redesign efforts to patient needs, and develop interventions that reduce avoidable complications and readmissions.

Response: We appreciate and sympathize with this commenter's concerns over avoidable complications and readmissions, as this is a major part of what TEAM is trying to reduce. If TEAM participants believe that collecting health equity data will help in this endeavor, they are free to do so, but TEAM participants will not incur the burden of submitting this data to CMS (as they may under the current voluntary policy), nor will CMS accept receipt of this data.

Comment: Some commenters supported CMS's decision to keep reporting requirements around patient demographic data, but remove specific portions relating to Social Determinants of Health (SDOH)

Response: We thank these commenters for their support.

Comment: Other commenters questioned why CMS should remove SDOH data from reporting requirements. These commenters noted that voluntary submission of SDOH data would help CMS and TEAM participants identify where disparities exist, tailor care redesign efforts to patient needs, and develop interventions that reduce avoidable complications and readmissions. These commenters stressed that collecting this data is not a burden to them but is considered an investment in using efficiently and effectively. They also believe this data collection aligns with the long-term goals of value-based care which leads to improving patient outcomes while reducing cost and raising quality of care.

Response: We appreciate these commenters concerns and their commitment to CMS's goals of improving quality while also reducing the cost of care for Medicare beneficiaries. We believe it is important to give TEAM participants more autonomy and flexibility to accomplish these goals. With this in mind, removing the SDOH reporting requirements from TEAM gives TEAM participants the flexibility to identify and focus on the non-medical needs for their specific patient population and cater their care redesign interventions to meet the needs of their patients. If TEAM participants believe collecting SDOH data will reduce costs and improve the quality of care, then TEAM participants are free to continue these data collection practices, but they will not need to report this data to CMS. However, if it is not clear to TEAM participants if this specific data collection will reduce costs or improve quality of care, there will no longer be any mechanisms in place for them to report such data to CMS.

After consideration of public comments, we are finalizing our proposal to remove Health Equity Plans from TEAM and remove the corresponding regulations at § 512.505 and § 512.563. We are also finalizing our proposal to remove voluntary reporting of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure from TEAM and remove the corresponding regulations at § 512.563(b). Lastly, we are finalizing our proposal to rename the ''gender'' variable to ''sex'' at § 512.562(c)(3).

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). We stated in the proposed rule that since a TEAM episode only lasts 30 days after the TEAM beneficiary is discharged from the hospital, the goal

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/./.*

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 noted in the proposed rule that 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 did not propose a change to the current policy. However, we were 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, we stated in the proposed rule that 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 sought 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 did not propose, 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. We explained in the proposed rule that 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 were 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 to 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 care services within the 2 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 recognized 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 did not propose, 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. In the proposed rule, we recognized 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 believed 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.

In the proposed rule, we noted that 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. We stated in the proposed rule that 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, we noted in the proposed rule that 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 recognized the primary care service referral may not be as impactful to driving primary care connections. We therefore considered, but did not propose, 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 stated in the proposed rule that 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, we also stated in the proposed rule that 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 stated in the proposed rule that 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 sought 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 sought comment on alternatives that we may not have considered.

The following is a summary of the public comments received on the proposed policy to maintain the primary care services referral requirement and alternatives to this requirement, and our responses to these comments:

Comment: Many commenters supported the referral to primary care services requirement. The majority of the commenters that supported the requirement supported a referral back to an established supplier of primary care services. Of those commenters that supported a referral back to an established supplier of primary care services, many had concerns with using historical claims to identify the established supplier of primary care services due to operational burden and lack of insight. Several commenters supported having the TEAM participant refer to the supplier of primary care services recorded at the initiation of the hospitalization or outpatient procedure. Other commenters that supported the requirement suggested that the referral go to the ordering or primary follow-up physician rather than a primary care provider. A commenter recommended using CPTII codes to ensure beneficiaries are connected back to a provider to which they are already aligned.

Response: We thank the commenters for their support. As we noted in the FY 2025 IPPS/LTCH PPS final rule, TEAM provides an opportunity to further integrate care during the transition from an acute event- an episode- back to longitudinal care relationships, such as primary care (89 FR 69850). As such, the intent of the referral to primary care services requirement is to ensure the TEAM beneficiary can have continual clinical management from a longitudinal care provider after the episode ends. We do not intend for this requirement to disrupt existing patient-provider relationships nor replace any follow-up or management clinically necessary from a specialist or the clinician who performed the surgery. We agree that when including a referral to a supplier of primary care services in hospital discharge planning for a TEAM beneficiary, that the TEAM participant should take into account the TEAM beneficiary's primary care provider recorded during the hospital admission to the anchor hospitalization or recorded during the intake for the anchor procedure. We believe improved beneficiary quality of care can be achieved through consistent care management from suppliers who have an established relationship with the TEAM beneficiary. However, we recognize that there may be times that a TEAM beneficiary's preferences may change over the course of the anchor hospitalization or anchor procedure. Therefore, it is imperative that TEAM participants comply with beneficiary freedom of choice requirements, as described in § 512.582(a), when including the referral for primary care services in the hospital discharge planning.

We agree that relying on claims data to identify an established supplier of primary care services would be operationally burdensome on the TEAM participant and that this data may not capture recent patient preferences, especially if the TEAM beneficiary moved or if the TEAM beneficiary opted to change providers.

We acknowledge the recommendation to use CPT II codes, as was used in BPCI Advanced for the Advanced Care Plan measure, to ensure a TEAM beneficiary is connected back to their established provider. However, we believe adding another step, such as including non-billable CPT II codes to a claim would increase TEAM participant burden unnecessarily.

We also recognize the value in referring the TEAM beneficiary to a supplier that may be more clinically attuned to managing the TEAM beneficiary's medical needs. As noted earlier, the referral to primary care services requirement should not replace any clinically appropriate follow-up care with a specialist or clinician that performed the surgical procedure. Outside of the referral to primary care services requirement, TEAM participants are not precluded from referring the TEAM beneficiaries to a specialist and we support the TEAM participant helping to coordinate a TEAM beneficiary's care with a specialist as that acute surgical event is typically the primary clinical focus after discharge from the hospital or hospital outpatient department. We believe the TEAM participant is well positioned to identify a supplier that they believe would be the most clinically appropriate to manage the TEAM beneficiary as long as the TEAM participant is complying with beneficiary freedom of choice requirements.

Given the majority of commenters' support for CMS to ensure TEAM beneficiaries are being referred to established suppliers, we believe that we need to modify the referral to primary care services requirement. Specifically, we will be adding clarifying language to § 512.564(a) to state that a TEAM participant must include in hospital discharge planning a referral to an established supplier of primary care services, as recorded on admission to the hospital or hospital outpatient department, for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. However, we recognize that there may be instances when a supplier of primary care services is not recorded on admission to the hospital or hospital outpatient department. We also want to prevent TEAM participants circumventing the documentation of an established supplier of primary care services to avoid the referral to primary care services requirement. In the event an established supplier of primary care services is not recorded on admission to the hospital or hospital outpatient department, such as because the TEAM beneficiary does not have an established supplier of primary care services, the TEAM participant must 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. In other words, if the supplier of primary care services was not recorded on admission to the hospital or hospital outpatient department, the existing referral to primary care services would apply. This ensures all TEAM beneficiaries are being connected back to a supplier of primary care services, not just those with an established supplier. No modifications will be made to § 512.564(b); therefore, TEAM participants must continue to comply with beneficiary freedom of choice requirements. This means TEAM participants must continue to take into account TEAM beneficiary preferences when referring to a supplier of primary care services, which may include consideration of the supplier's location in relation of the TEAM beneficiary's place of residence.

We believe this addition will ensure that TEAM beneficiaries are being referred to the established provider with whom they have an existing relationship. Further, we believe the referral to primary care services requirement will promote collaboration between the TEAM participant and primary care providers, so that the TEAM beneficiary is being managed by a care team that includes clinicians who

can manage the surgical procedure and clinicians who focus on preventative care and can manage underlying, chronic conditions.

Comment: Several commenters supported a referral to primary care services but recommended CMS to not make it a requirement of the model. These commenters requested flexibilities for the TEAM participant to determine when a referral is appropriate and suggested the referral only be applicable to beneficiaries that do not have a supplier of primary care services. Some commenters also recommended that CMS include incentives for hospitals that successfully integrate primary care referrals into their care coordination strategies, rather than imposing strict compliance measures.

Response: We appreciate the commenters' recommendations. We recognize that a model requirement, as opposed to an optional model feature, may have the potential to increase TEAM participant burden. However, we believe that a referral to primary care services is already a common component to hospital discharge planning procedures and, as such, we expect that many TEAM participants will already have this policy integrated into their standardized discharge planning procedures and therefore have a minimal impact on burden. We also understand why commenters suggested this model requirement just focus on TEAM beneficiaries that do not have a supplier of primary care services since these are the patients that may eventually lack proper care management after the episode ends. Nonetheless, we believe having the referral to primary care services requirement apply to all TEAM beneficiaries is the most appropriate because we view the referral to primary care services as an important component of care coordination. Given a goal of the model is to improve transitions between care settings and providers, we believe it would be best practice for TEAM participants to refer all TEAM beneficiaries not just those without an established supplier of primary care services.

We acknowledge that the referral to primary care services is a requirement of the model but we do not believe that TEAM participants should be incentivized above and beyond the existing model incentive structure. Rather, we view the requirement as a mechanism to establish a standard care practice that we believe many hospitals already implement. We also believe the policy supports a step towards whole-person health where TEAM beneficiaries are being managed by the providers with the clinical expertise of their acute surgical event and then subsequently connected back to providers with longitudinal primary care expertise.

Comment: Some commenters requested CMS extend the referral period to anytime during the episode of care rather than limiting it to the time period before the TEAM beneficiary is discharged from the anchor hospitalization or anchor procedure.

Response: We acknowledge the commenters' recommendations to extend the referral period, which would provide the TEAM participant with more time to submit a referral to a supplier of primary care services. Still, we believe the best opportunity to have conversations with the TEAM beneficiary regarding longitudinal care management is when the TEAM participant can have in-person interaction with the TEAM beneficiary or the TEAM beneficiary's family or caregivers. This means we believe the most appropriate time frame to have these face-to-face conversations would be during the anchor hospitalization or anchor procedure. Further, we also believe that having these face-to-face discussions during the anchor hospitalization or anchor procedure is conducive to ensuring beneficiary freedom of choice is taken into account when submitting the referral during discharge planning.

Comment: A couple of commenters did not support CMS's consideration of requiring hospitals to refer patients specifically to a supplier of primary care services they have visited in the past 2 years, based on claims information, due to the TEAM participant's burden since claims are not integrated into electronic health records (EHRs). They further indicated that patients may have moved or deliberately changed their usual source of care in the previous 2 years, which could prevent hospitals from connecting patients to a more appropriate source of care. Lastly, they indicated that patients that recently switched their supplier of primary care services would not necessarily have their current supplier of primary care services reflected in the claims available to the hospital at the time of discharge.

Response: We recognize the challenge TEAM participants may have to identify a supplier of primary care services that has an established relationship with a TEAM beneficiary in the 2 years prior to the anchor hospitalization or anchor procedure when relying on claims data. While Medicare providers and suppliers are generally good at submitting timely claims, we acknowledge that TEAM beneficiaries that have recently switched suppliers of primary care services may have their new suppliers and preferences inadvertently overlooked given the lag in claims data. Additionally, as the commenters noted, claims data is not necessarily integrated within a hospital's EHR technology, and we realize the limitation to accessing historical claims data, especially claims data for items and services outside of the hospital's claims. We also understand that TEAM beneficiaries can be transient or seek care from multiple clinicians over the span of the 2 years and thus relying on claims data in the 2-year period prior to the anchor hospitalization or anchor procedure to identify an established supplier of primary care services may not be the most reliable or clinically appropriate method to support continuity of care, especially in light of current medical needs after a surgical procedure. Therefore, we agree it may not be appropriate or operationally feasible to rely on claims data in the 2 years prior to the anchor hospitalization or anchor procedure to identify a supplier of primary care services for a TEAM beneficiary. Given these concerns, we are not requiring the TEAM participant to rely on claims data in the two years prior to the anchor hospitalization or anchor procedure to identify an established supplier of primary care services.

Comment: Many commenters had concerns with the referral to primary care services requirement. Specifically, commenters wanted CMS to consider the impacts of the national physician shortage. These commenters indicated that hospitals, depending on their location, might experience challenges when referring patients after discharge and CMS should implement safeguards that would prevent clinicians from being penalized for situations beyond their control. A couple of commenters noted this referral to primary care services requirement fails to account for situations where patients are offered but decline the option. Another commenter noted the challenges of identifying providers in remote cities/counties outside of their primary service area. A couple of commenters stated that the requirement could lead to increased costs for patients and contribute to patient dissatisfaction. Lastly, another commenter noted concerns with the requirement conflicting with ACO patient assignment and it potentially resulting in double payment for postoperative visits. The same commenter indicated that hospitals are already implementing this requirement due to hospital conditions of participation at § 482.24(d).

Response: We thank the commenters for sharing their concerns and we acknowledge the challenges that arise from provider shortages and the impact they have on the health care system and patient access to care. We agree that it would not be fair to have a policy that could result in remedial action when the conditions of the policy are beyond the provider's control. That is why the referral to primary care services only requires the TEAM participant to include a referral in discharge planning and does not require the follow-up appointment to be scheduled or for the TEAM beneficiary to be seen within a certain amount of time. While the goal is for the TEAM beneficiary to be connected back to a supplier of primary care services for ongoing longitudinal care, we recognize imposing requirements beyond a referral may unnecessarily put certain TEAM participants at a disadvantage, such as rural hospitals or hospitals where clinician supply is low. Further, the definition of primary care services, as defined at § 512.505, is a broad definition that encompasses many different types of potential primary care services that can make compliance with the requirement much easier for the TEAM participant, especially hospitals that face provider shortage challenges.

We disagree that the referral to primary care services requirement fails to account for instances where the TEAM beneficiary may decline follow up care to a supplier of primary care services. The referral to primary care services requirement includes a provision that requires the TEAM participant to comply with beneficiary freedom of choice, as described in § 512.564(b). This means that a TEAM beneficiary may decline being referred to a supplier of primary care services and the TEAM participant may not be subject to remedial action because they respected the TEAM beneficiary's choice. We note that just like any other discussion about the TEAM beneficiary's care during the anchor hospitalization or anchor procedure, documentation of the refusal should be included in the beneficiary's EHR.

We also disagree that the referral to primary care services would lead to increased patient costs and dissatisfaction. The conditions of participation the commenter referred to require hospitals to send notifications of admission and discharge/transfer to post-acute care providers or practitioners responsible for follow up care, not to identify specific primary care providers or refer beneficiaries to primary care services (42 CFR 482.24(d)). However, hospitals are required to have an effective discharge planning process which must be consistent with the patient's goals for care and treatment preferences, ensure an effective transition of the patient from hospital to post-discharge care, and reduce the factors leading to preventable hospital readmissions (42 CFR 482.43). Hospitals must also transfer necessary medical information to appropriate post-acute care providers at the time of discharge. We believe the model's referral to primary care services requirement is reinforcing existing Medicare conditions of participation, not increasing patient encounters or out-of-pocket costs. Further, proper ongoing care management may reduce unnecessary provider encounters leading to less patient out-of-pocket costs. We also disagree that the referral to primary care services would lead to patient dissatisfaction. On the contrary, we believe the referral to primary care services requirement will result in TEAM beneficiaries having improved care experiences because the referral supports communication and coordination between specialty and primary care, which ensures continuity of care and supports whole person health.

We disagree that the referral to primary care services requirement will disrupt beneficiary assignment in ACO models or result in duplicative post-operative visits. We believe that this requirement will promote better collaboration between TEAM participants and providers in ACOs models because TEAM participants should be referring TEAM beneficiaries to their established supplier of primary care services. Generally, beneficiaries aligned or assigned to an ACO have established suppliers of primary care services which would make compliance to the requirement easy and support handoff to longitudinal care management. We also disagree with the commenter that the referral to primary care services requirement would result in duplicative postoperative visits. The referral to primary care services requirement does not replace the specialty-specific care services, such as a postoperative visit with the surgeon specialist, a TEAM beneficiary may need after they are discharged from the anchor hospitalization or anchor procedure. Nor does the requirement require a follow-up visit with the supplier of primary care services during the episode of care or within a certain time period.

Lastly, we agree with the commenter that many hospitals may already be referring their patients to primary care services due to existing Medicare conditions of participation for hospitals. While the Medicare conditions of participation requirements do not explicitly require referral to a supplier of primary care services, the conditions do require hospitals to send notifications to post-acute care providers or practitioners responsible for follow up care, which may or may not be suppliers of primary care services. Further, the Medicare conditions of participation have similar goals as TEAM, such as ensuring effective care transitions and reducing preventable hospital readmissions. Therefore, we believe that TEAM's referral to primary care services requirement is complementary to the existing conditions of participation and does not create additional burden beyond what may already be required of hospitals participating in the Medicare program.

Comment: A commenter suggested that CMS should consider aligning the definition of primary care services with HEDIS measures for follow-up after ED visits for high-risk patients, or with primary care definitions used in the Medicare Shared Savings Program.

Response: We thank the commenter for their suggestion. We recognize there are multiple definitions of primary care services, and we understand the value of aligning across different CMS initiatives. However, we believe the broad definition of primary care services used in TEAM allows the TEAM participant flexibility to identify the most clinically appropriate supplier for the TEAM beneficiary's needs. We also believe that a narrow definition may result in a TEAM participant having difficulties identifying a supplier of primary care services when there are provider shortages.

Comment: A commenter suggested that CMS consider ways to ensure that primary care suppliers involved in care transitions take steps to prevent opioid misuse by requiring the TEAM participant to document a rationale for prescribing opioids and a plan for transitioning the beneficiary to a non-opioid alternative, as clinically appropriate. They also recommended for beneficiaries prescribed opioids at discharge, establishing a care plan that involves joint monitoring by the TEAM participant and primary care supplier to monitor for any signs of opioid misuse or opioid use disorder.

Response: We recognize that it is common for opioids to be prescribed after a surgical procedure for pain management and we support providers and suppliers taking action to prevent opioid misuse. Proper care management for beneficiaries that are prescribed

opioids may lead to better health outcomes, mitigate pain, and reduce risks associated with opioid use disorder, overdose, and death. We anticipate TEAM will drive improved care coordination between providers and suppliers and we encourage TEAM participants to work closely with a TEAM beneficiary's primary care provider to implement care plans attentive to the needs of the patient while promoting pathways to taper or discontinue opioid use, as clinically appropriate. We do not believe adding additional requirements, such as a documentation requirement, would result in reduced opioid misuse because we believe TEAM participants are already implementing safeguards to monitor patients for opioid misuse. TEAM participants are accountable for the quality of care and spending during an episode of care, which we believe will incentivize TEAM participants to closely manage beneficiaries and implement both patient-specific and patient-driven care plans. Further, the existing referral to primary care services requirement helps to connect TEAM beneficiaries back to primary care for continued care management beyond the episode which may help to minimize unnecessary long-term prescription opioid use.

Comment: A few commenters wanted to know if the referral to primary care services requirement was just a referral or if it included an actual follow-up visit to the supplier of primary care services. One of the commenters noted that post-operative follow-up visits are performed by the surgical specialist and not the primary care provider. Another commenter wanted to know if the TEAM participant needed to confirm a scheduled follow-up visit.

Response: We appreciate the commenters request to clarify the referral to primary care services requirement. TEAM participants are required to include in hospital discharge planning a referral to a supplier of primary care services for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. TEAM participants are not required to ensure a visit is scheduled, nor are they required to confirm the beneficiary had the visit with the supplier of primary care services. We recognize there may be challenges outside the control of the TEAM participant, such as provider shortages, that could make scheduling a visit or requiring an actual visit to be burdensome or potentially difficult to be in compliance with. Further, we want to be mindful of beneficiary freedom of choice requirements and a beneficiary's right to refuse follow-up care.

To address the commenter's statement about post-operative follow-up visits being with a surgical specialist and not a primary care provider, we want to highlight that the referral to primary care services requirement does not intend to replace or bypass any follow-up visit with a surgical specialist or the supplier who performed the procedure. The intent of the referral to primary care services requirement is to ensure that the TEAM beneficiary is connected back to primary care, and that they have a clinician who can help to manage their care after the episode end

After consideration of the public comments, we are modifying the referral to primary care services requirement at § 512.564(a) to add that a TEAM participant must include in hospital discharge planning a referral to an established supplier of primary care services, as recorded on admission to the hospital or hospital outpatient department, for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. In the event an established supplier of primary care services is not recorded on admission to the hospital or hospital outpatient department, the TEAM participant must 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.

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 with 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 3 stars or better for at least 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 proposed 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.

We stated in the proposed rule that 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 academic research on PAC access in rural areas,[408] we believed it was 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 indicated in the proposed rule that we agreed with stakeholders that there are fewer SNFs in rural areas. We also agreed 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 believed 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 what we proposed, and in line with the Medicare Shared Savings Program regulations at § 425.612(a)(1) introductory text and (a)(1)(iii)(A), we also proposed 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 stated in the proposed rule that we believe it is 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 proposed to revise § 512.580(b)(3) to specify that the minimum 3-star rating requirement for at least 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 indicated in the proposed rule that we did 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 reserved 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 noted in the proposed rule 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 believed 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 noted in the proposed rule that this scenario could occur when a beneficiary meets the generally applicable 3-day stay requirement. Thus, we did 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 did not propose, 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 believed that the inclusion of swing bed arrangements at other hospitals is better aligned with the swing bed eligibility requirements detailed in § 482.58.

We sought 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.

The following is a summary of the public comments received on the proposed policy 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, and our responses to these comments:

Comment: Many commenters supported the proposal 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, indicating that this proposed expansion of the SNF 3-day rule waiver would increase access to PAC for beneficiaries in rural and underserved areas and provide additional flexibility to TEAM participants in determining appropriate care pathways.

Response: We thank the commenters for their support and agree with the stated benefits of broadening the TEAM 3-day SNF rule waiver to include swing bed arrangements.

Comment: A commenter recommended that CMS permit the use of swing beds under the TEAM 3-day SNF rule waiver regardless of star rating.

Response: We note that as part of the proposed broadening of the TEAM 3-day SNF rule waiver to include swing bed arrangements at hospitals and CAHs, we proposed 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.

Comment: A commenter recommended that CMS monitor the availability of eligible SNFs and swing beds in TEAM-participating regions to identify any gaps and adjust policy as needed.

Response: We thank the commenter for their suggestion. We believe that broadening the TEAM 3-day SNF rule waiver to include swing bed arrangements at hospitals and CAHs will increase access to PAC in areas where PAC providers, especially eligible SNFs, are limited. As noted in the proposed rule and established in §§ 512.590 and 512.586(a), we reserve the right to monitor and audit the use of payment waivers. Such monitoring may include utilization of the 3-day SNF rule waiver across regions.

Comment: A commenter recommended that we align the TEAM 3-day SNF rule waiver with the MSSP 3-day SNF rule waiver.

Response: We note that the broadening of the TEAM 3-day SNF rule waiver to include swing bed arrangements at hospitals and CAHs

[408] Sharma, H., Bin Abdul Baten, R., Ullrich, F., MacKinney, A.C., & Mueller, K.J. (2024). Nursing home closures and access to post-acute care and long-term care services in rural areas. The Journal of rural health: official journal of the American Rural Health Association and the National Rural Health Care Association, 40(3), 557–564. *https://doi.org/10.1111/jrh.12822.*

mirrors the MSSP 3-day SNF rule regulations at § 425.612(a)(1).

After consideration of the public comments, we are finalizing without modification the 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.

We stated in the proposed rule that 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 noted 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 wanted 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. We stated in the proposed rule that 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 believed 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 believed removing this initiative from TEAM will allow TEAM participants to focus on the requirements of the model, rather than a voluntary initiative. We also believed that removing 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 noted in the proposed rule 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 proposed to remove the DRI from TEAM.

We sought comment on our proposal to remove the DRI from TEAM and remove the corresponding regulations at § 512.598.

The following is a summary of the public comments received on the proposed policy to remove DRI from TEAM, and our responses to these comments:

Comment: Multiple commenters support CMS's proposal to remove the voluntary decarbonization reporting requirements from TEAM. These commenters applauded CMS's commitment to streamlining program requirements by reducing potential administrative burden. Commenters who supported the proposed removal of the voluntary decarbonization reporting requirement also noted this allows TEAM participants to focus on other areas of TEAM implementation.

Response: We thank the commenters for their support. We agree that removal of the voluntary Decarbonization and Resilience Initiative from TEAM will allow TEAM participants to concentrate on other areas of the model, such as improving care transitions to drive quality improvements and finding efficiencies to reduce Medicare spending.

Comment: Multiple commenters did not support the removal of the voluntary decarbonization reporting requirements. Many of those opposed noted the United States healthcare system contributes more pollution than many other sectors of the U.S. economy and these reporting requirements could help healthcare providers better understand their impact on the environment.

Response: We acknowledge the U.S. healthcare industry is large and emits large amounts of carbon. CMS's proposal to remove the Decarbonization and Resilience initiative would simply remove the administrative burden to report this information to CMS. TEAM participants are not precluded from continuing their own efforts to reduce carbon emissions and CMS encourages TEAM participants to innovate in ways beyond model requirements to improve the healthcare system and population health.

Comment: A commenter noted that a Decarbonization and Resilience Initiative could give TEAM participants data that would inform efforts to save money on energy expenses.

Response: CMS is only proposing to remove the Decarbonization and Resilience Initiative, not dictating any internal process improvement efforts of TEAM participants. TEAM participants are still free, and encouraged, to find ways to lower energy costs that would save money to provide more quality patient care.

Comment: Numerous commenters noted that air pollution, natural disasters, and changing climates cause millions of health problems every year. They noted that removing the Decarbonization and Resilience Initiative would allow TEAM participants to better track these climate events and respond to the health needs that follow.

Response: We support any TEAM participants or healthcare providers who institute policies to reduce environmental impacts on their patients. This is a separate matter than TEAM participant reporting requirements, however, and we believe TEAM participants should be free to institute their own ecofriendly policies and procedures without CMS imposing a voluntary initiative that may not meet the unique needs of each TEAM participant.

Comment: Some commenters noted that they will continue their efforts to reduce their carbon footprints regardless of the Decarbonization and Resilience Initiative's inclusion in TEAM.

Response: We support any TEAM participants who would like to continue the Decarbonization and Resilience Initiative in their private capacity. CMS does not want to interfere with the internal decision-making process of healthcare providers. To this end, by removing the Decarbonization and Resilience Initiative, CMS is giving TEAM participants the freedom to continue, alter, or end their own decarbonization efforts without government oversight or imposing reporting requirements.

After consideration of public comments, we are finalizing our proposal to remove the Decarbonization and Resilience Initiative from TEAM and remove the corresponding regulations at § 512.598.

B. Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit, and Electronic Prior Authorization (HTI–2)

1. General Comments

ASTP/ONC received approximately 270 comment submissions on the broad

range of proposals included in the ''Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability'' proposed rule (HTI–2 Proposed Rule) (89 FR 63498). We thank all commenters for their thoughtful input. For the purposes of this final rule, we have reviewed and responded to comments on a narrowed set of proposals. Specifically, we summarize and respond to comments related to proposals to:

- Update or adopt certification criteria for electronic prescribing, real-time prescription benefit capabilities, provider prior authorization APIs, and related proposals;
- Adopt criteria for ''modular API capabilities'' related to decision support interventions and subscriptions capabilities;
- Adopt implementation specifications supporting electronic prior authorization criteria;
- Adopt additional implementation specifications that can support exchange of clinical data, administrative data, and provider directory information with payers; and
- Update code sets related to medications referenced in certain criteria finalized in the rule.

Comments received in response to other proposals from the HTI–2 Proposed Rule are beyond the scope of this final rule, are still being reviewed and considered, and may be the subject of subsequent final rules related to such proposals in the future.

2. Statutory Basis

The Health Information Technology for Economic and Clinical Health Act (HITECH Act), Title XIII of Division A and Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111–5), was enacted on February 17, 2009. The HITECH Act amended the Public Health Service Act (PHSA) and created ''Title XXX—Health Information Technology and Quality'' (Title XXX) to improve healthcare quality, safety, and efficiency through the promotion of health IT and electronic health information (EHI) exchange.

The 21st Century Cures Act (Pub. L. 114–255) (Cures Act) was enacted on December 13, 2016, to accelerate the discovery, development, and delivery of 21st century cures, and for other purposes. The Cures Act, through Title IV—Delivery, amended the HITECH Act by modifying or adding certain provisions to the PHSA relating to health IT.

Section 1860D–4(o) of the Act, as added by section 119 of Title I, Division CC of the Consolidated Appropriations Act, 2021, Public Law 116–260 (CAA, 2021), requires sponsors of prescription drug plans to implement one or more real-time benefit tools (RTBTs) that meet the requirements described in section 1860D–4(o)(2) of the Act, after the Secretary has adopted a standard for RTBTs and at a time determined appropriate by the Secretary. For purposes of the requirement to implement a real-time benefit tool in section 1860D–4(o)(1) of the Act, section 1860D–4(o)(2)(A) of the Act provides that one of the requirements for an RTBT is that it can integrate with electronic prescribing and EHR systems of prescribing healthcare professionals for the transmission of formulary and benefit information in real time to such professionals. Section 1860D–4(o) of the Act requires incorporation of RTBTs within both the Medicare Part D prescription drug program and the ONC Health IT Certification Program (Certification Program). Specifically, section 119(b) of the CAA, 2021 amends the definition of a ''qualified electronic health record'' (qualified EHR) in section 3000(13) of the PHSA to add a new subparagraph (C) that requires that a qualified EHR must include (or be capable of including) an RTBT.

a. Standards, Implementation Specifications, and Certification Criteria

The HITECH Act established two Federal advisory committees, the Health IT Policy Committee (HITPC) and the Health IT Standards Committee (HITSC). Each was responsible for advising the National Coordinator for Health Information Technology (National Coordinator) on different aspects of standards, implementation specifications, and certification criteria.

Section 4003(e) of the Cures Act amended sections 3002 and 3003 of the PHSA by replacing, in an amended section 3002, the HITPC and HITSC with one committee named the Health Information Technology Advisory Committee (Health IT Advisory Committee or HITAC). Section 3002(a) of the PHSA, as added by the Cures Act, establishes that the HITAC recommends to the National Coordinator policies and standards, implementation specifications, and certification criteria, relating to the implementation of a health information technology infrastructure, nationally and locally, that advances the electronic access, exchange, and use of health information. Further described in section 3002(b)(1) of the PHSA, this includes recommending to the National Coordinator a policy framework to advance interoperable health information technology infrastructure, updating recommendations to the policy framework, and making new recommendations, as appropriate. Section 3002(b)(2)(A) of the PHSA specifies that in general, the HITAC shall recommend to the National Coordinator for purposes of adoption under section 3004, standards, implementation specifications, and certification criteria and an order of priority for the development, harmonization, and recognition of such standards, specifications, and certification criteria. Like the process previously required of the former HITPC and HITSC, section 3002(b)(5) of the PHSA requires the HITAC to develop a schedule, updated annually, for the assessment of policy recommendations, which the Secretary publishes in the **Federal Register**.

Section 3004 of the PHSA establishes a process for the adoption of health IT standards, implementation specifications, and certification criteria and authorizes the Secretary to adopt such standards, implementation specifications, and certification criteria. As specified in section 3004(a)(1) of the PHSA, the Secretary is required, in consultation with representatives of other relevant federal agencies, to jointly review standards, implementation specifications, and certification criteria endorsed by the National Coordinator under section 3001(c) of the PHSA and subsequently determine whether to propose the adoption of such standards, implementation specifications, or certification criteria. Section 3004(a)(3) of the PHSA requires the Secretary to publish all such determinations in the **Federal Register**.

Section 3004(b)(3) of the PHSA, titled, Subsequent Standards Activity, provides that the Secretary shall adopt additional standards, implementation specifications, and certification criteria as necessary and consistent with the schedule published by the HITAC. We consider this provision in the broader context of the HITECH Act and Cures Act to grant the Secretary the authority and discretion to adopt standards, implementation specifications, and certification criteria that have been recommended by the HITAC and endorsed by the National Coordinator, as well as other appropriate and necessary health IT standards, implementation specifications, and certification criteria.

3. ONC Health IT Certification Program Rules

Section 3001(c)(5) of the PHSA provides the National Coordinator with

the authority to establish a certification program or programs for the voluntary certification of health IT. Section 3001(c)(5)(A) of the PHSA specifies that the National Coordinator, in consultation with the Director of the National Institute of Standards and Technology (NIST), shall keep or recognize a program or programs for the voluntary certification of health IT that is in compliance with applicable certification criteria adopted under section 3004 of the PHSA. The certification program(s) must also include, as appropriate, testing of the technology in accordance with section 13201(b) of the HITECH Act. Section 13201(b) of the HITECH Act requires that, with respect to the development of standards and implementation specifications, the Director of NIST shall support the establishment of a conformance testing infrastructure, including the development of technical test beds. Section 13201(b) of the HITECH Act also indicates that the development of this conformance testing infrastructure may include a program to accredit independent, non-federal laboratories to perform testing.

Section 4002(a) of the Cures Act amended section 3001(c)(5) of the PHSA by adding section 3001(c)(5)(D) of the PHSA, which requires the Secretary, through notice and comment rulemaking, to require conditions of certification and maintenance of certification for the Certification Program. Specifically, the health IT developers or entities with technology certified under the Certification Program must, in order to maintain such certification status, adhere to certain conditions and maintenance of certification requirements concerning information blocking; assurances regarding appropriate exchange, access, and use of electronic health information; communications regarding health IT; application programming interfaces (APIs); real world testing; attestations regarding certain conditions and maintenance of certification requirements; and submission of reporting criteria under the EHR Reporting Program in accordance with section 3009A(b) of the PHSA.

a. Regulatory History

The Secretary issued an interim final rule with request for comments on January 13, 2010, ''Health Information Technology: Initial Set of Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology'' (75 FR 2014), which adopted an initial set of standards, implementation specifications, and certification criteria. On March 10, 2010, the Secretary issued a proposed rule, ''Proposed Establishment of Certification Programs for Health Information Technology'' (75 FR 11328), that proposed both temporary and permanent certification programs for the purposes of testing and certifying health IT. A final rule establishing the temporary certification program was published on June 24, 2010, ''Establishment of the Temporary Certification Program for Health Information Technology'' (75 FR 36158), and a final rule establishing the permanent certification program was published on January 7, 2011, ''Establishment of the Permanent Certification Program for Health Information Technology'' (76 FR 1262).

We have engaged in multiple rulemakings to update standards, implementation specifications, certification criteria, and the Certification Program, a history of which can be found in the October 16, 2015, final rule ''2015 Edition Health Information (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications'' (80 FR 62602) (2015 Edition Final Rule). The history can be found at 80 FR 62606. A final rule making corrections and clarifications was published for the 2015 Edition Final Rule on December 11, 2015 (80 FR 76868), to correct preamble and regulatory text errors and clarify requirements of the Common Clinical Data Set (CCDS), the 2015 Edition privacy and security certification framework, and the mandatory disclosures for health IT developers.

The 2015 Edition Final Rule established a new edition of certification criteria (''2015 Edition health IT certification criteria'' or ''2015 Edition'') and a new 2015 Edition Base EHR definition. The 2015 Edition established the minimum capabilities and specified the related minimum standards and implementation specifications that certified EHR technology (CEHRT) would need to include to support the achievement of ''meaningful use'' by eligible clinicians, eligible hospitals, and critical access hospitals under the Medicare and Medicaid EHR Incentive Programs (EHR Incentive Programs). The Medicare and Medicaid EHR Incentive Programs are now referred to as the Medicare Promoting Interoperability Program and the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category.[409] The final rule also adopted a proposal to change the Program's name to the ''ONC Health IT Certification Program'' from the ONC HIT Certification Program, modified the Certification Program to make it more accessible to other types of health IT beyond EHR technology and for health IT that supports care and practice settings beyond the ambulatory and inpatient settings, and adopted new and revised Principles of Proper Conduct for ONC–ACBs.

After issuing a proposed rule on March 2, 2016, ''ONC Health IT Certification Program: Enhanced Oversight and Accountability'' (81 FR 11056), we published a final rule by the same title (81 FR 72404) (EOA Final Rule) on October 19, 2016. The EOA Final Rule finalized modifications and new requirements under the Certification Program, including provisions related to our role in the Certification Program.

On March 4, 2019, the Secretary published a proposed rule titled, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (84 FR 7424) (ONC Cures Act Proposed Rule). The proposed rule proposed to implement certain provisions of the Cures Act that would advance interoperability and support the access, exchange, and use of electronic health information.

On May 1, 2020, a final rule was published titled, ''21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program'' (85 FR 25642) (ONC Cures Act Final Rule). The final rule implemented certain provisions of the Cures Act, including Conditions and Maintenance of Certification requirements for health IT developers, the voluntary certification of health IT for use by pediatric health providers, and reasonable and necessary activities that do not constitute information blocking. The final rule also

[409] Section 101(b) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, April 16, 2015) sunset the Medicare EHR Incentive Program for Eligible Professionals, set forth at section 1848(o) of the Act. Section 1848(o)(2) of the Act has been incorporated into the MIPS Promoting Interoperability performance category's requirements via section 1848(q)(2)(B)(iv) of the Act. *See* the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive Under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models (the CY 2017 Quality Payment Program) final rule with comment period (81 FR 77018 and 77019) for more information regarding the sunsetting of the Medicare EHR Incentive Program for Eligible Professionals. The Medicaid EHR Incentive Program sunset in 2021 (84 FR 42592).

implemented certain parts of the Cures Act to support patients' access to their EHI, and the implementation of information blocking policies that support patient electronic access. Additionally, the final rule modified the 2015 Edition health IT certification criteria and Certification Program in other ways to advance interoperability, enhance health IT certification, and reduce burden and costs, as well as improving patient and health care provider access to EHI and promoting competition. On November 4, 2020, the Secretary published an interim final rule with comment period titled, ''Information Blocking and the ONC Health IT Certification Program: Extension of Compliance Dates and Timeframes in Response to the COVID–19 Public Health Emergency'' (85 FR 70064) (Cures Act Interim Final Rule). The interim final rule extended certain compliance dates and timeframes adopted in the ONC Cures Act Final Rule to offer the healthcare system additional flexibilities in furnishing services to combat the COVID–19 pandemic, including extending the applicability date for information blocking provisions to April 5, 2021.

On April 18, 2023, the Secretary published a proposed rule titled, ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' (88 FR 23746) (HTI–1 Proposed Rule). The HTI–1 Proposed Rule proposed to implement the Electronic Health Record (EHR) Reporting Program provision of the Cures Act by establishing new Conditions and Maintenance of Certification requirements for health IT developers under the Certification Program. The HTI–1 Proposed Rule also proposed to make several updates to certification criteria and implementation specifications recognized by the Certification Program, including revised certification criterion for: ''clinical decision support'' (CDS), ''patient demographics and observations'', and ''electronic case reporting.'' The HTI–1 Proposed Rule also proposed to establish a new baseline version of the United States Core Data for Interoperability (USCDI). Additionally, the HTI–1 Proposed Rule proposed enhancements to support information sharing under the information blocking regulations.

On January 9, 2024, the Secretary issued the ''Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing'' final rule (HTI–1 Final Rule), which implemented the EHR Reporting Program provision of the 21st Century Cures Act and established new Conditions and Maintenance of Certification requirements for health IT developers under the Certification Program (89 FR 1192). The HTI–1 Final Rule also made several updates to certification criteria and standards recognized by the Certification Program. The Certification Program updates included revised certification criteria for ''decision support interventions,'' ''patient demographics and observations,'' and ''electronic case reporting,'' as well as adopted a new baseline version of the USCDI standard, USCDI Version 3. Additionally, the HTI–1 Final Rule provided enhancements to support information sharing under the information blocking regulations. Through these provisions, we sought to advance interoperability, improve algorithm transparency, and support the access, exchange, and use of EHI. The HTI–1 Final Rule also updated numerous technical standards in the Certification Program in additional ways to advance interoperability, enhance health IT certification, and reduce burden and costs for health IT developers and users of health IT.

On November 15, 2023, the Secretary issued a proposed rule titled, ''Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' (88 FR 78476). This proposed rule proposed to adopt the National Council for Prescription Drug Programs (NCPDP) Real-Time Prescription Benefit standard version 13.

On June 17, 2024, the Secretary issued the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (Part D and Health IT Standards Final Rule) (89 FR 51238 through 51265). This final rule adopted the NCPDP Real-Time Prescription Benefit standard version 13 in 45 CFR 170.205(c)(1) and incorporated this standard by reference in 45 CFR 170.299(k). In this final rule, CMS also adopted requirements for Part D sponsors to use the standard in in 45 CFR 170.205(c)(1) when implementing an RTBT.

On August 4, 2024, the Secretary published a proposed rule titled Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (89 FR 63498) (HTI–2 Proposed Rule).

4. ONC Health IT Certification Program Updates

a. Standards and Implementations Specifications

(1) National Technology Transfer and Advancement Act

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to electing only standards developed or adopted by voluntary consensus bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. Agencies have the discretion to decline the use of existing voluntary consensus standards if it is determined that such standards are inconsistent with applicable law or otherwise impractical, and instead use a government-unique standard or other standard. In addition to the consideration of voluntary consensus standards, the OMB Circular A–119 recognizes the contributions of standardization activities that take place outside of the voluntary consensus standards process. Therefore, in instances where use of voluntary consensus standards would be inconsistent with applicable law or otherwise impracticable, other standards should be considered that: meet the agency's regulatory, procurement or program needs; deliver favorable technical and economic outcomes; and are widely utilized in the marketplace. In this final rule, all of the standards adopted are voluntary consensus standards.

(2) Compliance With Adopted Standards and Implementation Specifications

In accordance with Office of the Federal Register regulations related to ''incorporation by reference,'' 1 CFR part 51, which we follow when we adopt proposed standards and implementation specifications in any subsequent final rule, the entire standard or implementation specification document is deemed published in the **Federal Register** when incorporated by reference therein with the approval of the Director of the Federal Register. Once published, compliance with the standard and

implementation specification includes the entire document unless we specify otherwise. For example, for the HL7 (Fast Healthcare Interoperability Resources) FHIR® Da Vinci—Coverage Requirements Discovery Implementation Guide, Version 2.0.1—STU 2 (CRD IG) adopted in section IX.*B*.4.b.(6). of the preamble of this final rule, health IT certified to certification criteria referencing this IG would need to demonstrate compliance with all mandatory elements and requirements of the IG unless otherwise specified. If an element of the IG is optional or permissive in any way, it would remain that way for testing and certification unless we specified otherwise in regulation. In such cases, the regulatory text would supersede the permissiveness of the IG.

(3) ''Reasonably Available'' to Interested Parties

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(b)). To comply with these requirements, in section XI.*B*.4.b.(8). (''Incorporation by Reference'') of the preamble of this final rule, we provide summaries of, and uniform resource locators (URLs) to, the standards and implementation specifications we are adopting and subsequently incorporate by reference in the Code of Federal Regulations. To note, we also provide relevant information about these standards and implementation specifications throughout the relevant sections of the final rule.

b. New and Revised Standards and Certification Criteria

(1) Minimum Standards Code Sets Updates

In the final rule titled ''Health Information Technology: Standards, Implementation Specifications, and Certification Criteria for Electronic Health Record Technology, 2014 Edition; Revisions to the Permanent Certification Program for Health Information Technology'' (77 FR 54163) we discussed and revised our policy for adopting newer versions of minimum standards code sets, noting that this approach improves interoperability while creating little additional burden through the inclusion of new code sets (see 45 CFR 170.555 and 77 FR 54268). In the 2015 Edition Final Rule we made additional updates to code sets subject to this policy (80 FR 62612). As we stated in the HTI–1 Final Rule, when determining whether to propose newer versions of minimum standards code sets, we consider the impact on interoperability and whether a newer version would require substantive effort for developers of certified health IT to implement (89 FR 1224). If adopted, newer versions of minimum standards code sets serve as the baseline for certification and developers of certified health IT may use newer versions of these adopted standards on a voluntary basis. We reiterate that while minimum standard code sets update frequently, perhaps several times in a single year, these updates are confined to concepts within the code system, not substantive changes to the standards themselves.

In this final rule, we are only finalizing proposals in the HTI–2 Proposed Rule for minimum standard code sets relevant to medications in 45 CFR170.207(d), as these standards are referenced in two of the certification criteria in this final rule: the updated ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3) and the new ''real-time prescription benefit'' criterion in 45 CFR 170.315(b)(4).

(2) Medications

In the HTI–2 Proposed Rule, we proposed to revise the citations in 45 CFR 170.207(d) to improve organization of this section (89 FR 63527). Specifically, we proposed to revise 45 CFR 170.207(d)(1) to list standards for clinical drugs and to reference multiple releases of RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine. We proposed in 45 CFR 170.207(d)(1)(ii) to reference RxNorm, December 4, 2023, Full Monthly Release and incorporate it by reference in 45 CFR 170.299(r). We proposed to move the standard adopted in 45 CFR 170.207(d)(1), RxNorm, July 5, 2022, Release, to 45 CFR 170.207(d)(1)(i), and that the adoption of this standard would expire on January 1, 2028. We proposed to move the standard adopted in 45 CFR 170.207(d)(3), RxNorm, September 8, 2015, Release, to 45 CFR 170.207(d)(1)(iii) and proposed that the adoption of this standard would expire on January 1, 2026. Finally, we proposed to move National Drug Codes, currently included via cross-reference in 45 CFR 170.207(d)(4), to 45 CFR 170.207(d)(2). We noted that 45 CFR 170.207(d)(2) was reserved at the time of the proposed rule. We also proposed to reserve 45 CFR 170.207(d)(3) and remove 45 CFR 170.207(d)(4).

The following is a summary of the comments we received on the HTI–2 Proposed Rule and our responses:

Comment: We did not receive any public comments specific to the proposed updates to the code sets in 45 CFR 170.207(d) and reorganization of this section. Commenters generally supported our proposals to update minimum code sets.

Response: We thank commenters for their support. For a discussion of public comments on our proposals referencing the code sets in 45 CFR 170.207(d) as part of the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3) and the ''real time prescription benefit'' criterion in 45 CFR 170.315(b)(4), we refer readers to sections XI.B.4.b.(3) and XI.B.4.b.(4) of the preamble of this final rule, respectively.

After consideration of the public comments, we are finalizing the adoption of the proposed version of RxNorm as RxNorm, December 4, 2023, Full Update Release, and incorporating it by reference in 45 CFR 170.299(r). We are also finalizing the proposed reorganization of 45 CFR 170.207(d), with modification. To improve the organization of the regulation text, we are finalizing the adoption of the most recent version of RxNorm in 45 CFR 170.207(d)(1)(i) (December 4, 2023 release), and renumbering the versions with prior release dates to be in 45 CFR 170.207(d)(1), at (ii) (July 5, 2022 release) and (iii) (September 8, 2015 release).

We are not finalizing the expiration dates that we proposed in the HTI–2 Proposed Rule, specifically, an expiration date of January 1, 2028, for the RxNorm July 5, 2022 release proposed in 45 CFR 170.207(d)(1)(i), and an expiration date of January 1, 2026, for the RxNorm September 8, 2015 release proposed in 45 CFR 170.207(d)(1)(iii). As RxNorm is identified as a minimum standard code set, any release of RxNorm that we adopt in regulation serves as the baseline for certification. Under our policy in 45 CFR 170.555, developers of certified health IT may use newer versions of these adopted standards on a voluntary basis. Given the flexibility available for use of the minimum standard code sets, we believe finalizing expiration dates for certain releases of RxNorm may lead to confusion as we have finalized the use of expiration dates in other instances where we are seeking to ensure health IT developers utilize a new standard beginning on a certain date. However, as stated, under our policy for minimum standards code sets in 45 CFR 170.555, health IT

developers may voluntarily move to updated RxNorm releases.

(3) Revised Electronic Prescribing Certification Criterion

In the HTI–2 Proposed Rule, we proposed to update the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) (89 FR 63524). The proposed updates included updating the core standard for electronic prescribing to NCPDP SCRIPT standard version 2023011,[410] which was cross-referenced in 45 CFR 170.205(b)(2) in the proposed text in 45 CFR 170.315(b)(3)(ii)(A). We also proposed revisions to the transactions within the SCRIPT standard that would be required for the updated certification criterion and proposed to remove a number of transactions that are currently identified as optional for the criterion. Finally, we proposed to remove 45 CFR 170.315(b)(3)(i) from the CFR upon the effective date of this rule and reserve it as this version of the certification criterion is no longer valid for use in the Certification Program.

(a) Electronic Prescribing Standard

In the Part D and Health IT Standards Final Rule, which appeared in the **Federal Register** on June 17, 2024 (89 FR 51238 through 51265), we adopted NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2). We also finalized an expiration date for NCPDP SCRIPT standard version 2017071 of January 1, 2028, in 45 CFR 170.205(b)(1), which reflected a delay of one year from the expiration date we had proposed (88 FR 78501). We also finalized the removal of the NCPDP SCRIPT standard version 10.6, which was located in 45 CFR 170.205(b)(2) (89 FR 51258 and 51259). The finalization of these policies in the Part D and Health IT Standards Final Rule, and CMS' finalization of cross references to 45 CFR 170.205(b) in their requirements for the Part D Program, reflects a unified approach to aligning standards adoption across HHS programs that impact a common set of participants (88 FR 78486 through 78494).

In the HTI–2 Proposed Rule (89 FR 63524), we noted that we previously proposed to adopt NCPDP SCRIPT standard version 2022011 and made other proposals in the ''Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' proposed rule (2024 Part C/D Proposed Rule), which appeared in the **Federal Register** on December 27, 2022 (87 FR 79555). However, we subsequently withdrew these proposals in the ''Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications'' proposed rule (2025 Part C/D Proposed Rule), which appeared in the **Federal Register** on November 15, 2023 (88 FR 78476), and instead proposed to adopt the NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2) (88 FR 78501 through 78502).

In the HTI–2 Proposed Rule, we proposed in 45 CFR 170.315(b)(3)(ii)(A) that for the time period up to and including December 31, 2027, a Health IT Module certified to the ''electronic prescribing'' certification criterion at 45 CFR 170.315(b)(3) must enable a user to perform certain prescription-related electronic transactions in accordance with the standard specified in 45 CFR 170.205(b)(1) (NCPDP SCRIPT standard version 2017071) or 45 CFR 170.205(b)(2) (NCPDP SCRIPT standard version 2023011) (89 FR 63524). We also proposed that on and after January 1, 2028, a Health IT Module certified to the ''electronic prescribing'' certification criterion must enable a user to perform the following prescription-related electronic transactions in accordance with only the standard specified in 45 CFR 170.205(b)(2) (where we adopted NCPDP SCRIPT standard version 2023011). We stated that this means that a health IT developer may continue to maintain health IT certification conformance to NCPDP SCRIPT standard version 2017071 (in 45 CFR 170.205(b)(1)) for the time period up to and including December 31, 2027. We noted that on and after January 1, 2028, consistent with our policy in 45 CFR 170.402(b), developers of certified health IT with Health IT Modules certified to the ''electronic prescribing'' certification criterion would need to update those Health IT Modules to the standard in 45 CFR 170.205(b)(2) and provide them to customers. This is consistent with the date of January 1, 2028, that we finalized for the expiration of NCPDP SCRIPT standard version 2017071 in 45 CFR 170.205(b)(1) in the Part D and Health IT Standards Final Rule (89 FR 51259).

The following is a summary of the comments we received on the HTI–2 Proposed Rule and our responses:

Comment: Commenters supported our proposal to require the use of NCPDP SCRIPT standard version 2023011 in an updated version of the ''electronic prescribing'' criterion. Commenters stated that this version of the standard includes several new elements that will enhance the usability of the standard and add important functionality. Other commenters stated this update will enhance interoperability, improve patient safety and streamline prescription processes. A commenter highlighted features of this version of the standard that will be beneficial for pediatric populations.

Response: We thank the commenters for their support. We agree that the proposed version of the NCPDP SCRIPT standard includes important enhancements that will improve the interoperability of electronic prescription information.

Comment: Many commenters supported the proposal that health IT developers may maintain health IT certification conformance with the current version of NCPDP SCRIPT standard version 2017071 for the time period up to and including December 31, 2027, and must, by January 1, 2028, use NCPDP SCRIPT standard version 2023011. Commenters appreciated the alignment of this date with the requirement for Medicare Part D plan sponsors to implement the NCPDP SCRIPT standard version 2023011 by January 1, 2028, stating that this alignment will improve the functionality and overall interoperability of clinicians' electronic prescribing systems. Commenters also supported the proposal to allow health IT developers time to update their systems while maintaining certification for the current version of the SCRIPT standard. Another commenter stated that the proposed timeline would ensure developers and clinicians can adequately plan and prepare for these updates.

Response: We thank commenters for their support. We believe that the proposed timeline requiring health IT developers to update Health IT Modules certified to the ''electronic prescribing criterion to NCPDP SCRIPT standard version 2023011 by January 1, 2028, will provide a reasonable amount of time for health IT developers to develop updated products and provide these products to customers.

[410] *See https://standards.ncpdp.org/Access-to-Standards.aspx.*

Comment: A commenter recommended that ASTP/ONC extend the timeline by one year and require use of the NCPDP SCRIPT standard version 2023011 by January 1, 2029. The commenter suggested that while the standards are fully developed, the standards are not yet integrated into health IT vendor systems. The commenter stated the transition to the updated standard will take time, and health plan IT resources are invested in working toward the launch of CMS APIs in January 2027, which do not incorporate prescription drug requirements.

Response: We disagree with the commenter that the deadline for updating Health IT Modules to the updated version of the ''electronic prescribing'' criterion should be extended for an additional year. In the Part D and Health IT Standards Final Rule, we adopted NCPDP SCRIPT standard version 2023011 in 45 CFR 170.205(b)(2). We also finalized an expiration date for NCPDP SCRIPT standard version 2017071 of January 1, 2028, in 45 CFR 170.205(b)(1), which reflected a delay of one year from the expiration date we had proposed (88 FR 78501). We believe this period will provide health IT developers with sufficient time for development and implementation of an updated version of an existing criterion. We further clarify that the proposals in this final rule will affect health IT developers with Health IT Modules certified to the ''electronic prescribing'' criterion under the Certification Program.

After consideration of the public comments, we are finalizing our proposals with modifications. Specifically, we are revising and reorganizing 45 CFR 170.315(b)(3)(ii)(A) to increase clarity around the timelines for use of standards in the ''electronic prescribing'' criterion. We are finalizing in 45 CFR 170.315(b)(3)(ii)(A)(*1*) that a Health IT Module certified to the ''electronic prescribing'' certification criterion at 45 CFR 170.315(b)(3) must enable a user to perform specified prescription-related electronic transactions in accordance with the standard specified in 45 CFR 170.205(b)(1) (NCPDP SCRIPT standard version 2017071) or 45 CFR 170.205(b)(2) (NCPDP SCRIPT standard version 2023011) for the time period up to and including December 31, 2027. We are also finalizing in 45 CFR 170.315(b)(3)(ii)(A)(*2*) that a Health IT Module certified to the ''electronic prescribing'' criterion may only use the standard specified in 45 CFR 170.205(b)(2) on and after January 1, 2028.

(b) Proposed Transactions

In the HTI–2 Proposed Rule (89 FR 63524 through 63526), we proposed the following updates and changes to the transactions identified for the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3)(ii).

(i) New Prescriptions (NewRx) (45 CFR 170.315(b)(3)(ii)(A)(3)(i))

We proposed in 45 CFR 170.315(b)(3)(ii)(A)(*1*) to revise the name used for the NewRx transaction in our regulations from ''Create New Prescriptions (NewRx)'' to ''New Prescriptions (NewRx).'' We proposed this change to align with updated terminology used by NCPDP within the SCRIPT standard.

The following is a summary of the comments we received and our responses:

Comment: Commenters supported the revision of the name used for the NewRx transactions from ''Create New Prescriptions (NewRx)'' to ''New Prescriptions (NewRx)'' to align with the updated terminology used in NCPDP SCRIPT standard version 2023011.

Response: We thank commenters for their support.

After consideration of the comments and due to the reorganization we are finalizing of 45 CFR 170.315(b)(3)(ii)(A), we are finalizing our proposal to update the name of the transaction to ''New Prescriptions (NewRx)'' in 45 CFR 170.315(b)(3)(ii)(A)(*3*)(*i*).

(ii) Request and Receive Medication History (45 CFR 170.315(b)(3)(ii)(A)(3)(vi))

We proposed to remove the request and receive medication history transactions (RxHistoryRequest, RxHistoryResponse) as a requirement for the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3)(ii)(A)*(6)* and reserve this section.

In the ONC Cures Act Final Rule, ONC finalized the request and receive medication history transactions (RxHistoryRequest, RxHistoryResponse) in the ''electronic prescribing'' certification criterion (85 FR 25682). Since the final rule was published, health IT developers and health care providers have described several challenges meeting this requirement, including development burden; lower than expected adoption and use; and duplicative, overlapping, and sometimes contradictory data from multiple sources. Due in part to these challenges and market forces that have prevented some developers from adopting this functionality natively, developers have had to rely on third-party applications to achieve certification, and in some cases, are unable to achieve certification for electronic prescribing altogether. As such, in the HTI–2 Proposed Rule (89 FR 63525), we proposed these transactions would no longer be required for certification to the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3)(ii)(A)*(6).* We also proposed to reserve 45 CFR 170.315(b)(3)(ii)(A)*(6).*

In the HTI–2 Proposed Rule (89 FR 63525), we encouraged developers to continue to support these transactions where possible and to follow industry efforts to advance the exchange of patient medication histories through various means such as health information exchanges, health information networks, and prescription drug monitoring programs. We further noted that (if our proposals were finalized) health IT developers would not be required to demonstrate compliance with these transactions in order for a Health IT Module to be certified to the updated version of the ''electronic prescribing'' criterion, but that CMS still requires use of these transactions when appropriate for electronic exchange of prescription-related information by Part D sponsors and prescribers and dispensers of Part D drugs for Part D eligible individuals (88 FR 78486). In other words, despite not needing to demonstrate technical conformance for certification, health IT developers would still need to support these transactions for customers who utilize these transactions in order to exchange electronic Part D medication history information among Part D sponsors and prescribers and dispensers of Part D drugs for Part D eligible individuals in compliance with requirements at 42 CFR 423.160(b)(1)(i)(U).

The following is a summary of the comments we received and our responses:

Comment: A commenter supported the proposal to remove the request and receive medication history transactions (RxHistoryRequest, RxHistoryResponse) as a requirement for the ''electronic prescribing'' certification criterion and reserve this section.

Response: We thank commenters for their support.

Comment: Several commenters opposed the removal of request and receive medication history transactions (RxHistoryRequest, RxHistoryResponse) from the electronic prescribing certification criterion. A commenter noted that medication history is a critical piece of information for episodic

treatment as well as identifying lapses or gaps in care with medication changes over a period of time. Several commenters noted the proposal seems potentially harmful to patient safety as medication history queries are crucial for safe electronic prescribing and medication reconciliation. A commenter acknowledged the existing challenges with adoption and implementation of the request and receive medication history transactions, but believed the transaction should not be removed if it will support the ultimate goal of achieving seamless access to this data in the EHR for clinicians. A commenter disagreed that the rationale that some developers were unable to achieve certification for electronic prescribing was sufficient for removal of the transactions, stating that health IT certification criteria should be determined based on impact to patient care rather than burden for health IT developers. Other commenters suggested separating this transaction into a distinct criterion to address developer concerns and providing additional support or guidance to vendors struggling with this implementation, rather than removing the requirement entirely.

Response: We appreciate commenters' feedback, and we agree that the ability for providers to easily obtain medication histories is crucial to patient care including for patient safety and medication reconciliation. We appreciate commenters' concerns about the rationale we included as part of the proposal. While we believe it is important to consider the burden on health IT developers and challenges that developers may experience in meeting Certification Program requirements, we seek to balance these concerns with the potential for use of certified health IT to improve patient care and advance the exchange of information across participants in the health care system. We agree with commenters that there is significant value to patients and health care providers of continuing to require support for medication history, which must be weighed against the issues identified in the proposed rule. Regarding the recommendation to adopt a separate criterion focused on this transaction, we note that we did not propose such a criterion, and believe that developing multiple certification criteria which require conformance with the NCPDP SCRIPT standard could increase administrative complexity for health IT developers and users of certified health IT.

After consideration of the public comments received, we are not finalizing our proposal to remove the request and receive medication history transactions (RxHistoryRequest and RxHistoryResponse) as required for the ''electronic prescribing'' criterion. Due to the reorganization we are finalizing of 45 CFR 170.315(b)(3)(ii)(A), we are retaining the transactions for RxHistoryRequest and RxHistoryResponse in 45 CFR 170.315(b)(3)(ii)(A)*(3)*(*vi*). We recognize the need for Health IT Modules to support capabilities related to medication history, and we are keeping these transactions in the Certification Program at this time, as supported by commenters. We will continue to monitor the request and receive medication history transactions for ongoing use, interest and value.

(iii) Electronic Prior Authorization Transactions (45 CFR 170.315(b)(3)(ii)(A)(3)(x))

In the HTI–2 Proposed Rule (89 FR 63525), we proposed to require support for the following transactions for electronic prior authorization as part of the ''electronic prescribing'' criterion, at the time a health IT developer presents a Health IT Module for certification using the standard in 45 CFR 170.205(b)(2) (where we adopted NCPDP SCRIPT standard version 2023011): PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification.

In the ONC Cures Act Final Rule, ONC adopted these transactions in 45 CFR 170.315(b)(3)(ii)(B)(*9*) as optional for the ''electronic prescribing'' criterion (85 FR 25678). We stated that we adopted these transactions to support alignment with the ''Medicare Program; Secure Electronic Prior Authorization for Medicare Part D'' proposed rule (84 FR 28450), in which CMS proposed to require Part D sponsors to support NCPDP SCRIPT standard version 2017071 for four electronic prior authorization transactions, and proposed that prescribers would be required to use that standard when performing electronic prior authorization transactions for Part D covered drugs they wish to prescribe to Part D eligible individuals (85 FR 25685). CMS subsequently finalized in the ''Medicare Program; Secure Electronic Prior Authorization for Medicare Part D'' final rule in 42 CFR 423.160(b)(8)(ii) that beginning January 1, 2022, Part D sponsors and prescribers must use the NCPDP SCRIPT standard version 201701 (85 FR 86832). The ONC Cures Act Final Rule allowed health IT developers seeking certification to support these transactions through optional testing but did not require developers to certify health IT to these transactions.

In the HTI–2 Proposed Rule (89 FR 63525), we stated we received feedback from the public in support of requiring these transactions, most recently in response to the ''Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria'' (Electronic Prior Authorization RFI), which appeared in the **Federal Register** on January 24, 2022 (87 FR 3475). Commenters stated that requiring these transactions in the certification criterion would help to advance interoperability and reduce administrative burden around prior authorization processes for medications. We agreed with this input, and in the HTI–2 Proposed Rule we proposed to remove PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse in 45 CFR 170.315(b)(3)(ii)(B)(*9*) as optional, and to require these transactions in 45 CFR 170.315(b)(3)(ii)(A)(*10*) for the ''electronic prescribing'' certification criterion at the time a health IT developer presents a Health IT Module for certification using NCPDP SCRIPT standard version 2023011.

ONC also charged the HITAC to establish a Task Force in order to provide input and recommendations in response to the Electronic Prior Authorization RFI; the Task Force's recommendations were approved and submitted to ONC on March 10, 2022.[411] In the HTI–2 Proposed Rule (89 FR 63525), we stated that if finalized, the proposals would implement the Task Force's recommendation to update these prior authorization transactions from ''optional'' in the current version of the ''electronic prescribing'' certification criterion to ''mandatory,'' to better support electronic prior authorization processes for drugs covered under a prescription benefit.

We also proposed to adopt the PANotification transaction in 45 CFR 170.315(b)(3)(ii)(A)(*10*) as a required transaction for the ''electronic prescribing'' criterion to further support the exchange of electronic prior authorization information. We noted that PANotification is a new transaction introduced since NCPDP SCRIPT standard version 2017071. The PANotification transaction is used to alert the pharmacist or prescriber when

[411] *https://www.healthit.gov/sites/default/files/page/2022-03/2022-03-10_ePA_RFI_Recommendations_Report_Signed_508.pdf.*

a prior authorization has been requested or when a prior authorization determination has been received. The PANotification transaction is intended to improve electronic communication between prescribers and pharmacists, and to reduce duplicate submissions of prior authorization requests to payers. Notification may occur via a NewRx, RxChange or RxRenewal transaction, or as a standalone PANotification. We stated that we believe that requiring the PANotification transaction is an important complement to the other proposals related to electronic prior authorization described above.

The following is a summary of the comments we received and our responses:

Comment: Many commenters supported the proposal to require support for the electronic prior authorization transactions as part of the ''electronic prescribing'' criterion. A commenter stated that requiring prior authorization transactions as part of the criterion would help advance interoperability and reduce administrative burden associated with medication prior authorization processes and improve access to systems enabling electronic prior authorization. Other commenters stated that requiring these transactions would help ensure pharmacy data systems communicate consistently with certified health IT modules, thereby mitigating the need to build different prior authorization processes for different certified health IT systems. Another commenter believed that greater use of electronic prior authorization would address transparency and affordability gaps in the healthcare ecosystem.

Response: We appreciate commenters' support for our proposal to require electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification) as part of the ''electronic prescribing'' criterion. We agree with commenters that electronic prior authorization is an important capability for reducing the administrative burden associated with prior authorization processes for medications. We also agree that adopting these transactions will support interoperability between prescriber and payer systems and can lead to more efficient investments in technical infrastructure to support electronic exchange of prior authorization information.

Comment: A commenter noted it was unclear if the electronic prior authorization transactions have been tested in the real world to verify that they will achieve the intended goal of automating prior authorizations without also causing serious consequences, such as increasing prescriber burden or driving further consolidation in the EHR market toward a few large developers. The commenter noted that real world testing is critical to ensuring that health IT is effective and interoperable for the physicians, clinical staff, and other end-users that rely on EHRs.

Response: We appreciate commenters' interest in testing of these electronic prior authorization transactions and agree that ongoing testing and evaluation is important to improving standards. We note that the Council for Affordable Quality Healthcare found that in a survey of medical providers that 38 percent of respondents used the NCPDP standard to conduct electronic prior authorization transactions in 2023, an increase of eight percentage points from 2022,[412] indicating that the electronic prior authorization transactions specified in the NCPDP SCRIPT standard are being used in practice. ASTP/ONC will continue to work with implementers and the standards development community to evaluate findings from the implementation of these transactions. We also note that CMS finalized a requirement that Part D plan sponsors support certain electronic prior authorization transactions in the NCPDP SCRIPT standard version 2017071 in the ''Medicare Program; Secure Electronic Prior Authorization for Medicare Part D'' which appeared in the **Federal Register** on December 31, 2020 (85 FR 86824).

Finally, we acknowledge the commenters' concerns about provider burden that may be associated with adopting workflows based on these transactions and consolidation in the EHR market that may result from adding regulatory requirements to the ''electronic prescribing'' criterion. At this time, we believe the potential value of advancing electronic prior authorization and decreasing the administrative burden associated with prior authorization processes outweighs these concerns. However, we will continue to monitor public feedback and available data sources to track the impact of implementation of these transactions.

Comment: A commenter stated that requiring electronic prior authorization transactions was premature without sufficient assurances that the payer community will be ready to support the same standards and enable end-to-end electronic prior authorization for prescriptions. A commenter suggested payers should be the first to adopt electronic prior authorization standards in order to set the standard effectively. Another commenter recognized there are already many payers supporting these transactions, but did not believe that implementing electronic prior authorization would provide value until there is a specific criterion under the Certification Program defining standards for payer adherence. A commenter stated that requirements for payers should mandate the use of codified question sets as part of electronic prior authorization, ensuring that these solutions are not simply digitizing a paper-based process but effectively streamlining it. A commenter suggested ASTP/ONC create a separate criterion for electronic prior authorization functionality.

Response: We appreciate the importance of ensuring that all entities participating in exchange of electronic prior authorization information are using common standards. We note that CMS finalized a requirement that Part D plan sponsors support certain electronic prior authorization transactions in the NCPDP SCRIPT standard version 2017071 in the ''Medicare Program; Secure Electronic Prior Authorization for Medicare Part D'' which appeared in the **Federal Register** on December 31, 2020. CMS subsequently updated the version of the NCPDP SCRIPT standard required for electronic prescribing and electronic prior authorization to NCPDP SCRIPT standard version 2023011 by January 1, 2028.

Thus, requirements for Part D plan sponsors to support electronic prior authorization transactions were finalized in advance of the requirements for developers of certified health IT that we are finalizing in this rule, and we believe Part D plan sponsors already have experience supporting these transactions. We agree the availability of a certification criterion for health IT used by Part D plan sponsors may have benefits, for instance, increasing conformance with the standard through required testing. However, we also believe that the combination of the current requirement for Part D plan sponsors to support the NCPDP SCRIPT standard in 42 CFR 423.160 and our requirements for health IT developers will effectively enable interoperability between provider and payer systems when conducting electronic prior authorization for medications.

Regarding the use of codified question sets, we agree with the commenter that

[412] See *https://www.caqh.org/hubfs/Issue%20Briefs/CAQH_Insights_NCPDP_SCRIPT_Issue_Brief.pdf.*

consistent use of question sets by payers, which are supported as part of the electronic prior authorization transactions in the NCPDP SCRIPT standard, could help to further reduce burden for implementers. While requirements for how Part D plan sponsors support electronic prior authorization are out of scope for this rule, we are sharing these comments with the Part D program for consideration.

We do not agree with the commenter that we should create a separate criterion to address electronic prior authorization transactions under the NCPDP SCRIPT standard, as we believe consolidating certification requirements for all transactions specified in the NCPDP SCRIPT standard under a single criterion will minimize burden for health IT developers seeking to support electronic prescribing capabilities within a single Health IT Module.

After consideration of public comments, we are finalizing our proposal to require the transactions PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, and PACancelResponse and moving these transactions to 45 CFR 170.315(b)(3)(ii)(A)(*3*)(*x*), due to the revisions we are finalizing to reorganize 45 CFR 170.315(b)(3)(ii)(A). We are also finalizing our proposal to remove the above mentioned electronic prior authorization transactions from 45 CFR 170.315(b)(3)(ii)(B)(*9*), where they are identified as optional. We are also finalizing our proposal to include the PANotification transaction as part of the required electronic prior authorization transactions at 45 CFR 170.315(b)(3)(ii)(A)(*3*)(*x*). We are finalizing these transactions as required for the ''electronic prescribing'' certification criterion at the time a health IT developer presents a Health IT Module for certification using the standard finalized at 45 CFR 170.205(b)(2), where we adopted NCPDP SCRIPT standard version 2023011.

(iv) Optional Transactions (NewRxRequest, NewRxResponseDenied, RxFillIndicatorChange, GetMessage, Resupply, DrugAdministration, RxTransferRequest, RxTransferResponse, RxTransferConfirm, Recertification, REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse) (45 CFR 170.315(b)(3)(ii)(B)(1)–(8))

In the HTI–2 Proposed Rule (89 FR 63526), we proposed to remove the transactions in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*) which are currently identified as ''optional'' for the ''electronic prescribing'' certification criterion. We proposed to revise 45 CFR 170.315(b)(3)(ii)(B) to include requirements related to the exchange of race and ethnicity information in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*4*), which is discussed in greater detail later in this section.

Specifically, we proposed to remove the following transactions in 45 CFR 170.315(b)(3)(ii)(B) upon the effective date of the final rule:

- NewRxRequest, NewRxResponseDenied (45 CFR 170.315(b)(3)(ii)(B)(*1*))
- RxFillIndicatorChange (45 CFR 170.315(b)(3)(ii)(B)(*2*))
- GetMessage (45 CFR 170.315(b)(3)(ii)(B)(*3*))
- Resupply (45 CFR 170.315(b)(3)(ii)(B)(*4*))
- DrugAdministration (45 CFR 170.315(b)(3)(ii)(B)(*5*))
- RxTransferRequest, RxTransferResponse, RxTransferConfirm (45 CFR 170.315(b)(3)(ii)(B)(*6*))
- Recertification (45 CFR 170.315(b)(3)(ii)(B)(*7*))
- REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse (45 CFR 170.315(b)(3)(ii)(B)(*8*))

For completeness, we noted that 45 CFR 170.315(b)(3)(ii)(B) currently has transactions listed in 45 CFR 170.315(b)(3)(ii)(B)(*9*) related to electronic prior authorization. However, we proposed in the section above to remove 45 CFR 170.315(b)(3)(ii)(B)(*9*) and add the electronic prior authorization transactions currently in 45 CFR 170.315(b)(3)(ii)(B)(*9*) as required transactions in 45 CFR 170.315(b)(3)(ii)(A)(*10*).

We noted that in reviewing data from the Certification Program, we found that very few developers have elected to certify to the optional transactions in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*9*). We stated that we believe that the low rate of certification to these certification criteria indicates that health IT developers do not see a benefit in obtaining optional certification to these criteria. Accordingly, we stated that removing these optional transactions from the program would reduce the complexity and cost of the Certification Program with minimal impact on health IT developers.

We further noted that CMS requires use of these transactions when appropriate for electronic exchange of prescriptions and prescription-related information by Part D sponsors and prescribers and dispensers of Part D drugs for Part D eligible individuals. In other words, despite not needing to demonstrate technical conformance for certification, developers would still need to support these transactions for customers who utilize these transactions in order to exchange information electronically between prescribers and dispensers of Part D drugs for Part D eligible individuals in compliance with requirements in 42 CFR 423.160(b)(1)(i).

We requested comment on our proposal to remove the optional transactions in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*) from the ''electronic prescribing'' certification criterion. We also stated that alternatively, we considered proposing to require the optional transactions in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*) rather than removing them from the criterion. However, in the HTI–2 Proposed Rule, we did not identify additional reasons to propose to require any of these optional transactions (89 FR 63526). We requested comment on this alternative, including whether commenters believe requiring any of the optional transactions in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*) proposed for removal from the ''electronic prescribing'' certification criterion would be important to supporting interoperability between certified Health IT Modules and entities subject to Part D electronic prescribing requirements at 42 CFR 423.160.

We referred readers to Table 1A in the HTI–2 Proposed Rule (89 FR 63529) for a comparison of transactions identified in the existing NCPDP SCRIPT standard version 2017071 and the proposed certification criterion based on NCPDP SCRIPT standard version 2023011.

The following is a summary of the comments we received and our responses:

Comment: Many commenters supported removing the transactions in (45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*)) identified as optional. Some commenters noted removal would streamline the certification process and

promote consistency across certified health IT modules. Commenters noted RxTransfer transactions are not used by physicians but are instead used to transfer prescriptions between pharmacies. Other commenters stated Resupply, DrugAdministration, and Recertification are communications between a long-term or post-acute care facility and a pharmacy, excluding the prescriber system.

Response: We thank commenters for their support. We agree with many of the justifications offered by commenters to remove optional transactions identified as optional, including commenters who indicated that removal would streamline certification processes and promote consistent implementation of Health IT Modules certified to 45 CFR 170.315(b)(3). We further appreciate commenters' feedback regarding specific transactions that are not useful for physicians. Due to the low rate of certification to these optional transactions among health IT developers, we believe that removing certification for these transactions will have minimal impact on prescribers.

Comment: A commenter specifically recommended that the following transactions remain as optional: NewRxRequest, RxFillIndicatorChange, GetMessage and REMS.

Response: We appreciate the continued interest in certain optional transactions in 170.315(b)(3)(ii)(B)(*1*)–(*8*). However, commenters did not provide, and we have not identified, reasons to retain these specific optional transactions as part of the certification criterion that outweigh the rationale we provided for proposing to remove these optional transactions related to streamlining the Certification Program and reducing regulatory burden. We will continue to evaluate how these capabilities evolve and may consider whether to propose to require these transactions as part of the ''electronic prescribing'' criterion in the future.

After consideration of public comments, we are finalizing our proposal to remove the transactions identified as optional in 45 CFR 170.315(b)(3)(ii)(B)(*1*)–(*8*) in order to reduce the complexity and cost of the Certification Program.

(c) Additional Proposals

(i) Signatura (Sig) (45 CFR 170.315(b)(3)(ii)(D))

In 45 CFR 170.315(b)(3)(ii)(D), we proposed that a Health IT Module certified to the ''electronic prescribing'' criterion must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with the standard specified in 45 CFR 170.205(b)(2) (NCPDP SCRIPT standard version 2023011), at the time a health IT developer presents a Health IT Module for certification using the NCPDP SCRIPT standard version 2023011.

We stated that the Signatura or Sig is the information provided with a prescription to communicate how a prescriber intends for a patient to take a medication. These directions for use are essential for accurate prescription labeling, appropriate patient counseling and education from a pharmacist, and optimal medication use. The NCPDP Structured and Codified Sig Format Implementation Guide,[413] which is embedded in the NCPDP SCRIPT standard, is intended to standardize the portion of an electronic prescription containing the directions for use using existing, accepted electronic transmission standards, such as NCPDP SCRIPT. A ''structured and codified'' Sig conveys instructions in a consistent manner by mapping these directions to a defined set of elements representing the different components of these directions (for instance, dosing schedules and administration instructions). We stated that the Structured and Codified Sig Format includes 15 segments, each containing distinct fields to capture potential elements of patient instructions. This is intended to facilitate communication between prescribers and pharmacists, to improve the efficiency of prescribing and dispensing activities, and to help reduce the opportunity for errors. The NCPDP Structured and Codified Sig Format Implementation Guide contains the technical specifications and guidance for implementation of a structured and codified Sig.

When conducting electronic prescribing, prescribers frequently transmit the Sig Text segment as unstructured free text, which introduces inconsistency and limits reusability of the directions contained in the Sig, with potential impacts on patient safety and clinical outcomes.[414] Moreover, when unstructured free text is used, prescribers and pharmacists may have to engage in back-and-forth communication to clarify what is intended in the Sig instructions, increasing burden. In the HTI–2 Proposed Rule (89 FR 63527), we noted that research has shown more than half of all Sig directions sent in an ambulatory setting can be accurately represented by only 25 standardized concepts (for example, the directions ''take 1 tablet by oral route every day'' and ''Take one (1) tablet by mouth once a day'' can both be represented as the same Sig concept ''Take 1 tablet by mouth once daily''), indicating significant opportunities to reduce variation by expressing these directions through the structured and codified Sig format.[415]

Previously, in the 2015 Edition Final Rule, we did not finalize our proposal to require a Health IT Module certified to the ''electronic prescribing'' criterion to enable a user to enter, receive, and transmit codified Sig instructions in a structured format, based on commenters' concerns regarding the readiness of the standard and other issues such as limitations on the length of a Sig within the version of the NCPDP SCRIPT Structured and Codified Sig Format v1.2 available at the time of the proposal (80 FR 62643). We stated that we would reconsider this stance for future rulemaking based on newer versions of the NCPDP SCRIPT Standard Implementation Guide that may provide implementation improvements and finalized an optional certification provision that technology must be able to receive and transmit the reason for the prescription using the indication elements in the SIG segment in 45 CFR 170.315(b)(3)(i) (80 FR 62643). In the ONC Cures Act Final Rule, we also finalized this optional provision in 45 CFR 170.315(b)(3)(ii)(D) (85 FR 25686).

Since the 2015 Edition Final Rule, NCPDP has further advanced the structured and codified Sig format. The most recent version available is the NCPDP Structured and Codified Sig Implementation Guide version 2.2. The structured and codified Sig segment within the NCPDP SCRIPT standard has also been modified; changes to the Sig element from NCPDP SCRIPT standard version 2017017 are discussed in the NCPDP SCRIPT standard version 2023011 Implementation Guide.[416] As a result of additional improvements made to the structured and codified Sig format, as well as the additional time that industry has had to grow familiar with this functionality, we stated in the HTI–2 Proposed Rule (89 FR 63527) that

[413] *See https://standards.ncpdp.org/Access-to-Standards.aspx.*

[414] Schiff, G., Mirica, M.M., Dhavle, A.A., Galanter, W.L., Lambert, B., & Wright, A. (2018). A prescription for enhancing electronic prescribing safety. Health Affairs (Project Hope), 37(11), 1877–1883. doi:*https://doi.org/10.1377/hlthaff.2018.0725.*

[415] Yang, Y., Ward-Charlerie, S., Dhavle, A.A., Rupp, M.T., & Green, J. (2018). Quality and Variability of Patient Directions in Electronic Prescriptions in the Ambulatory Care Setting. Journal of managed care & specialty pharmacy, 24(7), 691–699. *https://doi.org/10.18553/jmcp.2018.17404.*

[416] *See https://standards.ncpdp.org/Access-to-Standards.aspx.*

we believe that it is appropriate to propose in 45 CFR 170.315(b)(3)(ii)(D) to require that a Health IT Module certified to the ''electronic prescribing'' criterion must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with the standard specified in 45 CFR 170.205(b)(2) (where we adopted NCPDP SCRIPT standard version 2023011), at the time a health IT developer presents a Health IT Module for certification using NCPDP SCRIPT standard version 2023011. We proposed to remove the optional provision that is currently in 45 CFR 170.315(b)(3)(ii)(D).

The following is a summary of the comments we received on this proposal and our responses:

Comment: Many commenters expressed support for our proposal that a health IT module certified to the ''electronic prescribing'' criterion must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with NCPDP SCRIPT standard version 2023011. Commenters agreed that communicating how a prescriber intends for a patient to take a medication is critical for delivering safe and effective care, and therefore standardizing prescription directions via a codified and structured Sig field has the potential to reduce medication errors and improve patient care. Another commenter noted use of Structured Sig will minimize inefficiencies that result from ambiguous prescriber-pharmacist communications and manual prescription entry into pharmacy management systems, which are prone to errors. Other commenters supported the codified Sig format instructions, stating they are essential for accurate prescription labeling, appropriate patient counseling and education from a pharmacist, increasing interoperability, providing data for research, and optimal medication use. A commenter noted that use of free text Sigs can lead to errors and recommended structuring as much of this information as possible to support safer transitions of care.

Response: We thank commenters for their support and agree with comments that use of structured Sigs support safer and more accurate prescriptions than free text Sigs when feasible.

Comment: Several commenters supported the proposal but requested clarification. A commenter noted that the statement in the HTI–2 Proposed Rule that the Structured and Codified Sig Format contains 15 segments did not reflect the complexity of the format, which contains approximately 180 distinct elements used to capture patient instructions. Another commenter stated that the Structured and Codified Sig format does not contain segments.

Response: We appreciate commenters' feedback. In the proposed rule we inadvertently referred to groupings of elements containing distinct fields to capture potential elements of patient instructions in the Structured and Codified Sig Format as ''segments.'' We agree with commenters' characterization of the Structured and Codified Sig format as including approximately 180 distinct elements, excluding repetitions and extensions, used to capture patient instructions.[417]

Comment: Commenters stated that the Structured and Codified Sig format is embedded in the required NCPDP SCRIPT standard and recommended that we remove separate reference to the Structured and Codified Sig Format.

Response: Regarding the proposal that a Health IT Module enable a user to enter, receive, and transmit structured and codified prescribing instructions in 45 CFR 170.315(b)(3)(ii)(D), we agree with commenters that, as noted in the proposed rule (89 FR 63526), that the Structured and Codified Sig Format is embedded within the NCPDP SCRIPT standard version 2023011. Therefore, we believe that if a Health IT Module implements NCPDP SCRIPT standard version 2023011 in a manner consistent with the requirements in the updated ''electronic prescribing'' criterion, it will implement the capability to transmit prescriptions according to the Structured and Codified Sig Format. Separately identifying a need to support these capabilities within the criterion would be redundant to requirements to support the NCPDP SCRIPT standard version 2023011.

Comment: A commenter supported the proposal but noted that not every prescription Sig can be accurately structured and codified due to the complexity and variability of medication instructions. To address this challenge, the commenter urged ASTP/ONC to support the inclusion of free text alongside structured and codified prescriptions. Allowing for free text will enable healthcare providers to convey essential nuances and specific patient needs that may not be captured in standardized formats. The commenter stated this approach helps to preserve flexibility while avoiding situations where the use of the same code to represent multiple terms can create significant challenges for the backward translation of prescription Sigs.

Response: We appreciate the commenter's input. We note that the capacity to transmit free text Sigs continues to be supported in NCPDP SCRIPT standard version 2023011. Nothing in the final ''electronic prescribing'' criterion would prohibit a prescriber from utilizing Sig free text elements as needed in order to provide information about a prescription.

Comment: A commenter recommended that ASTP/ONC not finalize the Sig proposal. The commenter stated that the proposed requirement was vague and could be interpreted as requiring all Sigs to be sent in a codified manner, which would impose significant burdens on health IT developers while resulting in diminishing returns for therapies requiring less common, complex instructions that are more easily communicated through free text. The commenter stated that the value of mapping uncommon Sigs decreases significantly, given how infrequently prescribers may issue such patient directions. The commenter also expressed doubt about the value of exchanging structured Sigs when other organizations, such as pharmacy groups, are not subject to requirements to support this standard. The commenter recommended that ASTP/ONC indicate more clearly the expectations regarding the implementation of structured Sigs.

Response: We thank the commenter for their input. The intent of our proposed requirement in 45 CFR 170.315(b)(3)(ii)(D) was not to require all Sigs to be sent in a structured and codified format, but rather to enable a user to utilize this functionality in accordance with NCPDP SCRIPT standard version 2023011. As the commenter's concern relates to the language of the proposed requirement in 45 CFR 170.315(b)(3)(ii)(D), we believe our decision to not finalize this provision addresses the commenter's concerns regarding the ambiguity of the proposed language.

After consideration of public comments, we are not finalizing the provision we proposed in 45 CFR 170.315(b)(3)(ii)(D) that a Health IT Module must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with the standard specified in § 170.205(b)(2) (NCPDP SCRIPT standard version 2023011), at the time a health IT developer presents a Health IT Module for certification using the NCPDP SCRIPT standard version 2023011. We believe that finalizing this provision in the text of the regulation is unnecessary as this functionality will be implemented as part of requirements to

[417] *https://www.ncpdp.org/.*

implement the NCPDP SCRIPT standard version 2023011.

We did not receive any comments on our proposal to remove the existing optional provision in 45 CFR 170.315(b)(3)(ii)(D) related to the ability to receive and transmit the reason for prescription using the Indication for use element in the SIG segment and we are finalizing to remove this provision and reserve 45 CFR 170.315(b)(3)(ii)(D) for future notice-and-comment rulemaking.

(ii) RxNorm and National Drug Codes (NDC)

In 45 CFR 170.315(b)(3)(ii)(A) we require that a Health IT Module certified to the ''electronic prescribing'' criterion enable a user to perform specified prescription-related electronic transactions in accordance with a specified minimum version of the RxNorm code set for coding medications, among other standards. RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine (RxNorm), is a drug terminology providing a set of normalized medication names and codes based on a collection of commonly used public and commercial vocabularies of drug names and their ingredients. In section III.B.5. of the HTI–2 Proposed Rule (89 FR 63519 and 63520), we proposed to adopt an updated release of RxNorm, specifically, the December 4, 2023, Full Monthly Release, in 45 CFR 170.207(d)(1)(ii). We also proposed to reorganize 45 CFR 170.207(d) to include the versions of RxNorm adopted in 45 CFR 170.207(d)(1), (2), and (3), under 45 CFR 170.207(d)(1).

In the HTI–2 Proposed Rule, for the ''electronic prescribing'' certification criterion, we proposed in 45 CFR 170.315(b)(3)(ii)(A) to remove the existing reference to RxNorm, September 8, 2015, Release in 45 CFR 170.207(d)(3), and require use of at least one of the versions of the standard adopted in 45 CFR 170.207(d)(1) (89 FR 63527). We stated that if finalized, this reference to 45 CFR 170.207(d)(1), where we adopted multiple versions of RxNorm, would permit a health IT developer to use any version of RxNorm that is listed in 45 CFR 170.207(d)(1) and for which adoption has not expired. We noted that this proposal would result in a requirement to use progressively more recent releases of the RxNorm code set as the baseline version of RxNorm which Health IT Modules must use for the ''electronic prescribing'' certification criterion.

Under NCPDP SCRIPT standard version 2020011 and greater, including NCPDP SCRIPT standard version 2023011, the National Drug Codes (NDC) element is required on all non-compounded medication electronic prescriptions (89 FR 63527).[418] National Drug Codes (NDC) provide a unique identifier for products such as vaccines or medications. Each product is assigned a unique 10- or 11-digit, 3-segment number that identifies the labeler, product, and trade package size. We adopted NDC in 45 CFR 170.207(d)(4) in the HTI–1 Final Rule (89 FR 1226) via a cross-reference to 45 CFR 162.1002(b)(2) as referenced in 45 CFR 162.1002(c)(1). In the HTI–2 Proposed Rule, we proposed to relocate this cross-reference from 45 CFR 170.207(d)(4) to 45 CFR 170.207(d)(2) as part of our reorganization of this section (89 FR 63519 and 63520). Consistent with the requirement in the NCPDP SCRIPT standard version 2023011 to include NDC with prescriptions, we proposed in 45 CFR 170.315(b)(3)(ii)(A) that a Health IT Module certified to the criterion must enable a user to perform specified prescription-related electronic transactions in accordance with NDC in 45 CFR 170.207(d)(2). We proposed that use of NDC would be required at the time a health IT developer presents a Health IT Module for certification using the NCPDP SCRIPT standard version 2023011 adopted in 45 CFR 170.205(b)(2).

The following is a summary of the comments we received and our responses:

Comment: Commenters expressed support for our proposal to revise the existing reference to RxNorm, September 8, 2015, Release, in 45 CFR 170.207(d)(3), and instead require use of at least one of the versions of the standard adopted in 45 CFR 170.207(d)(1), in which we proposed to include updated releases of RxNorm. A commenter agreed with ASTP/ONC's approach to use progressively more recent releases of the RxNorm code set as baseline version of RxNorm for the ''electronic prescribing'' certification criterion. Another commenter supported use of the more current RxNorm release, stating that this would ensure Health IT Modules use the same code sets and enable more effective communications with pharmacy data systems, benefiting prescribers, pharmacists, payers, and patients.

Response: We thank commenters for their support. We note that in the HTI–2 Proposed Rule, we inadvertently described the reference to RxNorm in 45 CFR 170.315(b)(3)(ii)(A) as referencing RxNorm, September 8, 2015, Release, in 45 CFR 170.207(d)(3) in preamble (89 FR 63527). This should have referred to RxNorm, July 5, 2022, in 45 CFR 170.207(d)(1) as stated in the text of the regulation.

As discussed in section XI.*B*.4.b.(3) of this final rule, we are not finalizing the expiration dates for releases of RxNorm that we proposed in 45 CFR 170.207(d)(1). We further remind readers that, pursuant to the policy in 45 CFR 170.555 regarding ''minimum standards'' code set updates, developers of certified health IT are able to use newer versions of these minimum adopted standards on a voluntary basis. In order to maintain alignment with the ''minimum standards'' code set policy in 45 CFR 170.555, we are finalizing the language proposed in 45 CFR 170.315(b)(3)(ii)(A) with a modification to retain the phrase ''at a minimum.'' Under this revision, we are conveying that any of the versions of the code set in 45 CFR 170.207(d)(1) (RxNorm) may serve as a baseline, but that, consistent with our ''minimum standards'' code sets policy, health IT developers may move to later versions of these code sets and maintain certification.

Comment: Commenters supported the use of NDCs in the ''electronic prescribing'' certification criterion. A commenter agreed that the use of NDC for drugs is beneficial for specific product identification in research, dispensing, and administrative workflows.

Response: We thank commenters for their support.

Comment: A commenter stated that requiring the use of a code set that is not adopted as an official standard seems contrary to the concept of conforming to standards. A commenter opposed the proposal to require both RxNorm and NDC. The commenter noted the value sets are duplicative, that the majority of the industry uses NDC to identify prescriptions, and that selecting one value set will improve interoperability.

Response: We disagree that referencing NDC would be contrary to the concept of conforming to standards. NDC is a standard that is maintained by HHS. While ASTP/ONC has not adopted NDC directly, it has been adopted by the Secretary in 45 CFR 162.1002 and we believe it reduces confusion to cross-reference these existing codes rather than separately adopting the standard.

We acknowledge the commenter's feedback regarding preference for use of one code set, but we disagree that these code sets are duplicative. RxNorm is used to identify a brand or generic

[418] For more information about the updates to NDC in the NCPDP SCRIPT standard *see https://ncpdp.org/NCPDP/media/images/Resources%20Items/NDC-Use-eRx-Fact-Sheet.pdf?ext=.pdf.*

medication, dose form and strength and is commonly used when ordering a medication. Additionally, an NDC code is used when the exact manufacturer and package size are known and identified to be dispensed and/or administered. We believe it is important to support both code sets as both are specified in the NCPDP SCRIPT standard version 2023011.

After consideration of public comments, we are finalizing our proposal to revise our reference to RxNorm in the ''electronic prescribing'' criterion in 45 CFR 170.315(b)(3)(ii)(A), with modification. Pursuant to our reorganization of the paragraph at 45 CFR 170.315(b)(3)(ii)(A), we are finalizing cross-references to 45 CFR 170.207(d)(1), where we have adopted versions of RxNorm, in both 45 CFR 170.315(b)(3)(ii)(A)(*1*)(*i*) and 45 CFR 170.315(b)(3)(ii)(A)(*2*)(*i*). We are revising our previous requirement specifying use of the standard at 45 CFR 170.207(d)(1) with a requirement to use, at a minimum, at least one of the standards adopted in 45 CFR 170.207(d)(1). We are finalizing this language for consistency with our policy in 45 CFR 170.555 regarding minimum standard code sets, discussed in section XI.*B*.4.b.(1) of this final rule. This revised reference clarifies that the ''electronic prescribing'' criterion requires the use of an RxNorm release that we include in 45 CFR 170.207(d)(1) as a baseline for certification.

We are also finalizing our proposed requirement in the ''electronic prescribing'' criterion to use the standard in 45 CFR 170.207(d)(2), where we have cross referenced NDC, with modification. Pursuant to our reorganization of the paragraph at 45 CFR 170.315(b)(3)(ii)(A), we are finalizing in 45 CFR 170.315(b)(3)(ii)(A)(*1*)(*ii*) a requirement to use NDC if using the standard in 45 CFR 170.205(b)(2) (where we adopted NCPDP SCRIPT standard version 2023011) in the period before December 31, 2027. We are finalizing a requirement for use of NDC after January 1, 2028 in 45 CFR 170.315(b)(3)(ii)(A)(*2*)(*ii*).

(iii) Diagnoses (45 CFR 170.315(b)(3)(ii)(C))

In 45 CFR 170.315(b)(3)(ii)(C) we require that a Health IT Module ''must be able to receive and transmit the reason for prescription using the diagnosis elements: <Diagnosis> <Primary> or <Secondary>'' for the set of prescription-related transactions identified in 45 CFR 170.315(b)(3)(ii)(C)(1)–(2).

In the HTI–2 Proposed Rule (89 FR 63527 and 63528), we proposed to make changes to the list of required and optional transactions in 45 CFR 170.315(b)(3)(ii)(C) to reflect the proposed required transactions for the updated version of the certification criterion in 45 CFR 170.315(b)(3)(ii)(A), and our proposal to remove certain optional transactions from the updated version of the criterion in 45 CFR 170.315(b)(3)(ii)(B). Specifically, we proposed in 170.315(b)(3)(ii)(C)(*1*) to rename ''Create New Prescriptions (NewRx)'' to ''New Prescriptions (NewRx).'' We proposed in 45 CFR 170.315(b)(3)(ii)(C)(*1*)(*vi*) to remove the transaction ''Receive medication history'' (RxHistoryResponse) and reserve this section. We proposed in 45 CFR 170.315(b)(3)(ii)(C)(*1*)(*vii*) to require the following electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse, PANotification) if using NCPDP SCRIPT standard version 2023011 (adopted in 45 CFR 170.205(b)(2)). Lastly, we proposed to remove the optional transactions in 45 CFR 170.315(b)(3)(ii)(C)(*2*)(*i*) through (*iv*) and reserve this section. We referred readers to Table 1A in the HTI–2 Proposed Rule (89 FR 63529) for a comparison of required and optional transactions identified in the current certification criterion based on NCPDP SCRIPT standard version 2017071 and the proposed updated criterion based on NCPDP SCRIPT standard version 2023011.

The following is a summary of the comments we received and our responses:

Comment: A commenter supported the inclusion of the Diagnosis field as proposed.

Response: We thank the commenter for their support.

Comment: A few commenters recommended updating the regulatory text to align with the new diagnosis structure in the NCPDP SCRIPT Standard Version 2023011, which allows for an unlimited number of diagnoses to be sent in prescription-related transactions. They proposed certifying only the diagnosis associated with the medication being dispensed, located in the MedicationPrescribed/Diagnosis element, and not certifying the Patient diagnosis found in Patient/HumanPatient/Diagnosis. They noted that this approach would ensure the focus remains on the medication-specific diagnosis rather than broader patient diagnoses.

Response: We appreciate commenters' feedback regarding the proposed regulation text at 45 CFR 170.315(b)(3)(ii)(C). We agree with commenters that the NCPDP SCRIPT Standard Version 2023011 accommodates an unlimited number of diagnoses to be sent in prescription-related transactions and that this updated version of the standard no longer utilizes the current <Diagnosis> <Primary> or <Secondary> diagnosis elements previously identified in the 45 CFR 170.315(b)(3)(ii)(C).

After consideration of the public comments, we are finalizing in 45 CFR 170.315(b)(3)(ii)(C) that a Health IT Module must be able to receive and transmit the diagnosis or diagnoses that are the reason for the prescription. We believe this language reflects the potential for multiple diagnoses as well as clarifying the requirement to support the diagnosis or diagnoses associated with the medication being prescribed. We further clarify that we are not finalizing any requirements under the ''electronic prescribing'' criterion that Health IT Modules must support diagnosis elements that are not related to the medication being prescribed.

(iv) Race and Ethnicity

In 2023, the Pharmacy Interoperability and Emerging Therapeutics Task Force provided a recommendation to the HITAC to support interoperability between pharmacy constituents by including race and ethnicity in the ''electronic prescribing'' certification criterion (PhIET–TF–2023_Recommendation 26).[419] The Task Force stated that demographic data is not always made available through reporting such as case reporting to public health agencies. Yet, in order to support the ability to perform analytics, all data feeds should have relevant race and ethnicity data, and other key demographic data, when available. The Task Force recommended that various prescribing and laboratory results reporting capabilities need to be able to support sharing of the relevant data when an alternative source is not consistently available. Additionally, the Task Force acknowledged that a prescriber will likely already have patient race or ethnicity documented. Exchanging this information through available transactions, such as those included in electronic prescribing, is one way to improve consistency in

[419] *See https://www.healthit.gov/sites/default/files/page/2023-11/2023-11-09_PhIET_TF_2023_Recommendations_Transmittal_Letter_508.pdf.*

documentation of demographic data across provider types.

Specifically, the Task Force recommended ONC include the ability to capture and exchange race and ethnicity as part of the ''electronic prescribing'' certification criterion and point to USCDI v4,[420] which references the CDC Race & Ethnicity Code System—CDCREC 1.2 (July 2021).[421] The CDC Race & Ethnicity Code System—CDCREC 1.2 code set facilitates use of federal standards for classifying data on race and ethnicity when these data are exchanged, stored, retrieved, or analyzed in electronic form. The NCPDP SCRIPT standard version 2023011, which we proposed to incorporate in the ''electronic prescribing'' certification criterion in the HTI–2 Proposed Rule (89 FR 63528), references reporting of race and ethnicity using the CDCREC 1.2 associated value set ''PHVS_Race_CDC'' version 2 (December 2018 [422]) from the code system code ''PH_RaceAndEthnicity_CDC'' as optional for certain transactions within the standard. This aligns with the code system code in CDCREC 1.2 which is ''PH_RaceAndEthnicity_CDC,'' and is available on the Public Health Information Network (PHIN) Vocabulary Access and Distribution System (PHIN VADS).[423]

Given the importance of the issues described by the Task Force, and the alignment between the recommendation and NCPDP SCRIPT standard version 2023011, we stated that we believe that it is appropriate to implement the Task Force recommendation through updates to the ''electronic prescribing'' certification criterion. Therefore, we proposed in 45 CFR 170.315(b)(3)(ii)(B) that a Health IT Module certified to the ''electronic prescribing'' certification criterion must enable a user to exchange race and ethnicity information for a patient when performing the following prescription-related electronic transactions, if using NCPDP SCRIPT standard version 2023011:

- Receive fill status notifications (RxFill).
- Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).
- Request to cancel prescriptions (CancelRx).
- Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

We stated we believe the transactions listed previously are an appropriate starting place to include race and ethnicity in the electronic prescribing certification criterion. We noted that we will continue to monitor changes to the NCPDP SCRIPT standard for additional updates to transactions to include race and ethnicity data fields.

We invited comments on this proposal and requested information on whether there are other SCRIPT transactions that include data fields for race and ethnicity we should consider specifying to enable exchange of race and ethnicity data with providers in pharmacy settings.

The following is a summary of the comments we received and our responses:

Comment: Several commenters supported our proposal to require that Health IT Modules certified to the ''electronic prescribing'' criterion enable users to capture race and ethnicity in the specific transactions. Commenters stated that expanding data collection requirements across certified health IT, including options for disaggregated coding of race, ethnicity and preferred language, would help to extend contextual understanding for electronic prescribing information.

Response: We thank the commenters for their support. We agree that enabling exchange of this information will increase its availability and can add useful information to electronic prescriptions.

Comment: A commenter stated that ASTP/ONC should consider the potential misuse of race and ethnicity information captured using certified Health IT Modules, while another commenter recommended making race and ethnicity data collection and sharing optional, so pharmacy staff on the ground can make informed decisions on when it is appropriate to ask questions on demographics.

Response: We appreciate commenters' feedback on the use of race and ethnicity data and agree that there are many important considerations around the collection and use of these data. The potential misuse of data is not unique to data elements of race and ethnicity. Users of certified health IT should comply with existing laws and regulations governing the use of health information (for instance, see the HIPAA Security and Privacy Rules in 45 CFR part 160 and subparts A, C and E of part 164). Additionally, organizations may establish their own data policies to support the accuracy of data. We note that the proposed requirement that Health IT Modules certified to the updated ''electronic prescribing'' criterion must enable a user to exchange this information would not establish a requirement for end users of Health IT Modules certified to the ''electronic prescribing'' criterion to capture and share this information. This proposal does not require the collection or disclosure of demographic information nor does it address the voluntary nature of patient disclosures of race and ethnicity data.

Comment: A commenter stated that ASTP/ONC should work with other agencies to ensure policies to support the collection and exchange of demographic data are patient-centric, respect patient privacy, and promote patient autonomy. Commenters recommended that all race and ethnicity information should be provided voluntarily by the patient and that ASTP/ONC and other agencies should work with stakeholders to implement feasible workflows, identify appropriate ways to share data, and ensure that patients always have an option to decline to respond.

Another commenter encouraged ASTP/ONC to more clearly identify specific uses for these data to reduce health inequities. A commenter recommended ASTP/ONC provide more rationale for requiring this information be captured as other areas of medicine are pushing to take race and ethnicity out of consideration when prescribing medications.

Response: We agree with commenters that prescribers should think carefully about how to ensure patient-centered principles are followed when designing workflows around collection of this information, and that patients must have a voice in the data that they choose to share and how that data is shared with others. We will continue to collaborate with other agencies to ensure that such principles are considered in efforts around data collection as appropriate.

Regarding additional rationale for our proposal, we refer readers to the findings of the 2023 HITAC Pharmacy Interoperability and Emerging Therapeutics Task Force report [424] that race and ethnicity data are crucial for public health reporting and analytics. Gaps in the completeness of case reporting necessitate additional means to capture and share these data, so they

[420] *See https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[421] *See https://www.cdc.gov/phin/resources/vocabulary/.*

[422] *See https://phinvads.cdc.gov/vads/ViewValueSet.action?id=9152A536-AEEC-E711-ACD6-0017A477041A.*

[423] *See https://phinvads.cdc.gov/vads/ViewCodeSystemConcept.action?oid=2.16.840.1.113883.6.238&code=1579-2.*

[424] *https://www.healthit.gov/sites/default/files/page/2023-11/2023-11-09_PhIET_TF_2023_Recommendations_Transmittal_Letter_508.pdf.*

may be included in public health reporting. Finally, we note that this requirement for certified Health IT Modules would not establish any requirements that end users must consider race and ethnicity data when making prescribing decisions.

Comment: Several commenters noted the most common transaction in the NCPDP SCRIPT standard, NewRx, does not currently support race and ethnicity information, which limits the potential impact of exchanging race and ethnicity using the standard. Another commenter noted that ASTP/ONC should clarify the requirement is only to send race and ethnicity data to a pharmacy and not receive it back, as health systems are unlikely to want pharmacy data to overwrite information gathered during their check-in processes.

Response: We acknowledge the comment regarding the lack of inclusion of race and ethnicity data in the NewRx transaction, and will continue to work with interested parties to further explore transactions where inclusion of this data may be useful. We confirm that our final rule requirement only specifies that the health IT module must enable a user to exchange this information. We did not propose any requirement for a Health IT Module to modify data or overwrite existing data based on information received from pharmacies.

Comment: A commenter recommended the proposed timelines for certification should parallel those set forth in OMB's recent Statistical Policy Directive No. 15: Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity (SPD 15) [425] regarding the collection of race and ethnicity data, which identified an implementation date of March 28, 2029. The commenter stated that federal agencies are required to plan for implementation of OMB's race and ethnicity data policy over the next five years, so aligning with this delayed date would provide an opportunity to move towards standardization and alignment of race and ethnicity data across healthcare and government.

Response: We appreciate commenters' input, however it is not necessary to parallel the timelines in OMB's SPD 15 directive with our policies in this final rule for the ''electronic prescribing'' criterion. OMB's SPD 15 directive provides the standards for maintaining, collecting, and presenting race and ethnicity data for all Federal information collection and reporting purposes. The SPD 15 standards do not require any agency or program to collect race and ethnicity data; rather they provide a common language for uniformity and comparability in the collection and use of race and ethnicity data by Federal agencies.[426] Our proposed update to the ''electronic prescribing'' criterion aims to enable the electronic exchange of race and ethnicity information when performing certain prescription-related electronic transactions, and does not establish requirements for how that information may be initially collected and recorded. We are working closely with OMB and other partners on the implementation of this directive and we will revisit this and other elements of the Certification Program as needed to align with the directive.

Comment: Another commenter noted that NCPDP SCRIPT standard version 2023011, references reporting of race and ethnicity using the CDCREC 1.2 associated value set ''PHVS_Race_CDC'' version 2 (December 2018 [427]) and stated that this value set includes over 900 codes. The commenter recommended that ASTP/ONC instead adopt OMB's revised race/ethnicity data policy directive that was finalized in March 2024, as it will be more feasible to implement these broader OMB race and ethnicity categories while the system gains experience using the updated standard.

Response: We appreciate the commenter's feedback. As noted by the commenter, the PHVS_Race_CDC value set is referenced in the NCPDP SCRIPT standard version 2023011 and we are requiring Health IT Modules to support exchange of race and ethnicity data consistent with this standard. Moreover, we note that this value set is not misaligned with the broader OMB categories but provides for the capability to capture more fine-grained information about race and ethnicity to better support patient care. We did not propose any restriction on a health IT module to additionally supporting the OMB categories on a voluntary basis.

After consideration of public comments, we are finalizing our proposal in 45 CFR 170.315(b)(3)(ii)(B) that a Health IT Module must enable a user to exchange race and ethnicity information when performing certain prescription-related electronic transactions, if using the standard in 45 CFR 170.205(b)(2) (where we adopted NCPDP SCRIPT standard version 2023011). The relevant transactions are RxFill, RxChangeRequest, RxChangeResponse, CancelRx, RxRenewalRequest, and RxRenewalResponse.

We note that we have further evaluated this proposal in light of guidance released since the publication of the HTI–2 Proposed Rule. Specifically, we have reviewed Executive Order 14151, ''Ending Radical and Wasteful Government DEI Programs and Preferencing,'' and have determined the proposal we are finalizing is not in conflict with the Executive Order. While this policy would potentially make additional data about populations available to public health agencies, this requirement for certified health IT would not mandate that users of this technology or this data take any actions identified as part of the Executive Order.

(v) Base EHR Definition

In the HTI–2 Proposed Rule (89 FR 63528), given our proposal in section III.B.9.b. to include the proposed ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) in the Base EHR definition in 45 CFR 170.102, we also proposed to add the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) to the Base EHR definition. Please see section III.B.9.b. of the HTI–2 Proposed Rule (89 FR 63930 through 63932) for further details on this proposal.

Please see the ''New Real-Time Prescription Benefit Criterion'' section XI.*B*.4.b.(4) of the preamble of this final rule for a summarization of the public comments received to add the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) to the Base EHR definition. As discussed in section XI.*B*.4.b.(4) of the preamble of this final rule, we are not finalizing this proposal, as ASTP/ONC is seeking to limit the Base EHR definition to elements of the Qualified EHR definition in PHSA section 3000 where possible.

(vi) Multi-Factor Authentication

In the HTI–2 Proposed Rule (89 FR 63528), we proposed in 45 CFR 170.315(b)(3)(ii)(G), that on and after January 1, 2028, a Health IT Module certified to 45 CFR 170.315(b)(3) must meet the multi-factor authentication requirements specified in 45 CFR 170.315(d)(13)(ii) for user-facing authentication. We stated that we believe this update is in line with industry information security best practice for an important authentication

[425] *https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and.*

[426] See *https://www.federalregister.gov/documents/2024/03/29/2024-06469/revisions-to-ombs-statistical-policy-directive-no-15-standards-for-maintaining-collecting-and.*

[427] See *https://phinvads.cdc.gov/vads/ViewValueSet.action?id=9152A536-AEEC-E711-ACD6-0017A477041A.*

use case in health IT, and that it is necessary to help better protect electronic health information. We referred readers to section III.B.17 of the HTI–2 Proposed Rule (89 FR 63574) for our proposal to revise the ''multi-factor authentication'' certification criterion 45 CFR 170.315(d)(13) and for background on the user level authentication use case targeted by this proposed requirement.

The following is a summary of the comments we received and our responses:

Comment: A commenter supported the proposal that after January 1, 2028, a certified health IT module must meet the multi-factor requirements specified for user-facing authentication. The commenter agreed with ASTP/ONC that this update is in line with industry information security best practices and will better protect electronic health information.

Response: We thank commenters for their support.

Comment: Another commenter suggested that ASTP/ONC should not finalize this requirement as written. The commenter noted that electronic prescribing for controlled substances already requires multi-factor authentication according to Drug Enforcement Administration (DEA) regulations. The commenter suggested that it is unclear what ASTP/ONC is additionally proposing to require, given these protections are already in place.

Response: We agree that requirements for use of this functionality are already in place and that prescribers are subject to requirements to use multi-factor authentication when electronically prescribing controlled substances. We further agree that finalizing such requirements as part of the ''electronic prescribing'' certification criterion is not necessary to ensure use of multi-factor authentication by clinicians, due to existing requirements.

After consideration of public comments, we are not finalizing the proposed requirement for multi-factor authentication in 45 CFR 170.315(b)(3)(ii)(G).

In summary, after consideration of the public comments, we are finalizing the proposed update to the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3)(ii) with the following modifications:

- As discussed in the preamble of this final rule, we are finalizing revisions to and a reorganization of the text of the regulation in 45 CFR 170.315(b)(3)(ii)(A) to increase clarity regarding our timelines for the use of standards for the ''electronic prescribing'' criterion, and renumbering subsequent paragraphs.
- We are finalizing revised language in 45 CFR 170.315(b)(3)(ii)(A)(*1*)(*i*) and (A)(*2*)(*i*) requiring the use, at a minimum, of at least one of the versions the standard specified in 45 CFR 170.207(d), where we adopted multiple versions of RxNorm.
- We are moving the required prescription-related electronic transactions listed at 45 CFR 170.315(b)(3)(ii)(A)(*1–9*) to 45 CFR 170.315(b)(3)(ii)(A)(*3*)(*i–x*), and renumbering the transactions as follows: (*i*) New prescriptions (NewRx), (*ii*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse), (*iii*) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse), (*iv*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse), (*v*) Receive fill status notifications (RxFill), (*vi*) Request and receive medication history (RxHistoryRequest, RxHistoryResponse), (*vii*) Relay acceptance of a transaction back to the sender (Status), (*viii*) Respond that there was a problem with the transaction (Error), (*ix*) Respond that a transaction requesting a return receipt has been received (Verify), and (*x*) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification).
- We are not finalizing the removal of the request and receive medication history transactions (RxHistoryRequest, RxHistoryResponse) in 45 CFR 170.315(b)(3)(ii)(A)*(6),* and retaining these transactions in 45 CFR 170.315(b)(3)(ii)(A)*(3)(vi).*
- We are finalizing revised language regarding the requirement to transmit the diagnosis or diagnoses that are the reason for the prescription in certain transactions in 45 CFR 170.315(b)(3)(ii)(C).
- We are not finalizing the provision requiring that a Health IT Module must enable a user to enter, receive, and transmit structured and codified prescribing instructions in accordance with the standard specified in § 170.205(b)(2) proposed in 45 CFR 170.315(b)(3)(ii)(D), as structured and codified Sig functionality is already embedded in the NCPDP SCRIPT standard version 2023011 and we do not believe a dedicated requirement is necessary.
- We are not finalizing the proposal in 45 CFR 170.315(b)(3)(ii)(G) to reference the proposed ''multi-factor authentication'' certification criterion in 45 CFR 170.315(d)(13) as part of the updated ''electronic prescribing'' criterion.
- We are not finalizing the proposal to add the ''electronic prescribing'' criterion to the Base EHR definition beginning on January 1, 2028. Please see the ''New Real-Time Prescription Benefit Criterion'' section XI.*B*.4.b.(4). of the preamble of this final rule for a summarization of the public comments received to add the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) to the Base EHR definition.

We have updated the table we originally presented in the HTI–2 Proposed Rule (89 FR 63529) to provide a comparison of transactions identified in the existing version of the criterion based on the NCPDP SCRIPT standard version 2017071, and the updated certification criterion we are finalizing in 170.315(b)(3)(ii) based on NCPDP SCRIPT standard version 2023011.

TABLE XI.B.-01: COMPARISON OF TRANSACTIONS IDENTIFIED IN THE VERSION OF THE CERTIFICATION CRITERION BASED ON NCPDP SCRIPT STANDARD VERSION 2017071 AND THE UPDATED CRITERION BASED ON NCPDP SCRIPT STANDARD VERSION 2023011

Transactions	Current Electronic Prescribing Criterion (NCPDP SCRIPT Standard Version 2017071)	Revised Electronic Prescribing Criterion (NCPDP SCRIPT Standard Version 2023011)
New prescriptions (NewRx).	Required for certification	Required for certification
Receive fill status notifications (RxFill).	Required for certification	Required for certification
Request and receive medication history (RxHistoryRequest, RxHistoryResponse).	Required for certification	Required for certification
Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).	Required for certification	Required for certification
Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).	Required for certification	Required for certification
Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).	Required for certification	Required for certification
Relay acceptance of a transaction back to the sender (Status).	Required for certification	Required for certification
Respond that there was a problem with the transaction (Error).	Required for certification	Required for certification
Respond that a transaction requesting a return receipt has been received (Verify).	Required for certification	Required for certification
Electronic prior authorization (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse).	*Optional* for certification	Required for certification
PANotification	*Not* required for certification	Required for certification
New prescription requests (NewRxRequest, NewRxResponseDenied).	*Optional* for certification	*Not* required for certification
RxTransferRequest, RxTransferResponse, RxTransferConfirm, and RxFillIndicatorChange.	*Optional* for certification	*Not* required for certification
Request to send an additional supply of medication (Resupply).	*Optional* for certification	*Not* required for certification
GetMessage.	*Optional* for certification	*Not* required for certification
Communicate drug administration events (DrugAdministration).	*Optional* for certification	*Not* required for certification
Recertify the continued administration of a medication order (Recertification).	*Optional* for certification	*Not* required for certification
Complete Risk Evaluation and Mitigation Strategy (REMS) transactions (REMSInitiationRequest, REMSInitiationResponse, REMSRequest, and REMSResponse).	*Optional* for certification	*Not* required for certification

(4) New Real-Time Prescription Benefit Criterion

(a) Background

The increasing costs of prescription drugs have long been a concern for patients, providers, and policymakers.[428] Increased drug costs can have several negative consequences for patients, including limited access to healthcare,[429] lower healthcare use,[430] medication nonadherence[431] [432] and financial stress, especially among underserved,[433] uninsured, and underinsured[434] populations. Merely having health insurance coverage does not necessarily confer medication affordability on patients.[435] These challenges continue to be the focus of legislation, such as the Inflation Reduction Act of 2022 (Pub. L. 117–169, August 16, 2022), which includes several provisions that are expected to decrease prescription drug costs and improve access to prescription drugs for the more than 68 million Americans enrolled in the Medicare program,[436] including allowing Medicare to directly negotiate prescription drug prices for the first time, eliminating cost sharing for certain adult vaccines under Part D, capping out-of-pocket costs for insulin, and capping Part D enrollee out-of-pocket spending annually starting in 2025 (see sections 11406, 11401, 1194, and 11201). E. O. 14087, Lowering Prescription Drug Costs for Americans, directed further actions to lower the cost of prescription drugs.

Research also suggests provider-patient discussions during clinical encounters about costs and affordability may lead to an overall reduction in out-of-pocket costs.[437] Real-time prescription benefit tools empower providers and their patients to compare the patient-specific cost of a drug to the cost of a suitable alternative, compare prescription costs at different pharmacy locations, view information about out-of-pocket costs, and learn whether a specific drug is subject to utilization management restrictions such as prior authorization, step therapy, or quantity

[428] A.S. Kesselheim, J. Avorn, A. Sarpatwari, The high cost of prescription drugs in the United States: origins and prospects for reform. JAMA, 316 (8) (2016), pp. 858–871.

[429] Daher, Al Rifai, M., Kherallah, R.Y., Rodriguez, F., Mahtta, D., Michos, E.D., Khan, S.U., Petersen, L.A., & Virani, S.S. (2021). Gender disparities in difficulty accessing healthcare and cost-related medication non-adherence: The CDC behavioral risk factor surveillance system (BRFSS) survey. Preventive Medicine, 153, 106779–106779. *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9291436/.*

[430] Roebuck, Liberman, J.N., Gemmill-Toyama, M., & Brennan, T.A. (2011). Medication adherence leads to lower health care use and costs despite increased drug spending. Health Affairs, 30(1), 91–99. *https://doi-org.ezproxyhhs.nihlibrary.nih.gov/10.1377/hlthaff.2009.1087.*

[431] SG Morgan, A. Lee. Cost-related non-adherence to prescribed medicines among older adults: a cross-sectional analysis of a survey in 11 developed countries. BMJ Open, 7 (1) (2017), Article e014287.

[432] DiMatteo MR, Giordani PJ, Lepper HS, Croghan TW. Patient adherence and medical treatment outcomes: a meta-analysis. Med Care. 2002; 40 (9): 794–811.

[433] Whaley C, Reed M, Hsu J, Fung V (2015) Functional Limitations, Medication Support, and Responses to Drug Costs among Medicare Beneficiaries. PLoS ONE 10(12): e0144236. *https://doi.org/10.1371/journal.pone.0144236.*

[434] Collins SR, Rasmussen PW, Beutel S, Doty MM. The problem of underinsurance and how rising deductibles will make it worse: findings from the Commonwealth Fund Biennial Health Insurance Survey, 2014. New York: Commonwealth Fund; 2015.

[435] Zhao, J., Zheng, Z., Han, X., Davidoff, A.J., Banegas, M.P., Rai, A., Jemal, A., & Yabroff, K.R. (2019). Cancer History, Health Insurance Coverage, and Cost-Related Medication Nonadherence and Medication Cost-Coping Strategies in the United States. Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research, 22(7), 762–767. *https://doi.org/10.1016/j.jval.2019.01.015.*

[436] See *https://data.cms.gov/tools/medicare-enrollment-dashboard.*

[437] Carroll JK, Farah S, Fortuna RJ, et al. Addressing medication costs during primary care visits: a before-after study of team-based training. Ann Intern Med. 2019;170(suppl 9): S46–S53. doi:10.7326/M18–2011.

limits. In the HTI–2 Proposed Rule (89 FR 63530), we stated that, when appropriate, use of these tools can allow the provider and patient to choose among clinically acceptable alternative medication treatments while weighing coverage and point-in-time costs. We also noted that access to this data within the electronic prescribing workflow may help to reduce provider burden associated with coverage determination and prior authorization appeals. We additionally stated that widespread adoption of such tools, along with increased awareness of drug cost information among patients and providers will likely spur more robust evaluations over time.

Section 1860D–4(o) of the Act, as added by section 119 of Title I, Division CC of the Consolidated Appropriations Act of 2021, (Pub. L. 116–260) (CAA, 2021), requires sponsors of prescription drug plans to implement one or more real-time benefit tools (RTBTs) after the Secretary has adopted a standard for RTBTs and at a time determined appropriate by the Secretary. Section 1860D–4(o)(3) of the Act requires that a qualifying RTBT must meet technical standards named by the Secretary, in consultation with ONC. Section 119(b) of the CAA, 2021 also amended the definition of a ''qualified electronic health record'' in section 3000(13) of the PHSA to specify that a qualified electronic health record ''includes, or is capable of including, a real-time benefit tool that conveys patient-specific real-time cost and coverage information with respect to prescription drugs that, with respect to any health information technology certified for electronic prescribing, the technology shall be capable of incorporating the information described in clauses (i) through (iii) of paragraph (2)(B) of section 1860D–4(o) of the Act.'' The information specified in (2)(B)(i) through (iii) of section 1860D–4(o) of the Act, as added by section 119(a) of the CAA, 2021, is:

- A list of any clinically appropriate alternatives to a covered Part D drug included in the formulary of such plan;
- Cost-sharing information and the negotiated price for a covered Part D drug and such alternatives at multiple pharmacy options, including the individual's preferred pharmacy and, as applicable, other retail pharmacies and a mail order pharmacy; and
- The formulary status of a covered Part D drug and such alternatives and any prior authorization or other utilization management requirements applicable to such drug and such alternatives included in the formulary of such plan.

The provision further specifies that the change to the definition of a ''qualified electronic health record'' shall be implemented ''at a time specified by the Secretary but not before the Secretary adopts a standard for such tools.''

In the HTI–1 Proposed Rule (88 FR 23848 through 23855), we included a request for information (RFI) about issues related to establishing a real-time prescription benefit certification criterion utilizing the NCPDP Real-Time Prescription Benefit (RTPB) standard, and ways in which the Certification Program could ensure real-time prescription benefit capabilities are implemented effectively for providers. We received many comments on this RFI and appreciate the input provided by commenters.

In the HTI–2 Proposed Rule (89 FR 63530), in order to implement section 119(b) of the CAA, 2021, we proposed to establish a ''real-time prescription benefit'' health IT certification criterion in 45 CFR 170.315(b)(4) and to include this certification criterion in the Base EHR definition in 45 CFR 170.102(3)(iv).

(b) Revision to the Base EHR Definition and Health IT Module Dependent Criteria Requirements

As noted previously, section 119(b) of the CAA, 2021, amended the definition of a ''qualified electronic health record'' (Qualified EHR) in section 3000(13) of the PHSA to specify that a qualified electronic health record ''includes, or is capable of including, a real-time benefit tool that conveys patient-specific real-time cost and coverage information with respect to prescription drugs.'' In the 2014 Edition Final Rule, we established the term ''Base EHR,'' based on the Qualified EHR definition in PHSA section 3000(13), for use within the Certification Program (77 FR 54262). We define Base EHR in 45 CFR 170.102, and this definition currently includes certification criteria under the Certification Program that align with the elements of the Qualified EHR definition in the PHSA.

Given that the statutory definition of Qualified EHR is implemented in regulation through the Base EHR definition in 45 CFR 170.102, in the HTI–2 Proposed Rule (89 FR 63531), we stated that we believe it is necessary to propose to update the Base EHR definition consistent with Congress' modification of the statutory definition of Qualified EHR to address real-time benefit tool functionality. Specifically, consistent with PHSA section 3000(13), as amended by section 119(b) of the CAA, 2021, we proposed to revise the Base EHR definition in 45 CFR 170.102 to add paragraph (3)(iv) to include the real-time prescription benefit certification criterion proposed in 45 CFR 170.315(b)(4) on and after January 1, 2028. We also stated that we believe including the ''real-time prescription benefit'' certification criterion as part of the Base EHR definition will increase the use of real-time prescription benefit tools and promote widespread adoption, which will help to lower drug costs for Medicare beneficiaries, consistent with section 119 of the CAA, 2021. We noted that use of real-time prescription benefit tools enables Medicare providers and enrollees to make cost-informed decisions about prescriptions, and a standardized approach will ensure that critical drug and drug price data is available to providers when they need it.

In the Part D and Health IT Standards Final Rule, CMS finalized the requirement that Part D plan sponsors adhere to NCPDP RTPB standard version 13 as part of requirements to provide a prescriber real-time benefit tool by January 1, 2027 (89 FR 51259 and 51260). We requested comment on whether we should seek to align the date when the ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) would be effective for the Base EHR definition (proposed to be January 1, 2028) with the date finalized in the Part D and Health IT Standards Final Rule for Part D plan sponsors' real-time benefit tools to adhere to the NCPDP RTPB standard version 13 (January 1, 2027) (89 FR 51260).

We noted that the amended definition of a Qualified EHR in PHSA section 3000(13)(c) further specifies that ''with respect to any health information technology certified for electronic prescribing, the technology shall be capable of incorporating the information described in clauses (i) through (iii) of paragraph (2)(B).'' In the HTI–2 Proposed Rule (89 FR 63531), we stated that we interpret this provision to mean, for the purposes of the Certification Program, that any health IT presented for certification for electronic prescribing capabilities should also be capable of incorporating the real-time benefit information specified in clauses (i) through (iii) of paragraph (2)(B) of section 1860D–4(o) of the Act, as described previously.

We stated that real-time prescription benefit functionality is closely related to electronic prescribing functionality, which provides the basic workflow within which a provider may seek to identify information about a patient's coverage for a certain prescription before transmitting that electronic prescription to the pharmacy. We noted

that in most cases, we expect health IT developers seeking certification to 45 CFR 170.315(b)(4) will already be certified to 45 CFR 170.315(b)(3), though there will be some variation due to the modularity of the Certification Program criteria. Accordingly, we proposed to revise 45 CFR 170.550(g) to add paragraph (g)(6) in order to require that any developer that obtains certification for the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) must also obtain certification for the proposed ''real-time prescription benefit'' criterion in 45 CFR 170.315(b)(4).

While we proposed to establish this dependency with the ''electronic prescribing'' certification criterion, the ''electronic prescribing'' certification criterion is not included as part of the current Base EHR definition in 45 CFR 170.102. We noted that although electronic prescribing is a widely used and fundamental capability of health IT, we have, to date, not included this certification criterion in the Base EHR definition for several reasons. First, the Qualified EHR definition in section 3000(13) of the PHSA does not specify electronic prescribing as a required element of a Qualified EHR and we have generally sought to limit the Base EHR definition in 45 CFR 170.102, which implements the Qualified EHR definition, to those capabilities that are required for the Qualified EHR definition by statute. Second, many health care providers have historically been required to adopt certified health IT for electronic prescribing in order to meet the requirements of the Medicare EHR Incentive Programs and their successors, the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. Objectives and measures for eligible professionals (now MIPS eligible clinicians [438]), eligible hospitals, and CAHs under these programs have included measures related to electronic prescribing since the implementation of the Medicare EHR Incentive Programs and we have maintained such measures in their successors. Specifically, for the MIPS Promoting Interoperability performance category, section 1848(o)(2)(A)(i) of the Act requires a MIPS eligible clinician to demonstrate that they use CEHRT in a meaningful manner, which includes the use of electronic prescribing as determined appropriate by the Secretary.

However, given the proposal to include the proposed ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) in the Base EHR definition, we stated our belief that it was also appropriate to add the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) to the Base EHR definition. While we previously did not include this capability in the Base EHR definition for the reasons we described, we noted that we believe that the inclusion of closely related ''real-time prescription benefit'' functionality in 45 CFR 170.315(b)(4) necessitated the inclusion of electronic prescribing functionality. We therefore proposed to include the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) within the Base EHR definition in 45 CFR 170.102. We further proposed to specify that this criterion would be effective for the Base EHR definition on and after January 1, 2028, which aligns with the date when the proposed ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) would be effective for the Base EHR definition.

We requested comment on these proposals, especially regarding the impact of these proposals on health IT developers seeking to ensure their products meet the Base EHR definition that are not currently separately certified to the ''electronic prescribing'' criterion. We sought information on the added burden to developers of requiring the ''electronic prescribing'' certification criterion as part of the Base EHR definition in addition to the proposed ''real-time prescription benefit'' certification criterion. We also requested comment on the implications for interoperability of electronic prescribing if we were to finalize our proposal to include the ''real-time prescription benefit'' certification criterion within the Base EHR definition but not finalize our proposal to include the ''electronic prescribing'' certification criterion in the Base EHR definition.

Lastly, we requested comment on the impact this proposed policy would have on any healthcare providers participating in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category who have historically been able to claim an exclusion from electronic prescribing measures in these programs, and, as a result have not adopted certified health IT for electronic prescribing in order to complete the actions associated with these measures. The definitions of certified EHR technology at 42 CFR 495.4 and 42 CFR 414.1305, which define technology requirements for these programs, cross-reference the Base EHR definition at 45 CFR 171.102. Thus, we noted that as a result of the statutory change enacted by Congress, and if the HTI–2 Proposed Rule proposals to add these certification criteria to the Base EHR definition were finalized, all providers and clinicians participating in these programs would, at a minimum, have to have health IT certified to the proposed ''real-time prescription benefit'' certification criterion and the ''electronic prescribing'' certification criterion. This would include participants that currently successfully participate in these programs without possessing certified health IT that supports these capabilities. We requested comment on whether finalizing these proposals would impose significant burden on these healthcare providers and clinicians.

The following is a summary of the comments we received and our responses on the HTI–2 Proposed Rule and our responses:

Comment: Many commenters supported our proposal to establish a ''real-time prescription benefit'' health IT certification criterion. Commenters stated that the ability to obtain real-time information about prescription benefits improve the care experience for patients and their care teams, allow for more informed and timely decision-making, enable informed cost-related conversations during clinical encounters, reduce administrative burden for both patients and providers (for example, calls to a physician's office when a medication is unaffordable, return trips to the clinic and/or the pharmacy), reduce care delays and patient frustration, and lead to improved medication adherence and clinical outcomes. Commenters also stated that these capabilities may benefit health plans by reducing the number of prior authorization requests from providers, and by steering providers toward recommending in-formulary, lower-cost medication options.

Response: ASTP/ONC thanks commenters for their support and agrees that real-time prescription benefit technology has the potential to empower providers and their patients to compare the patient-specific cost of a drug to the cost of a suitable alternative, compare prescription costs at different pharmacies, view information about out-of-pocket costs, and learn whether prior authorization for a specific drug is required.

Comment: Most commenters supported our proposal to include the ''real-time prescription benefit'' certification criterion in the Base EHR definition in 45 CFR 170.102(3)(iv). They noted that including the ''real-time prescription benefit'' certification criterion in the Base EHR definition will

[438] We define this term in our regulations at 42 CFR 414.1405 for purposes of MIPS.

support broader availability of certified health IT with these capabilities.

Response: ASTP/ONC thanks commenters for their support.

Comment: Some commenters opposed including the ''real-time prescription benefit'' criterion in the Base EHR definition at this time. Commenters stated that requiring technology that is not fully ready could increase burden on physicians. A commenter preferred for the ''real-time prescription benefit'' criterion to not be required as part of the Base EHR definition as the industry continues to improve on the technology. A commenter thought it was not necessary to include the ''real-time prescription benefit'' criterion in the Base EHR definition because the availability of the ''real-time prescription benefit'' criterion would be sufficient to ensure adoption of this capability.

Response: ASTP/ONC thanks the commenters for their concerns regarding the inclusion of the ''real-time prescription benefit'' criterion in the Base EHR definition in 45 CFR 170.102. While we recognize these concerns, we proposed to include the ''real-time prescription benefit'' criterion in the Base EHR definition in order to fulfill the statutory requirements of section 119(b)(3) of the CAA, 2021 (Pub. L. 116–260), which added RTBT functionality to the definition of a qualified EHR in section 3000 of the PHSA. We also note that RTBTs are already widely implemented across US provider organizations and practices, with about two-thirds of hospitals reporting access to an RTBT.[439] Given this degree of adoption, we anticipate that many physicians would not notice a change in their practice or workflow as a result of including the ''real-time prescription benefit'' criterion in the Base EHR definition.

Comment: Many commenters supported our proposal to include the ''real-time prescription benefit'' criterion in the Base EHR definition as of January 1, 2028. Commenters stated this date would allow payers, developers, and providers time to prepare, thus ensuring a smoother and more effective implementation. Some commenters supported this proposal due to the fact that it is a year after the compliance date of January 1, 2027, finalized by CMS for Part D plan sponsors to establish an RTBT that meets NCPDP standard version 13. Commenters stated that this staggering of dates will allow health IT developers to more effectively develop Health IT Modules based on real-world implementations by Part D plan sponsors.

Response: ASTP/ONC thanks the commenters for their support. We agree with commenters regarding the benefits of the proposed date of January 1, 2028, for including the ''real-time prescription benefit'' criterion in the Base EHR definition. The proposed date for inclusion in the Base EHR definition of January 1, 2028 would provide a window of more than 24 months from the publication of this final rule for health IT developers to make Health IT Modules certified to the criterion at 45 CFR 170.315(b)(4) available to their customers in order to meet the Base EHR definition. ASTP/ONC agrees that staggered compliance dates would provide more opportunities for developers to test Health IT Modules against standard-compliant RTBTs implemented by Part D plan sponsors prior to release, thus ensuring that Health IT Modules are able to successfully interact with the technology implemented by Part D plan sponsors.

Comment: Some commenters supported aligning the effective date of the Base EHR definition revision with the January 1, 2027, compliance date by which Part D plan sponsors must implement RTBTs compliant with NCPDP RTPB standard version 13. Commenters expressed concern that if the dates are not aligned, there may be challenges in implementation, increased administrative burden, or negative consequences for the quality and cost of healthcare. Some commenters requested clarification on whether the deadline finalized by CMS for Part D plan sponsors applies universally or if there are specific exemptions.

Response: ASTP/ONC appreciates this feedback. We acknowledge the discrepancy between the date we proposed for the ''real-time prescription benefit'' criterion to be included in the Base EHR definition and the deadline for Part D sponsors to offer an RTBT conformant with the NCPDP RTPB standard version 13. However, we do not believe this discrepancy will result in significant challenges for health care providers using certified health IT. While health care providers may use health IT that includes RTBTs as part of their participation in certain federal programs, we note that there is currently no HHS requirement for health care providers to use RTBTs as part of care delivery; for instance, there is no associated measure specifying the use of RTBTs in the Medicare Promoting Interoperability Program or the MIPS Promoting Interoperability performance category. Thus, health care providers will not face additional penalties if their health IT developer does not provide a Health IT Module certified to the ''real-time prescription benefit'' criterion prior to the deadline for inclusion of the criterion in the Base EHR definition.

We further note that health IT developers may certify to the criterion beginning as soon as the testing tools are available subsequent to the effective date of this final rule. They are not required to wait until January 1, 2028, to update certified technology and provide it to their customers. In addition, health IT developers that already incorporate RTBTs or provide access to RTBTs may work with payers and other intermediaries to complete any updates necessary to ensure seamless access to existing tools.

Regarding the commenters' question about the applicability of the deadline CMS has finalized for payer RTBTs to conform to NCPDP RTPB standard version 13, we note that CMS finalized in 42 CFR 423.160(b)(5) that beginning January 1, 2027, Part D sponsors' RTBT must comply with a standard in 45 CFR 170.205(c) (where we adopted the NCPDP RTPB standard version 13). This deadline is specific to the requirements for RTBTs established by Part D plan sponsors.

Comment: A few commenters noted that ASTP should ensure that the requirements in this proposed rule are consistent with the requirements finalized for Part D plan sponsors in the Part D and Health IT Standards Final Rule.

Response: We appreciate commenters' input on the intersection between this final rule and regulations for Part D plan sponsors. We agree that HHS should support consistency across regulations, and we have worked closely with CMS to ensure our regulations are complementary. For instance, our adoption of the NCPDP RTPB standard version 13 in 45 CFR 170.205(c) is cross-referenced by CMS in 42 CFR 423.160(b)(5).

Comment: Several commenters requested the adoption of a complementary ''role-based'' certification criterion focused on the health IT used by payers to participate in RTBT workflows. Commenters stated that without this foundation, developers and healthcare providers are at risk of spending time and money on functionality that provides little value. These commenters requested that ASTP work with CMS to develop separate ''real-time prescription benefit'' criterion for providers and payers, similar to the approach for electronic prior authorization transactions

[439] See *https://www.healthit.gov/data/quickstats/hospital-adoption-real-time-benefit-tools.*

proposed in the HTI–2 Proposed Rule. A few commenters recommended only including the ''real-time prescription benefit'' criterion in the Base EHR definition once a corresponding ''role-based'' criterion for technology used by payers has been adopted and successfully implemented. They argued that without a role-based criterion, developers and providers might invest in functionality that does not get fully utilized or might not be ready to contribute to the system's functionality.

Response: We appreciate the suggestion to adopt a complementary ''role-based'' certification criterion for payer health IT used to support RTBTs. We have collaborated closely with CMS to advance alignment between regulations impacting Part D plan sponsors and our regulations for health IT developers participating in the Certification Program. Through that collaboration, ASTP/ONC adopted the NCPDP RTPB standard version 13 in a joint rulemaking in which CMS finalized a cross-reference that includes this standard in its requirements for Part D plan sponsors (42 CFR 423.160(b)(5)). ASTP/ONC subsequently proposed to incorporate this standard within the ''real-time prescription benefit'' criterion.

ASTP/ONC did not propose a certification criterion focused on health IT used by Part D plan sponsors, so finalizing a ''role-based'' certification criterion for payers would be out of scope for this final rule. However, we believe that requiring RTBTs established by Part D plan sponsors and certified Health IT Modules to adhere to the same implementation specification (NCPDP RTPB standard) will ensure a substantial degree of interoperability between provider and health plan systems, in the absence of certification of technology used by Part D plan sponsors. While we may explore with CMS whether the availability of a ''role-based'' certification criterion would provide additional benefits in the future, we believe the degree of interoperability that can be achieved under the current and proposed regulatory approach will provide value to health care providers and patients and implementation based on inclusion in the Base EHR definition should not be delayed further.

We also appreciate the comment that ''role-based'' certification criteria would ensure that developers and providers are investing in functionality that can be fully utilized by all parties. However, even without a ''role-based'' certification criterion for payers at this time, we believe it is necessary to include the ''real-time prescription benefit'' criterion in the Base EHR definition in order to fulfill the statutory requirements of section 119(b)(3) of the CAA, 2021 (Pub. L. 116–260), which added RTBT functionality to the definition of a qualified EHR in section 3000 of the PHSA.

Comment: Many commenters supported our proposal to add the ''electronic prescribing'' certification criterion to the Base EHR definition, noting that electronic prescribing reduces administrative burden for clinicians and pharmacists and improves medication adherence for patients. A commenter recommended including the ''electronic prescribing'' criterion in the Base EHR definition, without the ''real-time prescription benefit'' criterion.

Response: We thank commenters for their support. We agree that electronic prescribing reduces administrative burden for clinicians and pharmacists and can improve medication adherence for patients among other benefits. We have advanced certification criteria for electronic prescribing for more than a decade and have updated our criteria to maintain conformance to the latest available standards. However, given the near universal adoption of the criterion and the baseline requirements under CMS programs, we believe that adding the criterion to the Base EHR definition creates administrative burden on developers in the certification process without adding benefit to providers, pharmacies, or patients. In order to avoid unnecessary developer burden, which might be passed on to users in higher costs, we are not finalizing the inclusion of the criterion in the Base EHR definition. Regarding the recommendation to include the ''electronic prescribing'' criterion in the Base EHR definition but not the ''real-time prescription benefit'' criterion, we note that we believe it is necessary to include the ''real-time prescription benefit'' criterion in order to ensure that the Base EHR definition is aligned with the requirements of a qualified EHR in PHSA section 3000, as amended by section 119(b)(3) of the CAA, 2021.

Comment: A commenter did not believe there was a need for electronic prescribing to be added to the Base EHR definition because electronic prescribing is already widely adopted as a criterion. Adding this criterion to the Base EHR definition will add work for developers without being of much benefit to users.

Response: We agree with commenters that electronic prescribing functionality has reached a high level of adoption and is unlikely to further benefit from being included in the Base EHR definition. We had proposed to add the ''electronic prescribing'' criterion to the Base EHR due to its close intersection with the functionality in ''real-time prescription benefit'' criterion which we are finalizing in this rule. However, we believe the benefits for doing so are limited. In addition, we believe it is preferable to limit the criteria referenced in the Base EHR definition to those criteria required under the qualified EHR definition in section 3000 of the PHSA where possible.

Comment: Several commenters noted the importance of minimizing the burden of RTBTs on clinicians and healthcare organizations. They recommended that EHR vendors integrate this new criterion with minimal disruption to EHR usability. They also recommended that developers prioritize clinical efficiency and minimizing potential alert fatigue when developing and implementing RTBTs. Another commenter expressed concern that the higher performance capacities needed may create challenges for smaller, rural practices with poor broadband capabilities, resulting in computer screens freezing, slow response times to data entry, and interruptions for the entire clinical practice team. They requested that ASTP work with CMS to establish flexibilities for these practices.

Response: We appreciate commenters' concerns with the potential workflow implications of these capabilities and effects these capabilities may have on EHR products. As part of the proposed ''real-time prescription benefit'' criterion, we did not address issues related to design, usability, or alert burden as certification to this capability is new to the Certification Program and we do not yet have information about how we should incorporate these elements into the criterion. ASTP/ONC welcomes further input from the public about these topics and may consider them in future rulemaking.

ASTP/ONC recognizes that RTPB transactions may be impacted by broadband challenges that generally impact information exchange, and that such issues may disproportionately impact healthcare providers in rural areas. Regarding the commenter's request that ASTP/ONC work with CMS to establish flexibilities for these providers, we note that for the MIPS Promoting Interoperability performance category, CMS has established flexibilities that may apply to rural providers at 42 CFR 414.1380(c)(2), such as flexibilities that apply to small practices defined in 42 CFR 414.1305 as further specified at 42 CFR 414.1380(c)(2)(i)(C)(9). Additionally, we

encourage developers to implement Health IT Modules certified to the ''real-time prescription benefit'' criterion in a manner that gives provider organizations the flexibility to decide how frequently RTBT alerts should be triggered. Providers in areas with poor broadband capabilities could then limit the frequency of these alerts (for example, only when potential cost savings are substantial).

Comment: Several commenters emphasized the importance of making RTBTs available at no cost to healthcare organizations. A commenter cautioned that RTBTs should not be an option in the EHR but should rather be a required feature, because EHR vendors might then charge healthcare organizations to add the RTBT option, thus shifting the financial burden of RTBT development and adherence to the NCPDP RTPB standard to providers.

Response: We acknowledge that adopting Health IT Modules certified to the ''real-time prescription benefit'' criterion may have associated costs for providers and provider organizations. We expect that health IT developers seeking to offer health IT products that meet the Base EHR definition, where we proposed to include the real-time prescription benefit'' criterion'' would include this criterion in future offerings. However, we note that the ONC Health IT Certification Program is voluntary, and ASTP/ONC does not have the authority to direct health IT developers to include certain certified health IT capabilities in their products. We note that health IT developers that include Health IT Modules on the Certified Health IT Product List must publicly describe certain information about cost structure and included elements of their products, which may be helpful to customers.

Comment: Several commenters recommended that ASTP/ONC take steps to ensure that the information displayed to users in the EHR is accurate and consistent with patient-facing RTBT systems that are available through some plans, as well as cost estimates available to pharmacists working at retail pharmacies. These commenters note that inaccurate information could reduce the utility of this technology and increase burden for clinicians. They recommend that: (1) cost estimates come directly from the payer, rather than from representative data created by third parties that are not connected to payer data and that might include averaged claims data; and (2) EHR vendors create a structure to ensure the accuracy of information.

Response: We agree with the commenters about the importance of prioritizing accuracy of the RTBT information delivered to healthcare providers. We recognize that clinicians have previously expressed concerns about the accuracy of RTBT cost estimates, though we do not have further information about the extent of accuracy issues of RTBT cost estimates. We understand that if clinicians cannot trust this information, then they are less likely to use RTBTs in clinical practice. We will continue to explore these issues in collaboration with CMS, which sets requirements for Part D plan sponsors to implement RTBTs.

Comment: A commenter requested ASTP/ONC establish a standard process for including new criteria in the Base EHR Definition that would progress from modular criterion without inclusion in the Base EHR Definition to addition to Base EHR Definition depending on developers' ability to meet the criterion and market demand. A commenter expressed concern that adding several new items to the Base EHR definition at once may increase the burden on physicians and risk driving consolidation in the EHR market.

Response: ASTP/ONC appreciates this suggestion, however, we note that we did not propose the creation of a standard process for including new criterion in the Base EHR definition in the HTI–2 Proposed Rule and such a process is out of scope for this final rule. We may consider this suggestion as we explore updates to the Base EHR definition in future notice-and-comment rulemaking. We appreciate these concerns regarding the effect of adding items to the Base EHR definition. We agree that it is important to consider factors such as provider burden and impact on the market for health IT products when determining whether to add items to the Base EHR definition. We must balance these considerations with both the need to align the Base EHR definition with the elements of the qualified EHR definition in section 3000 of the PHSA and potential benefits from increasing the availability of certain certified Health IT Modules through additions to the Base EHR definition.

After consideration of public comments, we are finalizing to include the ''real-time prescription benefit'' health IT certification criterion (45 CFR 170.315(b)(4)) in the Base EHR definition in 45 CFR 170.102(3)(iv). We are further finalizing in 45 CFR 170.102(3)(iv) to include the ''real-time prescription benefit'' criterion the Base EHR definition as of January 1, 2028. We are not finalizing our proposal to add the ''electronic prescribing'' criterion (45 CFR 170.315(b)(3)) to the Base EHR definition.

We note that we did not receive any comments on our proposal in 45 CFR 170.550(g)(6) to require that a developer that obtains certification for the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) must also obtain certification for the proposed ''real-time prescription benefit'' criterion in 45 CFR 170.315(b)(4), and we are finalizing as proposed.

(c) Real-Time Prescription Benefit Standard

In the HTI–2 Proposed Rule we proposed in 45 CFR 170.315(b)(4)(i) that a Health IT Module certified to the ''real-time prescription benefit'' certification criterion must enable a user to perform certain real-time prescription benefit electronic transactions in accordance with at least one of the versions of the standard adopted in 45 CFR 170.205(c). Under this paragraph, ONC adopted the NCPDP RTPB standard version 13 [440] on behalf of HHS in 45 CFR 170.205(c)(1) in the Part D and Health IT Standards Final Rule, which appeared in the **Federal Register** on June 17, 2024 (89 FR 51238 through 51265). We stated in the HTI–2 Proposed Rule (89 FR 63532) that if we adopt subsequent versions of the NCPDP RTPB standard in 45 CFR 170.205(c), we believe our proposal to require the use of at least one of the versions of the standard adopted in 45 CFR 170.205(c) would enable health IT developers to use any version of the standard adopted under this paragraph, unless we specify an adoption ''expiration'' date which indicates a certain version of the standard may no longer be used after that date.

The NCPDP RTPB standard version 13 enables the exchange of patient eligibility, product coverage, and benefit financials for a chosen product and pharmacy, and identifies coverage restrictions and alternatives when they exist. The benefits of the more recent NCPDP RTPB standard version 13 relative to NCPDP RTPB standard version 12 include improvements to the NCPDP RTPB Patient Segment, Product and Alternative Product Segments, and new elements, new values, and updated values to the schema, as well as administrative corrections that support consistency and clarity.

Because the NCPDP RTPB standard is relatively new and not yet widely implemented, we stated that we expect additional enhancements and improvements to the standard over time as more health IT developers adopt and implement the standard and more

[440] *See https://standards.ncpdp.org/Access-to-Standards.aspx.*

exchange partners engage in the standards development process with NCPDP. We also stated that we encourage developers to remain familiar with updates occurring in newer versions of the NCPDP RTPB standard.

The following is a summary of the comments we received and our responses:

Comment: Many commenters supported our proposal to require use of the NCPDP RTPB standard version 13 for certification to the ''real-time prescription benefit'' certification criterion. Commenters believed that adoption of the standard would lead to wider adoption and increased utilization of RTBTs.

Response: ASTP/ONC thanks the commenters for their support.

Comment: A commenter encouraged ASTP/ONC to monitor for developments in the RTPB standard and explore requiring the most up-to-date and relevant features when available.

Response: ASTP/ONC recognizes the importance of implementers' ability to utilize improved versions of the standards we require for use in the Certification Program. We also understand that the regulatory process can be lengthy and may delay the adoption of updated standards requirements in a timely fashion. We continue to monitor updates to standards including the NCPDP RTPB standard, as well as receiving input from the public and through bodies such as the Health IT Standards Advisory Committee on updated versions of standards recommended for adoption in regulation. We also note that we have implemented measures under the Certification Program providing added flexibility for implementers, such as the Standards Version Advancement Process (SVAP). SVAP permits health IT developers to voluntarily update health IT products certified under the Certification Program to newer versions of adopted standards as part of real world testing Condition and Maintenance of Certification requirements under the Certification Program in 45 CFR 170.405.

Comment: A commenter expressed concerns regarding the applicability of NCPDP RTPB standard version 13 in long-term care settings.

Response: We note the commenter's concerns and will work with interested parties to ensure that standards continue to evolve to support all care settings, including long-term care and post-acute care facilities.

After consideration of public comments, we are finalizing our proposal in 45 CFR 170.315(b)(4)(i) to require that a Health IT Module certified to the ''real-time prescription benefit'' certification criterion enable a user to perform specified transactions in accordance with at least one of the versions of the standards adopted in 45 CFR 170.205(c) (where we adopted NCPDP RTPB standard version 13). We clarify that under the final version of the criterion, only a version of the standard in 45 CFR 170.205(c) that is not expired would be allowed for the conformance with the certification criterion.

(d) Sending and Receiving Real-Time Prescription Benefit Information

In order to execute real-time prescription benefit checks in accordance with the NCPDP RTPB standard version 13, a provider originates the request for prescription benefit information for a specific patient from within their health IT. In return, a processor, pharmacy benefit manager, or adjudicator provides the appropriate response. In the HTI–2 Proposed Rule (89 FR 63532), we proposed in 45 CFR 170.315(b)(4)(i) that a Health IT Module certified to the ''real-time prescription benefit'' criterion must enable a user to perform specified transactions in accordance with at least one of the versions of the standard adopted in 45 CFR 170.205(c) (where we adopted NCPDP RTPB standard version 13), as well as one of the versions of the standard in 45 CFR 170.207(d)(1) (where we adopted RxNorm) and the standard in 45 CFR 170.207(d)(2) (where we have cross-referenced National Drug Codes (NDC)).

We proposed in 45 CFR 170.315(b)(4)(i)(A) that a Health IT Module certified to the proposed criterion must enable a user to request patient-specific prescription benefit information, estimated cost information, and therapeutic alternatives, in accordance with the RTPBRequest transaction. We proposed in 45 CFR 170.315(b)(4)(i)(B) that a Health IT Module certified to the proposed criterion must enable a user to receive patient-specific prescription benefit information, estimated cost information, and therapeutic alternatives in response to a request, in accordance with the RTPBResponse transaction. RTPBRequest and RTPBResponse transactions are determined by patient, benefit, and product-specific information. Each request and response are unique with information conditioned on factors associated with each transaction. We noted that Health IT Modules certified to the proposed certification criterion should support transaction segments and associated data elements necessary to reflect both the information needed for a successful RTPBRequest and the information contained in a detailed RTPBResponse. As such, a Health IT Module must have the capability to send and receive both mandatory and situational transaction segments and associated data elements for RTPBRequests and RTPBResponse transactions as specified in NCPDP RTPB standard version 13. Finally, we proposed in 45 CFR 170.315(b)(4)(i)(C) that a Health IT Module certified to the proposed criterion must enable a user to be notified of errors when there is a problem with a real-time prescription benefit transaction, in accordance with the RTPBError transaction.

We requested comments on these proposals and whether we should consider other capabilities for the certification criterion in the future. The following is a summary of the comments we received and our responses:

Comment: A commenter noted the limitations of RxNorm and cautioned against its use. The commenter cautioned that using RxNorm may lead to inaccuracies in formulary and benefit information presented by RTBTs, because (1) some medications that are actively in the pharmacy supply chain are erroneously listed as ''archived'' (that is, no longer in supply) in the RxNorm lexicon and so may be listed as not covered by the RTBT; (2) it is not clear how frequently the RxNorm lexicon is updated when new medications enter the market; and (3) conversion between other medication lexicons used by insurers and pharmacies (for example, RxCUI and NDC) is imperfect. For example, the commenter noted that if an insurer uses RxCUI to place medication A in tier 1 and medication B in tier 2, an imperfect conversion may lead an RTBT to list both medication A and medication B in tier 1. The commenter cautioned that these problems may create inaccuracies in cost estimations, data quality checks, and formulary lookup databases. The commenter suggested more extensive testing of RxNorm lexicon conversions to ensure that they are accurate.

Response: ASTP/ONC appreciates the inputs provided regarding the challenges associated with the use of RxNorm. We recognize that instances may occur where RTBTs present inaccurate cost estimates or coverage information due to these issues and that such occurrences could lead to discouraging experiences. We encourage further testing of the accuracy of the RxNorm lexicon as well as the NDC-RxCUI conversion and may explore ways to advance further progress in this area. Despite these issues, these standards are necessary components of the ''real-time prescription benefit''

criterion and are widely adopted across the health IT industry. For example, RxNorm codes are used by Health IT Modules certified to the ''electronic prescribing'' criterion at 45 CFR 170.315(b)(3), and are deployed across the majority of hospitals and office physicians in the US.

Comment: A commenter requested clarification on whether the ''estimate cost information'' referenced in 45 CFR 170.315(b)(4)(i)(A) and (i)(B) pertains to patient out-of-pocket costs, overall plan costs, or both.

Response: The estimated cost information referred to in the proposed language related to the RTPBRequest and RTPBResponse transactions only pertains to patient out-of-pocket costs. Prescribers using RTBTs that use NCPDP RTPB standard version 13 also have the capability to request and receive information on overall costs (field names are ''estimated net plan cost'' and ''estimated combined plan and patient savings'') but only when allowed and provided by the plan.

Comment: A commenter discussed the term ''therapeutic alternative'' used in the proposed language in 45 CFR 170.315(b)(4)(i)(A), (i)(B), and (ii). The commenter requested this term be expanded or a definition added clarifying that it is inclusive of ''clinically equivalent therapeutic alternatives.'' The commenter stated that it was important to convey that ''therapeutic alternatives'' should not only be similar in terms of therapeutic effects, but also considered interchangeable based on clinical guidelines and patient needs.

Response: We respectfully disagree with the recommendation to clarify that the term ''therapeutic alternative'' is inclusive of the term ''clinically equivalent therapeutic alternative.'' Therapeutic alternatives are suggested based on the rules outlined by a PBM, responding organization, or their third-party drug compendia. Therefore, a medication identified as a therapeutic alternative may produce a similar therapeutic response, but not be equivalent based on pharmaceutical active ingredient, dosage form, route of administration or safety profiles.

We further note that the NCPDP RTPB standard version 13 uses the terminology ''alternative product,'' which is more inclusive of medications and other products. We believe that using this term, instead of the proposed term ''therapeutic alternative.'' In order to provide additional consistency between our regulation text and the language used in the NCPDP RTPB standard we are finalizing a modification of the term ''therapeutic alternative'' as proposed in 45 CFR 170.315(b)(4)(i)(A) and (B) to ''alternative product.''

Comment: Several commenters noted that the NCPDP RTPB Standard Version 13 does not contain an RTPBError transaction, as referenced in proposed 45 CFR 170.315(b)(4)(i)(C). Instead, the name of the transaction for a plan to notify a prescriber that a system error occurred is ''Error.'' Some commenters also noted that errors are flagged when RTPBResponse is returned as a reject code and recommended not requiring the ''Error'' transaction as part of the certification criterion. A commenter stated that displaying the Error transaction to end-users would be inappropriate since end-users cannot resolve errors and displaying this information could contribute to alert fatigue. The commenter recommended making the error transaction only available to system administrators.

Response: ASTP/ONC appreciates commenters' concerns with our proposal to require a Health IT Module certified to the ''real-time prescription benefit'' criterion enable a user to be notified of errors when there is a problem with a real-time prescription benefit transaction. We also acknowledge that we inadvertently referred to an ''RTPBError'' transaction within NCPDP RTPB standard version 13. We further agree with commenters that it is not necessary to finalize a separate requirement related to this capability within the certification criterion. Health IT developers that implement the transactions in the NCPDP RTPB standard version 13 we have specified would already be implementing the capability to receive a reject code—also called ''Error'' as noted by the commenter—in response to the RTPBRequest transaction as part of fully implementing the requirements in NCPDP RTPB standard version 13. We also agree with commenters that it would be more appropriate for health IT developers to determine how errors are received or presented by a Health IT Module, which will allow developers to determine what is most useful for their customers.

Comment: A commenter disagreed with the statement in the proposed rule that a Health IT Module be capable of sending and receiving all situational segments and data elements specified in NCPDP RTPB standard version 13. The commenter noted that the standard states that ''situational or optional fields and segments may be added to or deleted from the transmission as necessary to accommodate changing needs'' and that health IT developers should have flexibility in how, when, and what to display to users based on feedback from those users on what is most valuable.

Response: We thank the commenter for their concerns. In the HTI–2 Proposed Rule, we stated that a Health IT Module must have the capability to send and receive both mandatory and situational transaction segments and associated data elements for RTPBRequest and RTPBResponse transactions (89 FR 63532). This statement was intended to convey that health IT developers must implement products that are able to transmit information in segments with these designations, consistent with the required implementation of NCPDP RTPB standard version 13. The NCPDP RTPB standard provides additional details on which situations require which situational fields for each transaction type. This statement was not intended to require specific expectations related to how, when, or what to display to users. We also note that we did not propose requirements to support optional field segments.

Comment: Commenters provided a number of additional recommendations related to the proposals in this section. Several commenters suggested incorporating standards that would provide clinicians and patients with information on availability of ordered medications at the selected pharmacy (that is, on their formulary, in stock, time to delivery or pick-up) to prevent delays in access to medications. Other commenters suggested considering additional standards that would facilitate visibility into potential cost savings attributable to drug discount programs. Several commenters requested consideration of real-time price transparency capabilities for other types of care in the future, including medications covered under the medical benefit. Finally, a commenter recommended making data from real-time benefit transactions accessible to third party clinical decision support tools that could then configure their medication recommendations to take cost and coverage into account or eventually integrate such information and display it alongside a clinical decision support recommendation. Another commenter requested that ASTP/ONC implement protections to prevent the use of data submitted or received as part of real-time prescription benefit activities for purposes besides electronic prescribing or to monetize the data.

Response: ASTP/ONC thanks commenters for their additional recommendations to improve RTBT functionality. Regarding availability of

ordered medications at the selected pharmacy, we note that standards development organizations are currently pursuing activities in this area and invite commenters to learn more about these initiatives. Regarding incorporation of out-of-pocket cost information related to drug discount programs, we agree incorporation of this information could provide additional price transparency and additional opportunities for cost savings for patients. We will continue to monitor developments to support queries to all drug discount programs. Regarding transparency for medications under a medical benefit, we note that while prescription medications are often one of the most expensive aspects of patient care, patients could also benefit from access to easily accessible, real-time cost estimates for other aspects of their care (for example, procedures, imaging, laboratory tests, and medications covered under Part B) and we will work with partners across HHS on efforts to address these capabilities through future rulemaking and other initiatives. Finally, we appreciate the comments about the benefits of making RTBT data accessible to third-party clinical decision support tools. The recommendations made by RTBTs for lower-cost alternatives are currently based on insurer formularies and preferred pharmacies, without accounting for other clinically important information. For example, if a clinician prescribes an antidepressant that is not preferred on a patient's insurance formulary, the RTBT's recommendations for alternatives in the same therapeutic class will not account for medications that the patient has previously tried and failed, or the possibility of interactions with other medications the patient is currently prescribed. We appreciate commenters' concerns about data privacy and will continue to closely monitor public feedback and developments in data privacy in collaboration with other HHS partners, including OCR.

Comment: A commenter requested that ASTP/ONC clarify expectations for the amount of time it should take for queried information to be returned.

Response: Given the time pressures on clinicians, we agree that it is important for queried information to be returned promptly. The amount of time it takes for queried information to be returned may be based on a number of factors, including the systems of the Part D sponsor, PBM, or other third-party vendor providing the information, as well as local broadband capabilities. We recognize that health IT developers have limited ability to control these factors as part of certified Health IT Modules, but we encourage developers to consider features that can mitigate the impact of variable response times on users' experience.

Comment: A commenter expressed concern that one potential unintended consequence of out-of-pocket cost availability is that clinicians and patients will engage in excessive cost-based scrutiny of clinically appropriate treatment.

Response: We understand that a potential impact of price transparency policy is that patients will engage in cost-based scrutiny. We note, however, that there is robust evidence that patients frequently use cost-based scrutiny outside of the clinic already. For example, a fifth of patients forgo prescribed medications due to cost and do so at high cost to their health.[441] [442] Patients generally make decisions about which medications to forgo when they are at the pharmacy, without input from their physician. We believe the availability of real-time prescription benefit information provides patients and clinicians with the opportunity to engage in more appropriate cost-based scrutiny. By discussing both financial and clinical tradeoffs at the time of the clinic visit, clinicians can help patients find the treatment that is both most clinically appropriate for the patient and financially affordable. These interactions can also help clinicians to ensure that they fully understand a patient's circumstances when using real-time prescription benefit information to inform recommendations to the patient.

After consideration of public comments, we are finalizing our proposed requirements in 45 CFR 170.315(b)(4)(i)(A)–(B) with modifications. Specifically, we are finalizing a modification of the term ''therapeutic alternative'' as proposed in 45 CFR 170.315(b)(4)(i)(A), (i)(B), 45 CFR 170.315(b)(4)(ii) to ''alternative product.'' We are not finalizing our proposal at 45 CFR 170.315(b)(4)(i)(C) that a Health IT Module certified to the proposed criterion must enable a user to be notified of errors when there is a problem with a real-time prescription benefit transaction, in accordance with the ''RTPBError transaction'' referred to in the proposed rule.

[441] Dusetzina, Stacie B., et al. ''Cost-related medication nonadherence and desire for medication cost information among adults aged 65 years and older in the US in 2022.'' *JAMA Network Open* 6.5 (2023): e2314211–e2314211.

[442] Nekui, Farrah, et al. ''Cost-related medication nonadherence and its risk factors among Medicare beneficiaries.'' Medical care 59.1 (2021): 13–21.

(i) Use of XML Format

We proposed in 45 CFR 170.315(b)(4)(i) that a Health IT module certified to the criterion must enable a user to perform the specified transactions using the XML format. While the NCPDP RTPB standard version 13 supports both EDI and XML formats, in response to the RFI included in the HTI–1 Proposed Rule (88 FR 23746), we received many comments in support of testing the XML format of the RTPB standard alone or with the EDI format as optional. Additionally, commenters recommended that ONC should test the format each individual health IT developer has chosen for its own system to be tested in. Some commenters also shared a desire to move away from XML and EDI altogether, preferring the JSON format instead, noting industry plans for the future retirement of XML and EDI. A commenter suggested certification in either format, with requirements that health IT be capable of demonstrating translation capabilities between EDI and XML. We stated in the HTI–2 Proposed Rule (89 FR 63532) that we believe that proposing to only require use of the XML format will simplify testing for health IT developers. We noted that ONC will continue to monitor syntax and format updates and development for real-time benefit transactions and associated standards.

The following is a summary of the comments we received and our responses:

Comment: Several commenters supported the proposal that a Health IT module certified to the ''real-time prescription benefit'' criterion must enable a user to perform the specified transactions using the XML format, arguing that this would simplify testing for health IT developers, increase standardization, and enhance interoperability. Commenters recommended that ASTP/ONC monitor developments in this area since NCPDP is in the process of transitioning its standards to JSON, which may present enhanced interoperability capabilities in the future. A commenter recommended offering the flexibility to choose between XML and JSON, arguing that allowing for either option would accommodate a broader range of use cases and preferences among developers and organizations, would promote innovation, and would ensure that systems are more adaptable to varying technical environments.

Response: We thank the commenters for their support of the proposal to require a Health IT Module certified to the ''real-time prescription benefit''

criterion to enable users to perform specified transactions using the XML format and agree that this is the most appropriate format for inclusion as part of the ''real-time prescription benefit'' criterion. We appreciate the comments regarding the use of JSON; however, NCPDP RTPB standard version 13 does not currently support JSON. We will consider requiring support for the JSON format in future rulemaking as it is incorporated into future versions of the NCPDP RTPB standard. As discussed in the proposed rule, NCDP's RTPB Standard Version 13 supports only XML and EDI formats (89 FR 63532). We did not propose to require support for EDI because it is an older format that is being used with less frequency by developers.

After consideration of public comments, we are finalizing our proposal in 45 CFR 170.315(b)(4)(i) to require that a Health IT Module certified to the ''real-time prescription benefit'' criterion must enable users to perform the specified transactions using the XML format.

(e) Additional Topics

(i) Display

We proposed in 45 CFR 170.315(b)(4)(ii) that a Health IT Module certified to the criterion must display to a user in human readable format patient-specific prescription benefit information, estimated cost information, and therapeutic alternatives in accordance with at least one of the versions of the standard in 45 CFR 170.205(c) (where we adopted NCPDP RTPB standard version 13). We noted that the ability to display RTPB data provides access to this information and is essential for a user to be able to use the information to inform shared decision-making as the provider and patient determine the treatment that will be best for them.

Comment: A commenter supported the proposal that a Health IT Module certified to the ''real-time prescription benefit'' criterion must display to a user in human readable format patient-specific prescription benefit information, estimated cost information, and therapeutic alternatives. A commenter noted that lack of usability of real-time benefit information particularly impacts patients who are dually insured.

Response: We thank the commenters for their support. We encourage health IT developers to continue to improve the usability of how real-time benefit information is displayed to end users, including for patients with more complex coverage.

After consideration of public comments, we are finalizing our proposal in 45 CFR 170.315(b)(4)(ii) regarding the display of benefit information in a human readable format with modification. We are changing the term ''therapeutic alternative,'' which was used in proposed in 45 CFR 170.315(b)(4)(ii), to ''alternative products'' for consistency with the revisions to similar proposed language that we are finalizing in 45 CFR 170.315(b)(4)(i)(A)–(B). We describe the reasons for revising this term in section XI.*B*.4.b.(4)(d). of this final rule.

(ii) Scope

The NCPDP RTPB standard version 13 supports real-time prescription benefit requests and responses for a variety of items manufactured for sale such as medications, vaccines, and medical devices or supplies.[443] While the majority of products covered by an individual's pharmacy benefit will be medications, Part D drugs, as defined at 42 CFR 423.100, can include prescription medications, vaccines, and supplies associated with the injection of insulin (for example, syringes, alcohol pads, gauze), and are represented by RXCUIs [444] on the formulary file.

In the HTI–1 Proposed Rule we requested comment on the appropriate scope for a ''real-time prescription benefit'' certification criterion, including whether a ''real-time prescription benefit'' certification criterion should require support for products that are not defined as medications but may also be included in a RTPB transaction, namely vaccines and medical devices or supplies (87 FR 23853). We received several comments in response to our request for information on this topic, with several commenters encouraging an initial focus on medications for the certification criterion.

In the HTI–2 Proposed Rule (89 FR 63533), we stated that, in addition to medications, we believe it is important to require Health IT Modules certified to the ''real-time prescription benefit'' criterion to be able to support vaccines, and note that under Part D regulations and guidance, plans include most commercially available vaccines on their formularies.[445] However, we stated that we are not proposing to include devices and supplies in the proposed certification criterion at this time. We noted that the NCPDP RTPB standard version 13 does yet not support the FDA Unique Device Identification System unique device identifiers (UDIs), which are identified as the standard for the Unique Device Identifier—Implantable data element in the Medical Devices data class in the USCDI.[446] Additionally, we noted that devices covered under a pharmacy benefit may be defined as a drug under Section 201(g) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(g)) rather than a device under Section 201(h) and therefore are not assigned a Unique Device Identifier for Implantable Devices. We stated that ONC will continue to monitor advancements to the NCPDP RTPB standard to support unique identifiers for devices, any related developments at the FDA, and updates to the standardization and exchange of device and supplies data.

In summary, we proposed in 45 CFR 170.315(b)(4)(iii) that the scope of the criterion is limited to medications and vaccines covered by a pharmacy benefit. We invited comments on this proposal.

The following is a summary of the comments we received and our responses:

Comment: Many commenters agreed that vaccines should be included in the scope for the ''real-time prescription benefit'' criterion, as proposed. A commenter believed that vaccine cost estimation capabilities were not necessary, noting that it is atypical for clinicians to write prescriptions for vaccines. A commenter requested clarification on whether providers should be expected to receive a message if a vaccine is not covered.

Response: We recognize that clinicians do not commonly write prescriptions for vaccines. Additionally, the Inflation Reduction Act of 2022 (Pub. L. 117–169) eliminated cost sharing and deductibles for adult vaccines recommended by the Advisory Committee on Immunization Practices (ACIP) covered under Medicare Part D. However, Part D-covered vaccines are included in insurance formularies with other Part D-covered medications. Therefore, we did not propose and are not finalizing to exclude vaccines from the scope of the criterion, even though clinicians may be unlikely to seek out benefit information on vaccines.

[443] *See https://www.ncpdp.org/Access-to-Standards.aspx.*

[444] An RXCUI is a machine-readable code or identifier that points to the common meaning shared by the various source names grouped and assigned to a particular concept. More information can be found at *https://www.nlm.nih.gov/research/umls/rxnorm/overview.html.*

[445] *See* ''Medicare Prescription Drug Benefit Manual: Chapter 6—Part D Drugs and Formulary Requirements'' 30.2.7 at *https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/part-d-benefits-manual-chapter-6.pdf.*

[446] *See* USCDI v4: *https://www.healthit.gov/isa/taxonomy/term/821/uscdi-v4.*

Regarding whether a response is generated in response to a request regarding a vaccine, we note that when a RTPBRequest segment is processed, the RTPBResponse provides information on whether the product is covered, not covered, or covered with restrictions.

Comment: Regarding supplies, several commenters disagreed with the statement in the proposed rule that NCPDP RTPB standard version 13 does not yet support FDA Unique Device Identification System unique device identifiers (UDIs) (89 FR 63533). Commenters stated that the RTPB standard version 13 supports the communication of the mandatory, fixed Device Identifier portion of the UDI as issued by FDA Accredited Issuing Agencies, enabling support for information related to products and services covered under the pharmacy benefit, including medications, vaccines, supplies, devices, and prescription digital therapeutics. A commenter emphasized the importance of providing cost estimates for diabetes supplies, which comprise a substantial proportion of diabetes-related expenses. A few commenters supported limiting the RTPB scope to just medications and supplies.

Response: We appreciate the feedback from commenters. We agree with commenters that the NCPDP RTPB standard version 13 supports the exchange of information using the FDA UDI system. We also agree that there are important applications for real-time benefit services for supplies, which can be an important source of out-of-pocket costs for patients, such as the diabetes supplies noted by a commenter. Being able to understand costs for supplies has the potential to improve patients' financial security and access.

After consideration of the public comments, we are not finalizing the proposed language at 45 CFR 170.315(b)(4)(iii) specifying a scope for the ''real-time prescription benefit'' certification criterion as we believe that it is unnecessary to limit the scope of the criterion. In the absence of this limitation, we expect that Health IT Modules certified to the ''real-time prescription benefit'' criterion will enable the exchange of information for any product and service covered under a pharmacy benefit consistent with the specifications in the NCPDP RTPB standard version 13.

(iii) Formulary and Benefit

In the HTI–1 Proposed Rule, we requested comment on whether we should further explore capabilities for Health IT Modules to support access to formulary and benefits information and provided detail about how access to formulary and benefits information was previously supported within the Certification Program. We noted that in the 2015 Edition Final Rule, ONC included a ''Drug-formulary and preferred drug list checks'' certification criterion in 45 CFR 170.315(a)(10). However, ONC did not adopt the proposed NCPDP Formulary and Benefit standard version 3.0 to support this criterion due to comments received in response to the 2015 Edition Proposed Rule (80 FR 16821). The drug formulary and preferred drug list checks 45 CFR 170.315(a)(10) certification criterion was later removed from the Certification Program in the ONC Cures Act Final Rule (85 FR 25660) because this functionality was widely available, and there was not sufficient reason to justify the burden on developers and providers of meeting Certification Program compliance requirements specific to this criterion. We noted that updates, enhancements, and corrections have been made to the NCPDP Formulary and Benefit standard since we considered adopting version 3.0, and many of these updates addressed concerns commenters expressed previously (87 FR 23854).

Subsequently, in the Part D and Health IT Standards Final Rule, we finalized adoption of NCPDP Formulary and Benefit standard version 60 in 45 CFR 170.205(u) (89 FR 51260), reflecting an aligned approach with the Part D Program to adoption of standards that support electronic prescribing. In the same rulemaking, CMS finalized, in 42 CFR 423.160(b)(3), a cross-reference to a standard in 45 CFR 170.205(u), which includes NCPDP Formulary and Benefit standard version 60, as part of the requirements for transmitting formulary and benefit information between prescribers and Part D sponsors (89 FR 51250 through 51251). However, we did not make any updates to the Certification Program to incorporate the proposed Formulary and Benefit standard as part of certification criteria.

In response to our request for comment in the HTI–1 Proposed Rule, some commenters supported incorporation of capabilities to access formulary and benefits information within the Certification Program based on the NCPDP Formulary and Benefit standard. However, many stated that a certification criterion based on the standard is not necessary as this functionality is already widespread in the industry due to existing CMS regulatory requirements. Furthermore, these commenters stated that a criterion based on the NCPDP Formulary and Benefit standard may limit innovation around other approaches to obtaining formulary and benefit information currently being explored by the industry.

In the HTI–2 Proposed Rule (89 FR 63533), we stated we considered the comments received in response to the RFI and have determined not to propose new functionality related to formulary and benefits information within the Certification Program at this time. We also noted that we proposed to adopt the HL7 FHIR Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2, in 45 CFR 170.215(m)(i) in the HTI–2 Proposed Rule. In this final rule, we are finalizing adoption of this IG in 45 CFR 170.215(m)(i). Use of the PDex Drug Formulary IG supports the availability of a payer's drug formulary via a FHIR interface, providing an alternative pathway for making this information available for those payers that have not implemented the NCPDP Formulary and Benefit standard.

The following is a summary of the comments we received and our responses:

Comment: Several commenters noted the importance of providing formulary and benefit information to clinicians to aid in decision making, reduce delays in care, and reduce administrative burden. A commenter requested that ASTP/ONC work to ensure accuracy of formularies and identified several concerns related to formulary accuracy. They further recommended steps to improve formulary accuracy, including standardizing and harmonizing search scopes across formularies, ensuring availability and interoperability of additional information that may be contained in formularies, and requiring the use of and dissemination of a standardized public identifier for each distinct formulary an insurer maintains.

Response: We thank commenters for their feedback. While we did not make any proposals related to formulary information in the proposed rule, we will continue to work with CMS and other HHS partners on issues around improving formulary accuracy. We acknowledge that for RTBTs to be valuable and trustworthy, the cost and coverage information they present must be accurate. Part D plan sponsors should ensure that formulary files are updated in a timely manner, so that when RTPB transactions are sent, they return accurate coverage information.

We did not make and are not finalizing any proposals related to formulary and benefits.

(iv) Negotiated Price

Section 1860D–4(o)(2)(B)(ii) of the Act, as added by section 119(a) of the CAA, 2021, specifically requires real-time benefit tools capable of providing information on ''cost-sharing information and the negotiated price'' for drugs and alternatives. In the HTI–2 Proposed Rule (89 FR 63533), we noted that we have not proposed to include negotiated price in the proposed 45 CFR 170.315(b)(4) certification criterion. We stated the NCPDP RTPB standard version 13 does not include fields to support the exchange of negotiated price. We solicited comments regarding negotiated price in response to the RFI, and commenters expressed strong disapproval for the inclusion of negotiated price in RTBTs. Additionally, we noted concerns were shared that plan negotiated prices may be confusing to providers and patients and are not likely to assist or improve the utility or usability of technology certified to a real-time prescription benefit certification criterion. We also noted that the exchange of negotiated price by Part D sponsors when implementing an electronic real-time benefit tool is not currently supported by the NCPDP RTPB standard version 13. NCPDP RTPB standard version 13, which we proposed to incorporate into the proposed ''real-time prescription benefit'' certification criterion, is the best available standard for use currently to provide patient specific cost-sharing information. Unfortunately, we have not identified a standard or any consistent approach to deliver reliable negotiated price information in real-time. We stated that ONC will continue to work with CMS and other interested parties to determine how negotiated price information may be made available and what technical approaches exist to support transparency in negotiated prices of drugs.

The following is a summary of the comments we received and our responses:

Comment: A commenter noted that NCPDP RTPB Standard Version 13 does not currently contain negotiated price fields. Several commenters expressed disappointment that the standard does not include negotiated price, and that including negotiated price would enhance transparency and ensure that all stakeholders have a clear understanding of the financial implications of medical decisions.

Response: In prior rulemaking, some commenters have requested a display of full negotiated price, while others have expressed concerns that disclosing negotiated prices would have anticompetitive effects (89 FR 51249). We appreciate the interest in this information and acknowledge the requirement in section 119(b) of Subtitle B of Title I of Division CC of the CAA, 2021 that a qualified electronic health record (as defined in in section 3000(13) of the Public Health Service Act) include an RTBT capable of transmitting cost sharing information and the negotiated price of a drug and its formulary alternatives, among other requirements. As noted in the HTI–2 Proposed Rule, at this time, NCPDP RTPB standard version 13, which we have incorporated in the ''real-time prescription benefit'' criterion, lacks fields that support the exchange of negotiated prices, but it is the best available standard and otherwise meets the statutory requirements for RTBTs (89 FR 63533 through 63534). CMS and ASTP/ONC will continue to work with other interested parties to determine how and at what time negotiated price information may be made available in RTBTs and certified Health IT Modules supporting access to real-time benefit information.

We did not make and are not finalizing any proposals related to negotiated price.

In summary, after consideration of the public comments, we are finalizing adoption of the proposed ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) with the following modifications:

- We are replacing the term ''therapeutic alternatives'' in 45 CFR 170.315(b)(4)(i)(A), (i)(B), and (ii) with the term ''alternative products.''
- We are clarifying that a Health IT Module must enable a user to conduct transactions in accordance with one of the versions of RxNorm ''at a minimum'' to ensure alignment with the existing minimum standards code set policy in the Certification Program in 45 CFR 170.555.
- We are not finalizing the proposed requirement 45 CFR 170.315(b)(4)(i)(C) that a Health IT Module enable a user to be notified of errors when there is a problem with a real-time prescription benefit transaction.
- We are not finalizing the provision at 45 CFR 170.315(b)(4)(iii) to limit the scope of the criterion to medications and vaccines covered by a pharmacy benefit.

(5) New Certification Criteria for Modular API Capabilities

(a) Background

In the HTI–2 Proposed Rule, we proposed to add a new paragraph (j) to 45 CFR 170.315 titled ''modular API capabilities.'' We stated that this new certification criteria category would promote the Certification Program's modular certification approach and, importantly, would enable different combinations of capabilities across Health IT Modules depending on future use case needs. We noted in the HTI–2 Proposed Rule (89 FR 63567) that, in general, we expect the capabilities in 45 CFR 170.315(j) to be standards-based and include a combination of new and existing standards, many of which are currently referenced in 45 CFR 170.315(g)(10). Additionally, we stated we anticipate that the proposed capabilities in 45 CFR 170.315(j) would enable the Certification Program to better support a growing number of clinical, public health, and administrative use cases over the long-term, as well as foster innovation and competition in these spaces by providing flexibility for modular development approaches among developers of certified health IT.

We discussed in the HTI–2 Proposed Rule (89 FR 63567) that since 2020, the standards development community has undertaken work to: (1) update existing standards and implementation specifications (for example, US Core IG from version 3.1.1 to 7.0.0 [447]); (2) formalize previously functional capabilities as part of implementation specifications (for example, token introspection is now part of SMART App Launch 2.0 [448]); and (3) support new and revised capabilities that are modular and use case agnostic (for example, HL7 CDS Hooks [449], FHIR Subscriptions [450], and UDAP Security FHIR IG [451], among other implementation specifications). These developments have changed the heath IT landscape and helped support a wider range of potential technical solutions for healthcare use cases that previously may not have been supported, or were ineffectively supported, by health IT.

We noted that by using the term ''modular'' we mean certification criteria in the Certification Program that are scoped to limited capabilities to enable health IT developers to certify to the specific certification criteria that apply to Health IT Modules they wish to certify, rather than large, multi-functionality, and all-encompassing certification criteria that would give

[447] *https://hl7.org/fhir/us/core/history.html.*

[448] *https://hl7.org/fhir/smart-app-launch/STU2/token-introspection.html.*

[449] *https://cds-hooks.hl7.org/.*

[450] *https://hl7.org/fhir/uv/subscriptions-backport/STU1.1/.*

[451] *https://build.fhir.org/ig/HL7/fhir-udap-security-ig/branches/main/index.html.*

developers less flexibility for certifying in the Certification Program.

Based on our analysis of the continued evolution of standards and the real-world implementation scenarios for certified health IT to enable FHIR-based APIs, we proposed in the HTI–2 Proposed Rule (89 FR 63568) to adopt new certification criteria as modular API capabilities proposed as certification criteria in 45 CFR 170.315(j).

Under the narrow focus for this final rule, we are only finalizing two criteria proposed in 45 CFR 170.315(j) that we proposed to reference within the proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34). Specifically, we are finalizing the ''workflow triggers for decision support interventions—clients'' criterion that supports workflow triggers for decision support interventions client capabilities in 45 CFR 170.315(j)(20), and the ''subscriptions—client'' criterion that supports subscriptions client capabilities in 45 CFR 170.315(j)(21) (proposed in 45 CFR 170.315(j)(24)). At this time, we are not finalizing any of the other certification criteria we proposed in 45 CFR 170.315(j). However, we may consider finalizing these criteria in future notice-and-comment rulemaking.

(b) Modular API Capabilities Certification Criteria

(i) Workflow Triggers for Decision Support Interventions—Client

In the HTI–2 Proposed Rule, we proposed to adopt the CDS Hooks Release 2.0 implementation specification (CDS Hooks IG) in 45 CFR 170.215(f)(1) to support the Certification Program requirements for the proposed certification criterion in 45 CFR 170.315(j)(20), which establishes requirements for ''clients'' participating in API-based workflow triggers for decision support (89 FR 63570).

CDS Hooks is a specification that describes a ''hook''-based pattern for invoking or triggering decision support from within a clinician's workflow (typically the ''client'' side of this pattern). We described that this pattern facilitates a clinician's ability to either pull in results from decision support directly into a clinician's workflow or can be used to launch an interactive application (89 FR 63571).

We proposed that a Health IT Module presented for certification to 45 CFR 170.315(j)(20) support the requirements of the implementation specification in 45 CFR 170.215(f)(1) (where we proposed to adopt CDS Hooks Release 2.0) as a ''CDS Client,'' including support for the registration of ''CDS Services'' according to the implementation specification in 45 CFR 170.215(f)(1), in 45 CFR 170.315(j)(20)(i), and support for authentication and authorization [452] according to the implementation specification in 45 CFR 170.215(f)(1), in 45 CFR 170.315(j)(20)(ii) (89 FR 63570).

We also proposed in 45 CFR 170.315(j)(20)(iii) that Health IT Modules certified to 45 CFR 170.315(j)(20) support the execution of decision support workflow triggers in accordance with the implementation specification in 45 CFR 170.215(f)(1), as well as demonstrate the ability to send a decision support request to a CDS Service according to the implementation specification in 45 CFR 170.215(f)(1), in 45 CFR 170.315(j)(20)(iv) (89 FR 63570).

As part of the capability to send a decision support request to a CDS Service, we proposed in 45 CFR 170.315(j)(20)(iv)(A) that a Health IT Module support the ability to deliver a CDS Hook request with pre-fetched information according to the ''Pre-fetch Template'' section of the implementation specification in 45 CFR 170.215(f)(1). We also proposed that the Health IT Module support access to HL7 FHIR Resources via a RESTful API to support decision support intervention workflows according to the ''FHIR Resource Access'' section of the implementation specification in 45 CFR 170.215(f)(1), in 45 CFR 170.315(j)(20)(iv)(B). Finally, we proposed that a Health IT module support the receipt of a decision support response according to the implementation specification in 45 CFR 170.215(f)(1), in 45 CFR 170.315(j)(20)(iv)(C), including support for the display of the contents of a decision support response to an end-user and support for the ability to launch internal apps and SMART apps from decision support responses according to the implementation specification in 45 CFR 170.215(f), including support for the ''Link'' field ''appContext,'' in 45 CFR 170.315(j)(20)(iv)(C)(*1*) and 45 CFR 170.315(j)(20)(iv)(C)(*2*), respectively.

In the HTI–2 Proposed Rule, we noted that the proposed workflow triggers criterion in 45 CFR 170.315(j)(20) did not define or propose specific workflows associated with decision support, including how and when clinicians use decision support capabilities (89 FR 63571). Rather, we proposed to include standards-based interfaces in 45 CFR 170.315(j)(20) to enable clinical systems to call other systems offering decision support services in a standardized manner to support the exchange and use of these services.[453] [454] [455]

We requested comment on these proposals. The following is a summary of the comments received on the HTI–2 Proposed Rule and our responses:

Comment: Several commenters supported our proposal to adopt the ''workflow triggers for decision support interventions—client'' certification criterion at 45 CFR 170.315(j)(20) to enable clinical systems to call other systems offering decision support services in a standardized manner, leveraging the CDS Hooks standard proposed for adoption at 45 CFR 170.215(f)(1). Many commenters supported our proposed requirements to reference the ''workflow triggers for decision support interventions—client'' criterion in the proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34) to facilitate prior authorization workflows. Other commenters highlighted broader benefits of CDS Hooks to support adherence to clinical guidelines, reduce medical errors, and support real-time notifications for patient visits.

Response: We thank commenters for their support.

Comment: Several commenters offered recommendations on whether and which ''hooks'' the Certification Program should require Health IT Modules to support in the ''workflow triggers for decision support interventions—client'' criterion. Many commenters supported the number and types of hooks we proposed to be supported by Health IT Modules in the Certification Program. Other commenters recommended we finalize support for fewer hooks and that we finalize a policy of flexibility that would enable developers of certified health IT

[452] CDS Hooks Release 2.0 includes authentication and authorization of endpoints and identity of the CDS Client. We direct readers to the implementation specification for more detail.

[453] Bradshaw, R.L., Kawamoto, K., Kaphingst, K.A., Kohlmann, W.K., Hess, R., Flynn, M. C., . . . Del Fiol, G. (2022). GARDE: a standards-based clinical decision support platform for identifying population health management cohorts. *Journal of the American Medical Informatics Association: JAMIA, 29*(5), 928–936. doi:10.1093/jamia/ocac028.

[454] Morgan, K.L., Kukhareva, P., Warner, P.B., Wilkof, J., Snyder, M., Horton, D., . . . Kawamoto, K. (2022). Using CDS Hooks to increase SMART on FHIR app utilization: a cluster-randomized trial. *Journal of the American Medical Informatics Association: JAMIA, 29*(9), 1461–1470. doi:10.1093/jamia/ocac085.

[455] Watkins, M., & Eilbeck, K. (2020). FHIR Lab Reports: using SMART on FHIR and CDS Hooks to increase the clinical utility of pharmacogenomic laboratory test results. *AMIA Summits on Translational Science proceedings, 2020,* 683–692.

to support at least one hook based on what will provide the most value for their particular customer base. Some commenters recommended the Certification Program require Health IT Modules to support ''order-select'' as a required hook for initial implementation to support earlier decision support in workflows and reduce interruptions. Other commenters suggested the Certification Program also require support for the ''order-sign,'' ''patient-view,'' and ''appointment book'' hooks. One of these commenters additionally recommended that the Certification Program add required support for the ''suggestions'' and ''feedback'' capabilities of the CDS Hooks standard. Still other commenters supported the adoption of specified hooks only when an IG exists to support a specific use case, noting that any hook will need to be use case-specific in order to provide industry value.

Response: We thank commenters for their input regarding whether and which hooks to require support for across the Certification Program. We note that within our proposals for the certification criterion in 45 CFR 170.315(j)(20) we did not specify which hooks Health IT Modules would be required to support. Rather, we specified hooks within proposed criteria referencing 45 CFR 170.315(j)(20), including the proposed ''prior authorization API—provider'' certification criterion, at 45 CFR 170.315(g)(34)(i)(B). As described in the ''Coverage Requirements Discovery'' section IX.*B*.4.b.(6) of this final rule we are finalizing one required hook (the ''order-sign'' hook) as part of ''provider prior authorization API—coverage requirements discovery'' criterion at 45 CFR 170.315(g)(31)(i)(B). We are not finalizing any specific hooks in 45 CFR 170.315(j)(20). We understand commenters' concerns regarding the scope of requirements for this new specification and, consistent with these concerns, we are finalizing only one required hook in the Certification Program at this time.

Comment: Some commenters questioned whether proposed timelines for implementation were appropriate and requested more emphasis on testing and validation of CDS Hooks.

Response: We did not propose and are not finalizing an implementation timeline or other deadlines for Health IT Modules to be certified to 45 CFR 170.315(j)(20).

Comment: Some commenters requested more specific guidance on ''pre-fetch templates'' while others recommended that ASTP/ONC finalize that certified health IT is not required to support any pre-fetch templates.

Response: We appreciate commenters' concerns with our proposals related to ''pre-fetch templates.'' We are not finalizing the ''pre-fetch'' requirements proposed at 45 CFR 170.315(j)(20)(iv)(A) to provide industry additional time to refine the specifications and capabilities supporting ''pre-fetch.'' We anticipate that given the complexity and potential value of ''pre-fetch'' capabilities, the standards development community and other interested parties will continue to improve standards and guidance in this area, and we will monitor this work for potential future inclusion in the Certification Program.

After consideration of the public comment, we are finalizing our proposal to adopt the CDS Hooks implementation specification under 45 CFR 170.215(f) by adopting the CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2 at 45 CFR 170.215(f)(1), and incorporating it by reference in 45 CFR 170.299(g). We note that we proposed to adopt CDS Hooks Release 2.0; however, since the publication of the proposal a newer version of the implementation specification, CDS Hooks Version 2.0.1, was published on March 12, 2025. CDS Hooks Implementation Guide, Version 2.0.1 is an errata release that does not introduce substantive changes to the specification from Release 2.0. Rather, version 2.0.1 updates the publishing mechanism and formatting of the implementation guide. We believe adoption of this errata release will benefit Certification Program compliance by referencing a version of the implementation specification with the same substantive content as the proposed release but in an improved publication format. Adoption of version 2.0.1 of this specification will also support consistent implementation across industry because it is the latest and most correct version of the CDS Hooks implementation guide.

We are also finalizing our proposal to adopt a ''workflow triggers for decision support interventions—client'' criterion at 45 CFR 170.315(j)(20) with modification. We are finalizing adjustments to the proposed language to streamline and clarify the regulation text without introducing substantive changes to the proposal with the exceptions of the removal of the requirements to support ''pre-fetch'' proposed at 45 CFR 170.315(j)(20)(iv)(A) and the removal of the requirement proposed at 45 CFR 170.315(j)(20)(iv)(C)(2) to support the ''Link'' field ''appContext''. Non-substantive changes to the proposed language include revising specification references from 45 CFR 170.215(f)(1) to 45 CFR 170.215(f) to consistently reference the CDS Hooks specification, consolidating several proposed references to the specifications at 45 CFR 170.215(f) into a single reference in the paragraph at 45 CFR 170.315(j)(20), and rephrasing the required registration capabilities in 45 CFR 170.315(j)(20)(i) in terms of ''CDS Clients.'' The structure of 45 CFR 170.315(j)(20) that we are finalizing remains largely the same as the proposal except for the addition of two subparagraphs under 45 CFR 170.315(j)(20)(ii) to specify authentication and authorization requirements with additional clarity, and the removal of the requirements to support ''pre-fetch'' proposed at 45 CFR 170.315(j)(20)(iv)(A). The requirements we are finalizing at 45 CFR 170.315(j)(20)(ii)(A) and (B) clarify that client authentication must be supported using JSON web tokens (JWT), and data access authorization of a ''CDS Service'' using access tokens must be supported, respectively. This additional specificity resolves potential ambiguity regarding whether certain authentication and authorization capabilities from the CDS Hooks IG are required to be supported for the ''workflow triggers for decision support interventions—client'' criterion. Finally, we are finalizing 45 CFR 170.315(j)(20) without the regulation text proposed at 45 CFR 170.315(j)(20)(iv)(C)(2). We did not receive any comments regarding our proposal at 45 CFR 170.315(j)(20)(iv)(C)(2) to support the ability to launch internal apps and SMART apps from decision support responses according to the implementation specification 45 CFR 170.215(f)(1), including support for the ''Link'' field ''appContext.'' We have removed this requirement from the regulation text in our finalization of 45 CFR 170.315(j)(20) to provide health IT developers certifying to the 45 CFR 170.315(j)(20) criterion with the flexibility to support this optional CDS Hooks capability as applicable to their workflows.

(ii) Subscriptions—Client

In the HTI–2 Proposed Rule, we discussed the HL7 FHIR Subscriptions Framework, which describes a standardized method for clients to subscribe to notifications from servers based on pre-negotiated criteria (89 FR 63572). Once the subscription is established, servers can proactively notify a client when new information has been added or existing information has been updated in its system. Once a notification has been received by a

client, the client can take appropriate action, including querying the server for the desired information. The HL7 FHIR Subscriptions Framework also describes methods to transmit payloads with notifications, which may help simplify some interorganizational transactions by enabling real-time updates, selective data transmission, and interoperability, making data exchange between organizations more efficient and effective.

We anticipated that API-based subscriptions would support several use cases across clinical, public health, administrative, and research domains. Specific to public health use cases, we envisioned that future implementation guides could leverage the HL7 FHIR Subscriptions Framework for case reporting processes, immunization reporting processes, syndromic surveillance, reportable laboratory tests and values, and transmitting cancer case information to state cancer registries, among others. We welcomed comments on this approach, particularly with respect to the readiness of this standard to support public health reporting and any potential benefits or limitations to this approach that should be considered.

We stated that the HL7 FHIR Subscriptions Framework has undergone a significant redesign during the development of the HL7® FHIR® Release 5 (R5) standard, including the use of ''SubscriptionTopic'' HL7 FHIR Resources that define the criteria for standardized subscription notifications. We noted that we structured our proposal in 45 CFR 170.315(j)(23) to best accommodate health IT developers' and the industry's maturity so that API-based subscriptions can be more easily implemented in the current health IT landscape. While the HL7 FHIR Subscriptions Framework in HL7® FHIR® R5 is well developed, the health IT industry is largely using HL7® FHIR® Release 4, Version 4.0.1 (HL7® FHIR® R4), for HL7 FHIR standards-based exchange. We stated that updating all the criteria in the Certification Program to HL7® FHIR® R5 to accommodate the updated HL7 FHIR Subscriptions Framework would not be practicable nor prudent given the full-scale industry redesign that would be necessary to do so and impacts on users. In order to enable health IT developers using HL7® FHIR® R4, to support the improvements made in the HL7 FHIR Subscriptions Framework in HL7® FHIR® R5, the HL7 standards community created the Subscriptions R5 Backport Implementation Guide version 1.1.0, which specifies some of the HL7® FHIR® R5 Subscriptions Framework enhancements in a way that is compatible with HL7® FHIR® R4.

We proposed that a Health IT Module presented for certification to the ''subscriptions—client'' criterion in 45 CFR 170.315(j)(24) support API-based subscriptions according to HL7 FHIR Subscriptions Framework included in the HL7 FHIR Subscriptions R5 Backport Implementation Guide version 1.1.0 (hereafter referred to as ''Subscriptions IG''), which we proposed to adopt in 45 CFR 170.215(h)(1). We described that the proposals in 45 CFR 170.315(j)(24) specify constraints on the implementation specification proposed in 45 CFR 170.215(h)(1), which intended to ensure that Health IT Modules certified to 45 CFR 170.315(j)(24) could conform to separate but related aspects and functions of the implementation specification in 45 CFR 170.215(h).

Recognizing the importance of reducing burden on health IT developers while also striving to improve nationwide interoperability, we proposed to adopt the Subscriptions IG in 45 CFR 170.215(h)(1) to support the certification criterion for API-based subscriptions in 45 CFR 170.315(j)(24) ''subscriptions—client'' requirements. We described that the Subscriptions IG includes API-based subscription functionality that goes beyond the scope of FHIR R4, but for the purposes of the Certification Program, we proposed in 45 CFR 170.315(j)(24)(i) that Health IT Modules support the requirements specified in section ''1.6 Topic-Based Subscriptions—FHIR R4'' of the implementation specification in 45 CFR 170.215(h)(1).

Additionally, we proposed in 45 CFR 170.315(j)(24)(ii) that Health IT Modules support the ''R4/B Topic-Based Subscription'' profile as specified in the Subscriptions IG. We noted that while this profile is compatible with both HL7® FHIR® R4.0.1, and HL7® FHIR® R4B, we proposed it for use with HL7® FHIR® R4, at this time.

We proposed in 45 CFR 170.315(j)(24)(iii) that Health IT Modules support the accompanying client capabilities for the minimum requirements included in the ''R4 Topic-Based Subscription Server Capability Statement'' of the implementation specification in 45 CFR 170.215(h)(1), including support for ''create,'' ''update,'' and ''delete'' interactions for HL7 FHIR Subscription Resources according to the implementation specification in 45 CFR 170.215(h)(1).

Finally, we proposed in 170.315(j)(24)(iv) that Health IT Modules support the ability to receive subscription notifications, according to the ''1.6 Topic-Based Subscriptions—FHIR R4'' section of the implementation specification in 45 CFR 170.215(h)(1). We proposed to include in 45 CFR 170.315(j)(24)(iv)(A) that support for ''id-only'' Payload Types is required as specified in the ''Payload Types'' section of the implementation specifications in 45 CFR 170.215(h)(1). We noted there are three options available when specifying contents of a notification: empty, id-only, and full-resource. We stated we believe that id-only provides a good balance between security and performance.

We noted that proposals in 45 CFR 170.315(j)(24) included in this section reflected public feedback we received in the HTI–1 Proposed Rule. We described that the REST-hook channel uses the RESTful model which is extensively used in FHIR standard and is considered to present the lowest bar for implementation. We proposed to include in 45 CFR 170.315(j)(24)(iv)(B) required support for consuming notifications via the ''REST-Hook'' channel as specified in the ''Channels'' section of the implementation specifications in 45 CFR 170.215(h)(1).

We noted that we included a reference to the proposed certification criterion in 45 CFR 170.315(j)(24) in the proposed ''prior authorization API—provider'' certification criterion in 45 CFR 170.315(g)(34) and referred readers to that section for more information on the proposals.

We stated we believe our proposal and alternative proposals 45 CFR 170.315(j)(24) reflected the public feedback we received during the HTI–1 rulemaking process. We acknowledged that the standards may have matured beyond the prior recommended feedback from the HTI–1 Proposed Rule and requested comment on these proposals and whether interested individuals and organizations would prefer to implement other standards listed in the Subscriptions IG, including API-based subscriptions based on HL7 FHIR R5.

The following is a summary of the comments we received and our responses:

Comment: Many commenters supported our proposal to incorporate the modular API capabilities from the Subscriptions IG Version 1.1.0 into certified health IT.

Response: We thank commenters for their support.

Comment: A few commenters supported the subscription proposal with modification requesting that ASTP/ONC adopt the FHIR R4B

standard to simplify implementation and reduce complexity to ensure consistency across different systems and leverage enhanced backport for security reasons.

Response: We thank commenters for their recommendation. However, we are finalizing our proposal to only require support for the ''R4/B Topic-Based Subscription'' profile according to HL7® FHIR ® Release 4.0.1 at 45 CFR 170.315(j)(21)(ii), rather than require support for the broader FHIR R4B standard. Requiring broader support for R4B is not necessary to support the Subscriptions IG Version 1.1.0. Further, requiring support for the broader FHIR R4B standard would represent a significant and complex undertaking across all Health IT Modules supporting criteria that reference IGs that use FHIR R4.

Comment: A commenter expressed uncertainty about the overarching subscriptions proposals citing that the subscriptions specification could benefit from more real-world use experience before being adopted as a standard for certification.

Response: We thank commenters for their concern and are finalizing a simplified version of our proposals in response to concerns over implementation experience in the real world. Specifically, we are not requiring support for the ''id-only'' payload type at this time. We believe that requiring a specific payload type in the ''subscriptions—client'' criterion in 45 CFR 170.315(j)(21) is premature. This flexibility will give developers of certified health IT the option to choose the most appropriate payload types when certifying to this criterion.

Comment: Many commenters expressed concerns regarding both the proposed ''subscriptions—server'' criterion in 45 CFR 170.315(j)(23) and ''subscriptions—client'' criterion at 45 CFR 170.315(j)(24). However, the concerns raised included technical feedback involving topic complexity, implementation burden, and subscription delivery methods applied specifically to the server-side functionality proposed under 45 CFR 170.315(j)(23). Several commenters also expressed confusion about the distinction between client and server responsibilities, with some mistakenly referring to 45 CFR 170.315(j)(24) as the server requirement. A few commenters requested clearer delineation between the roles to avoid misinterpretation.

Response: We thank commenters for their concern. In this final rule we are only finalizing the ''client'' capabilities described in our subscription proposals. We anticipate that ''server'' capabilities will be a necessary component of the ecosystem for prior authorization workflows, as well as other potential uses for subscriptions capabilities, and we anticipate that some developers of certified health IT may support server capabilities currently. However, we are not finalizing such server capabilities in the Certification Program at this time, and we reiterate that we are only requiring support for ''client'' capabilities for subscriptions at 45 CFR 170.315(j)(21).

Comment: A few commenters raised issues that are out of scope for this final rule, including modular API capabilities for subscription proposals specific to Public Health Agencies (PHAs) and the feasibility and resources needed to support the PHA use cases.

Response: We thank commenters for their feedback specific to PHAs and as stated previously, we have limited our focus to those criteria in 45 CFR 170.315(j) that relate to the ''prior authorization API—provider'' criterion we proposed in 45 CFR 170.315(g)(34). We will consider the commenters' suggestions in future rulemaking.

After consideration of the public comment, we are finalizing adoption of the Subscriptions IG Version 1.1.0 at 45 CFR 170.215(h)(1) and incorporating it by reference in 45 CFR 170.299(g). We are also finalizing the ''Subscriptions—client'' certification criterion at 45 CFR 170.315(j)(21), which corresponds to the criterion proposed at 45 CFR 170.315(j)(24), with modifications. We are finalizing a simplified version in recognition of comments regarding need for real-world experience with implementation. Specifically, we are finalizing 45 CFR 170.315(j)(21) without support for ''id-only'' Payload Types as specified in the ''Payload Types'' section of the implementation specifications in 45 CFR 170.215(h)(1) as proposed in 45 CFR 170.315(j)(24)(iv)(A). Since we are not finalizing support for ''id-only'' Payload Types, we consolidated paragraph 45 CFR 170.315(j)(24)(iv)(B) into 45 CFR 170.315(j)(21)(iv) without substantive changes.

(6) New Certification Criteria for Electronic Prior Authorization

(a) Overview

In section III.B.20. of the HTI–2 Proposed Rule we proposed to adopt a set of certification criteria in 45 CFR 170.315(g)(30)–(36) to support data exchange between healthcare payers, providers, and patients (89 FR 63580 through 63594). We stated that these proposed certification criteria would enable the exchange of data including clinical and coverage information, drug formulary information, and prior authorization information between patients, providers, and payers as appropriate to each exchange. We noted that these proposed certification criteria were based on a series of policies finalized by CMS (89 FR 63580). We stated that these certification criteria, if finalized, would be available for health IT developers (which may include payers and other developers providing technology to payers) seeking voluntary certification for health IT products supporting these use cases. We also proposed to adopt a set of API implementation specifications on behalf of the Secretary, in 45 CFR 170.215(j), (k), (m), and (n), for HHS use, which we proposed to reference in the proposed certification criteria. We noted that the proposed implementation specifications included recommended implementation specifications identified in CMS' finalized policies for payer API requirements (89 FR 8945).

In this final rule, we are finalizing a subset of the proposals in section III.B.20 of the HTI–2 Proposed Rule. Specifically, we are adopting electronic prior authorization criteria in 45 CFR 170.315(g)(31), (32), and (33) based on the capabilities originally proposed for the ''prior authorization API—provider'' certification criterion in 45 CFR 170.315(g)(34), and finalizing related proposals extending the applicability of certain Condition and Maintenance of Certification and real world testing provisions under the Certification Program to these electronic prior authorization criteria. We are also adopting a series of implementation specifications for HHS use that support these criteria, as well as other exchange use cases between payers, providers, and patients. We may consider finalizing other proposals in section III.B.20. of the HTI–2 Proposed Rule in future rulemaking.

(b) Background

(i) Background on CMS Interoperability Rulemaking

On May 1, 2020, the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage (MA) Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, and Health Care Providers'' final rule (85 FR 25510) appeared in the **Federal Register** (hereinafter referred to as the ''CMS Interoperability and Patient

Access Final Rule''). CMS required impacted payers [456] to implement and maintain a FHIR-based Patient Access API to allow patients, through the health application of their choice, to easily access their claims and encounter information as well as clinical data, including laboratory results, and provider remittances and enrollee cost-sharing pertaining to such claims, if maintained by the impacted payer (85 FR 25559). CMS also required impacted payers to maintain a Provider Directory API to make available information such as contracted provider names, addresses, and phone numbers (85 FR 25563).

On February 8, 2024, the ''Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program'' (CMS Interoperability and Prior Authorization Final Rule) appeared in the **Federal Register** (89 FR 8758). Final policies in this rule included: expanding the content available via the existing Patient Access API to include information about prior authorizations; requiring impacted payers to implement and maintain a Provider Access API to make patient data available to in-network providers with whom the patient has a treatment relationship; and requiring impacted payers build and maintain a Payer-to-Payer API to exchange patient data when a patient moves between payers or has concurrent payers. CMS also required impacted payers to implement and maintain a Prior Authorization API to facilitate electronic prior authorization processes. Finally, the rule added the Electronic Prior Authorization measures to the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (89 FR 8909 through 8926).

In the CMS Interoperability and Patient Access Final Rule (85 FR 25510 through 25640) and the CMS Interoperability and Prior Authorization Final Rule (89 FR 8758 through 8988), CMS required impacted payers to use certain standards and implementation guides, as well as the USCDI standard, which ASTP/ONC has adopted on behalf of HHS in 45 CFR 170.215 and 45 CFR 170.213 respectively. Specifically, CMS finalized technical requirements for the following APIs: Patient Access API (85 FR 25558 through 25559, 89 FR 8784 through 8787), Provider Access API (89 FR 8817 through 8820), Payer-to-Payer API (89 FR 8855 through 8856), Prior Authorization API (89 FR 8897 through 8901), and the Provider Directory API (85 FR 25563 through 25564). In the CMS Interoperability and Prior Authorization Final Rule, CMS also recommended a number of implementation guides that may be used to support effective implementation of the required payer APIs (89 FR 8945).

(ii) Background on Electronic Prior Authorization

In the HTI–2 Proposed Rule, we stated that prior authorization processes [457] have contributed significantly to patient and provider burden, for instance, through delays experienced by patients and clinicians as they seek to satisfy the requirements associated with prior authorization rules set by payers (89 FR 63587).[458] ONC's Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs,[459] released in 2020, identified challenges associated with the prior authorization process faced by patients and healthcare providers, including: (i) difficulty in determining whether an item or service requires prior authorization; (ii) difficulty in determining payer-specific prior authorization requirements for those items and services; (iii) inefficient use of provider and staff time to navigate communications channels such as fax, telephone, and various web portals; and (iv) unpredictable and lengthy amounts of time to receive payer decisions. The Strategy noted that payers and health IT developers have addressed prior authorization in an ad hoc manner with interfaces that reflect individual payer technology considerations, payer lines of business, and customer-specific constraints. We described a 2022 physician survey conducted by the American Medical Association that demonstrated significant negative impacts associated with the current prior authorization and beneficiary information exchange processes.[460] Nearly 94 percent of physicians reported care delays associated with prior authorization, and 80 percent reported that issues related to the prior authorization process can sometimes lead to treatment abandonment. In addition, survey respondents reported that physicians and their staff spend almost two business days each week completing prior authorizations, with nearly 35 percent of physicians retaining staff who work exclusively on prior authorizations. Today, hospitals and provider practices widely continue to use telephone and fax to conduct prior authorization processes. According to the Council for Affordable Quality Healthcare, only 28 percent of 228 million prior authorization contacts were fully electronic in 2022.[461]

In 2020, ONC charged the HITAC to establish the Intersection of Clinical and Administrative Data (ICAD) Task Force to produce information and considerations related to the merging of clinical and administrative data for electronic prior authorization. The ICAD Task Force's final report,[462] approved in November 2020, recommended that ONC work with CMS, other federal actors, and standards development organizations to ''establish standards for prior authorization workflows.'' Specifically, the Task Force recommended that entities should develop API specifications ''such that the authorization and related documentation may be triggered in workflow in the relevant workflow system where the triggering event for the authorization is created.''

In January 2021, ONC published an RFI titled ''Request for Information:

[456] For the purposes of the CMS Interoperability and Patient Access and Interoperability and Prior Authorization Final Rules discussed in this section, impacted payers include Medicare Advantage (MA) organizations, state Medicaid fee-for-service (FFS) programs, state Children's Health Insurance Program (CHIP) FFS programs, Medicaid managed care plans, CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally-facilitated Exchanges (FFEs).

[457] Generally defined as rules imposed by healthcare payers that require approval for a medication, procedure, device, or other medical service be obtained prior to payment for the item or service.

[458] Office of the National Coordinator for Health Information Technology. Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs [PDF file]. February 2020. Retrieved from *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[459] Office of the National Coordinator for Health Information Technology. Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs [PDF file]. February 2020. Retrieved from *https://www.healthit.gov/sites/default/files/page/2020-02/BurdenReport_0.pdf.*

[460] *https://www.ama-assn.org/practice-management/prior-authorization/prior-authorization-research-reports.*

[461] *https://www.caqh.org/sites/default/files/2023-05/2022-caqh-index-report.pdf.*

[462] *https://www.healthit.gov/sites/default/files/facas/ICAD_TF_FINAL_Report_HITAC_2020-11-06_508_0.pdf.*

Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria'' to seek input from the public regarding electronic prior authorization standards, implementation specifications, and certification criteria that could be adopted within the ONC Health IT Certification Program (87 FR 3475). ONC received approximately 130 responses to this RFI from a wide range of entities. Comments on the RFI broadly supported the incorporation of electronic prior authorization capabilities within the Certification Program, while highlighting concerns about the current readiness and maturity of available implementation specifications to support these capabilities. Commenters also provided input on how certification criteria related to electronic prior authorization should be structured and how certification criteria should address other federal requirements around the use of standards for electronic prior authorization transactions. Finally, commenters provided input on the benefits of improving electronic prior authorization for patients, providers, health IT developers and payers, as well as potential challenges associated with implementation.

ONC also charged the HITAC to establish a Task Force in order to provide input and recommendations in response to the RFI; the Task Force's recommendations were approved and submitted to ONC on March 10, 2022.[463] We noted that the proposals in section III.B.20. of the HTI–2 Proposed Rule would implement several recommendations from the Task Force, specifically recommendations to:

- Create a suite of electronic prior authorization health IT certification criteria for health IT systems supporting both providers and payers that can enable health IT developers to certify to one or more specific functional capabilities that together, across participating health IT systems, enable the full electronic prior authorization workflow.
- Ensure new certification criteria for electronic prior authorization provide for health IT systems that perform prior authorization on behalf of payers to ensure that their solutions are compliant to consensus-based standards for electronic prior authorization and are able to send and receive information needed to meet the prior authorization business case.
- Work with the Da Vinci Project and key healthcare stakeholders (for example, providers, developers, patients) to develop appropriate health IT certification criteria that incorporate key functional capabilities for prior authorization.
- Ensure certification requirements that allow a FHIR-enabled process for prior authorization transactions do not require translation to X12.
- Prioritize criteria based on the Da Vinci Prior Authorization Support (PAS) IG that allow data, C–CDA, or FHIR documents to be provided in a FHIR construct.

(c) Standards and Certification Criteria for Electronic Prior Authorization

(i) Implementation Specifications for Prior Authorization

We proposed to adopt a ''prior authorization API—provider'' certification criterion in 45 CFR 170.315(g)(34) to establish requirements for Health IT Modules that can be used to facilitate a provider's request of coverage information and request for a prior authorization decision. We stated that this certification criterion would help support real-time access for providers to payer approval requirements, documentation, and rules at point of service, as well as enable providers to request and receive authorization. We noted that technology certified to these capabilities would help to automate and streamline the prior authorization process for healthcare providers and payers, ensure treatment decisions are made in a timely fashion, avoid delays in care, and reduce administrative burden on healthcare providers and payers associated with assembling and reviewing required documentation.

We proposed to adopt three HL7 FHIR Da Vinci Burden Reduction IGs in 45 CFR 170.215(j) as the basis for the proposed ''prior authorization API—provider'' criterion and incorporate these IGs by reference in 45 CFR 170.299(g):

- HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2 (proposed in 45 CFR 170.215(j)(1)(i)).[464]
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2 (proposed in 45 CFR 170.215(j)(2)(i)).[465]
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide, Version 2.0.1—STU 2 (proposed in 45 CFR 170.215(j)(3)(i)).[466]

Taken together, these implementation specifications support a comprehensive workflow for conducting electronic prior authorization transactions. These specifications are based upon HL7® FHIR® Release 4, Version 4.0.1: R4. In concert with CMS, ASTP/ONC has led or participated in a variety of activities related to monitoring and evaluating the standards and implementation specifications identified in the proposed rule, utilizing available mechanisms for gathering input on these standards from a wide variety of experts. The Da Vinci Project [467] is a private sector initiative that brings together payers, health IT developers, providers, and other public participants to facilitate the definition, design, and creation of use case specific reference implementations of solutions based upon the HL7 FHIR platform that involve managing and sharing clinical and administrative data between industry partners. Because the Da Vinci Project is aligned with HL7, solutions developed through the project may become industry standards. The Da Vinci Project's use case requirements, test scenarios, and test data, as well as the resulting implementation guides and reference implementations, are available without licensing requirements (89 FR 63581).

We proposed to adopt these implementation specifications under PHSA section 3004 and make them available for HHS use. We further noted that the proposed certification criterion included proposals that required the use of at least one version of each of the implementation specifications adopted in 45 CFR 170.215(j)(1)–(3) (89 FR 63588). We noted that if we were to adopt subsequent versions of the implementation specifications in 45 CFR 170.215(j)(1) (CRD IG), (j)(2) (DTR IG), and (j)(3) (PAS IG), respectively, proposals that require the use of at least one implementation specification adopted in one of these locations would enable health IT developers to use any version adopted at the specified location, unless we specified an adoption ''expiration'' date which indicates a certain version of the specification may no longer be used after that date (89 FR 63588).

The following is a summary of the comments received on the HTI–2 Proposed Rule and our responses:

Comment: Many commenters supported our proposals to adopt

[463] *https://www.healthit.gov/sites/default/files/page/2022-03/2022-03-10_ePA_RFI_Recommendations_Report_Signed_508.pdf.*

[464] *See https://hl7.org/fhir/us/davinci-crd/STU2/.*

[465] *See https://hl7.org/fhir/us/davinci-dtr/STU2/.*

[466] *See https://hl7.org/fhir/us/davinci-pas/STU2/.*

[467] For more information about the Da Vinci Project, please visit *https://www.hl7.org/about/davinci/.*

certification criteria and implementation specifications for health IT to enable electronic prior authorization. In general, commenters believed that electronic prior authorization activities enabled by technology meeting the proposed ''prior authorization API—provider'' criterion would address burdensome manual prior authorization processes, and that widespread adoption of such technology solutions has the potential to reduce the time that clinicians and other staff must spend on administrative tasks related to prior authorization. Commenters further stated that finalization of this criteria would be an important mechanism for ensuring health IT developers include such functionality in certified health IT products.

Response: We thank commenters for their support of the proposed ''prior authorization API—provider'' criterion. We agree with commenters about the benefits that may be realized from incorporating standardized electronic prior authorization capabilities into their workflows.

Comment: Several commenters expressed concerns about the implementation challenges and other burdens that healthcare providers may experience implementing certified health IT for electronic prior authorization. Commenters noted that while under-resourced healthcare providers are impacted by the administrative burden associated with current prior authorization processes, such practices would also bear significant burden associated with implementation of new prior authorization functionality and associated workflows. Commenters urged ASTP/ONC and HHS to ensure any new functionality would be available at an affordable cost for small practices.

Response: We appreciate commenters' concerns about the potential for additional burden associated with adopting certified health IT for electronic prior authorization. We acknowledge that healthcare providers may incur costs acquiring health IT certified to these new criteria, and that integrating this new functionality may require development of new workflows and updates to existing workflows. However, we believe that by automating the prior authorization process providers of all sizes, but especially small practices, will benefit greatly from resource and administrative burden reductions. We refer readers to regulatory impact analysis in Appendix A section I.G.13. of this final rule for detailed discussion of costs and benefits of our finalized policies. While ASTP/ONC does not have authority to limit the costs of adopting new Health IT Modules, including for small practices, health IT developers must make information about material types of costs and limitations available for their products via the Certified Health IT Product List (CHPL) website.[468]

Comment: Many commenters did not support our proposals to adopt the Da Vinci CRD, DTR, and PAS IGs and incorporate them into the ''prior authorization API—provider'' criterion. Commenters stated that the implementation guides are not mature enough to be included as required standards at this time and that additional iterations of the proposed versions of the implementation guides would be needed before they were ready for adoption. Commenters stated that the implementation guides reflect the contributions of a limited group of industry partners, are not well-grounded in real-world use at this time, and have not undergone sufficient testing and piloting. Commenters also noted that there are a number of unresolved issues in the current versions of the implementation guides and provided examples of these issues. For instance, a commenter noted that the current versions of the IGs do not account for the full complexity of electronic prior authorization interactions focusing on binary responses and failing to account for less common scenarios that may arise in conducting these activities. Another commenter stated that the three IGs lack common data definitions, which may impede these functions from successfully working together as intended, and identified issues with a foundational specification which informs these IGs that may introduce unnecessary complexity as part of the workflow.

Response: We acknowledge the concerns raised by commenters regarding the maturity and readiness of the Da Vinci CRD, DTR, and PAS IGs. However, we emphasize the significant progress these guides represent in addressing longstanding challenges in a primarily manual prior authorization process. We believe adoption of these IGs, as proposed, is a critical step toward reducing administrative burden and improving care delivery with interoperable prior authorization workflows. Further, we note that iterations and refinements to the versions of CRD, DTR, and PAS IGs we proposed in the HTI–2 Proposed Rule have now been balloted by HL7 and will be available for use in the Certification Program, as described in more detail later in this section, via the Standards Version Advancement Process (SVAP).[469] These refinements and enhancements address common data definitions by supporting USCDI v3 and better support the full complexity of prior authorization workflows.

While acknowledging commenters' concerns about the maturity of the proposed versions of the CRD, DTR, and PAS IGs (versions 2.0.1), and the existence of unresolved issues in the proposed versions of the guides, it is important to note that these guides continue to evolve and improve based on real-world implementation feedback. For example, since publication of the HTI–2 Proposed Rule in August 2024, HL7 has published Version 2.1.0 of all three IGs. These updates have addressed gaps identified during early implementations and enhanced functionality to improve the interoperability of data necessary to enable electronic prior authorization workflows. Notably:

- HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.1.0—STU 2.1 [470] includes more than 20 changes setting clearer expectations for handling failure states, correcting contexts for order-dispatch, clarifying expectations for mandatory hook support, and setting expectations for endpoints and endpoint discovery.
- HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.1.0—STU 2.1 [471] includes more than 30 updates from Version 2.0.1, such as aligning endpoint discovery language with CRD IG requirements, addressing CMS enforcement discretion regarding the use of X12, and requiring DTR Clients to appropriately manage access to data that is sensitive per policy and regulatory requirements when responding to queries from a DTR application.
- HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide, Version 2.1.0—STU 2.1 [472] includes more than 50 updates, including: clarifying how to cancel an entire Prior Auth Claim instead of cancelling individual items, addressing concerns about required fields that are specified in the license restricted X12 TRN03 guide (which is

[468] See: *https://chpl.healthit.gov/#/search*.

[469] See Standards Version Advancement Process (SVAP): *https://www.healthit.gov/topic/standards-version-advancement-process-svap*.

[470] *See https://hl7.org/fhir/us/davinci-crd/STU2.1/*.

[471] *See https://hl7.org/fhir/us/davinci-dtr/STU2.1/*.

[472] *See https://hl7.org/fhir/us/davinci-pas/STU2.1/*.

referenced within the PAS IG), and updating the guide to be compliant with US Core v3.1.0, v6.0.1, and v7.0.0.

As noted previously, HL7 has iterated new versions for each IG in the months since we first proposed to adopt these IGs, and we anticipate future iterations to continue. We intend to continue to monitor the evolution of the standards and make subsequent versions of the adopted IGs available for use in the Certification Program when appropriate via the SVAP as discussed further in section IX.*B*.4.b.(6)(e) of this final rule. Through SVAP, developers of certified health IT will have the flexibility to use subsequent versions of these IGs in Health IT Modules certified to 45 CFR 170.315(g)(31), (g)(32) and (g)(33) and maintain their certification status based on use of an updated version of the adopted standard. This approach balances the need for immediate action to address prior authorization inefficiencies by ensuring certification is available upon the effective date of this final rule, while continuing to support use of the best available standard on an ongoing basis. We note that CMS has finalized similar provisions allowing impacted payers to use updated versions of HHS-adopted standards when implementing CMS' payer API requirements under certain circumstances, including standards approved for use by the National Coordinator under SVAP (see 89 FR 8935 for more details). Together, these policies enable both providers and payers to use health IT aligned with the most recent and advanced standards for purposes related to prior authorization.

The assertion that the IGs reflect contributions from a limited group of industry partners overlooks the collaborative nature of the IGs' development. The HL7 Da Vinci Project has engaged a broad spectrum of stakeholders, including providers, payers, and health IT developers, to ensure the guides address real-world needs.[473] The guides are grounded in real-world experiences and have been tested in both controlled settings and in real world pilot implementations, demonstrating their applicability and value.[474] We encourage all interested parties to participate in the processes managed by HL7 to continue to evolve and improve these IGs.

Comment: As an alternative to adopting and requiring use of the Da Vinci CRD, DTR, and PAS IGs, commenters recommended that ASTP/ONC finalize a functional criterion and recommend, but not require, use of the proposed IGs. Commenters pointed to the CMS Interoperability and Prior Authorization final rule, in which CMS recommended the use of the Da Vinci CRD, DTR, and PAS IGs, as well as other IGs, but did not require their use (89 FR 8937). Commenters expressed concern that requiring use of the current versions of the IGs would not allow industry the flexibility to address issues likely to be corrected or further developed in future versions, and that developers would be ''locked'' into an immature version of the IG. While commenters acknowledged that the SVAP is intended to provide flexibility to health IT developers who wish to use subsequent versions of a standard approved by ASTP/ONC within certified Health IT Modules, some commenters believed that the SVAP would not be rapid enough to provide assurances to developers that updated versions of the Da Vinci IGs were approved for use in a timely manner. Commenters stated that this delay would create confusion for developers around knowing which version of the IG a developer must certify to. Commenters also noted that in the case of IGs in earlier stages of development, including the Da Vinci CRD, DTR, and PAS IGs, subsequent versions may include breaking changes, and older versions may not be implementable as written.

Response: We appreciate comments suggesting that we finalize a functional criterion and recommend, rather than require, the use of the Da Vinci CRD, DTR, and PAS IGs. However, we believe that adopting these IGs and requiring their use in health IT certification criteria is essential to achieving the goals of interoperability, reducing administrative burden, and streamlining the prior authorization process. While flexibility is important, the absence of required standards for prior authorization capabilities risk perpetuating the fragmentation and manual inefficiencies that have long plagued prior authorization workflows. Moreover, a functional criterion does not support interoperability or adherence to standardized capabilities. Recommending the use of IGs without requiring them would likely result in inconsistent implementations, as developers may choose different approaches to meet functional requirements. This fragmentation would undermine the goal of creating a seamless and efficient prior authorization process. As discussed in more detail in this section, we are finalizing adoption of three certification criteria at 45 CFR 170.315(g)(31)–(33) that are standards-based, rather than functional.

We recognize commenters' concerns about the timeliness of the SVAP for approving updated versions of the IGs, including those who believed SVAP may not be rapid enough to keep pace with IG development. However, we note that SVAP has a proven track record of enabling developers of certified health IT to voluntarily use newer versions of HHS-adopted standards on an annual cadence, closely mirroring HL7's biannual balloting cycle. This cadence and process ensures that developers of certified health IT are not ''locked'' into older versions of IGs, and the voluntary nature of SVAP provides flexibility to industry to choose whether a newer version is sufficiently mature to use in production. While we believe that commenters' concerns that newer versions of adopted standards may include breaking changes are valid, we will consider this possibility for each standard when we determine whether a standard (including these implementation guides) should be approved for SVAP.

We note that while the CMS Interoperability and Prior Authorization Final Rule recommended the use of the Da Vinci IGs without requiring them, our approach reflects the distinct needs of the Certification Program and reflects our goal to advance standards-based interoperability. The adoption of required IGs creates testable expectations of conformance to these IGs and ensures that all stakeholders are aligned on a common set of implementation specifications. This reduces variability in deployed technology and enhances the efficiency of prior authorization workflows. We further note that while CMS determined at the time of the CMS Interoperability and Prior Authorization Proposed Rule that it was most appropriate to recommend the versions of the implementation specifications available at that time, CMS also stated that it intends to evaluate future versions of these specifications and will consider proposing to require conformance to versions of these implementation specifications in future rulemaking (89 FR 8921).

While commenters' recommendation to finalize a functional criterion and recommend the use of IGs reflects a desire for flexibility, it does not address the critical need for standardization and

[473] See Da Vinci Project Members at *https://confluence.hl7.org/spaces/DVP/pages/144978522/Da+Vinci+Project+Members.*

[474] See HIPAA Exception Pilot Report at *https://confluence.hl7.org/download/attachments/113675673/HL7%20Da%20Vinci%20Exception%20Report_Final%20(June%2025%2C%202024).pdf?version=1&modificationDate=1731382945836&api=v2.*

interoperability in prior authorization workflows.

After consideration of the comments, for this and other stated reasons, we are finalizing our proposals to adopt the proposed Da Vinci CRD, DTR, and PAS IGs at 45 CFR 170.215(j)(1)(i), (j)(2)(i), and (j)(3)(i), respectively, and are incorporating them by reference in 45 CFR 170.299(g). We reiterate that SVAP provides flexibility for developers to adopt updated versions of these standards, while mechanisms for managing breaking changes ensure that the transition to newer versions is smooth and effective. We encourage stakeholders to support the further development of these IGs, as needed, through the process managed by HL7 and the Da Vinci Project.

(ii) Organization of the Proposed Prior Authorization API Criteria

In the January 2021 ''Request for Information: Electronic Prior Authorization Standards, Implementation Specifications and Certification Criteria,'' we requested comment on the most appropriate way to structure health IT certification criteria enabling a health care provider to conduct electronic prior authorization transactions (87 FR 3480). We received a wide range of input on this topic with commenters noting that different types of systems, including EHRs, revenue cycle and patient management systems, and third-party applications may be responsible for different elements of the electronic prior authorization workflow. Some commenters recommended that ONC consider proposing individual criteria that map to each of the Da Vinci IGs (the CRD, DTR, and PAS IGs), which we discussed in the RFI. Other commenters suggested creating more granular certification criteria which reflect specific capabilities and key interactions within the prior authorization workflow, so that these capabilities can be implemented as stand-alone solutions to provide incremental value. The Task Force charged by the HITAC to provide a response to the January 2021 RFI also provided recommendations on this topic.[475]

In the HTI–2 Proposed Rule (89 FR 63590), we proposed a single ''prior authorization API—provider'' certification criterion in 45 CFR 170.315(g)(34). However, we noted that existing guidance in the Certification Program could provide flexibility around the use of distinct technology products that may be utilized to perform the capabilities that were outlined in the proposed certification criterion. Specifically, we described that health IT developers are permitted to use ''relied upon software'' (76 FR 1276) to demonstrate compliance with certification criteria adopted at 45 CFR part 170, subpart C.[476] Relied upon software is typically third-party software that is not developed by the health IT developer presenting its health IT for testing and certification. Relied upon software may be used to demonstrate compliance with a portion of an adopted certification criterion or an entire certification criterion. When a health IT developer relies upon software to demonstrate compliance with a certification criterion, such relied upon software must be included in the scope of the certification issued to the Health IT Module. In cases where a Health IT Module may be paired with multiple ''relied upon software'' products for the same capability, it must be tested with at least one such product to demonstrate compliance with a certification criterion's requirements. Afterwards, the Health IT Module developer is permitted to list all additional ''relied upon software'' products for the same capability paired with the certified Health IT Module without having to test each one with the ONC-Authorized Testing Laboratory (ATL). A health IT developer always remains responsible for its product's conformance to a certification criterion even when the ''relied upon software'' contributes to, or is the cause of, a non-conformity.

We invited additional comments on the most appropriate way to structure the proposed ''prior authorization API—provider'' certification criterion. Specifically, we were interested in the public's input on how organization of the proposed certification criteria would affect the ability of developers to effectively offer certified health IT products that meet the criteria, and what impact the organization of the proposed criteria would have on customers who may already possess technology products that can be used to conduct electronic prior authorization transactions. We also requested comment on whether or to what degree existing guidance for the Certification Program, such as the relied upon software policy described previously, would address scenarios in which distinct health IT products are used to support different elements of the prior authorization workflow. Finally, we invited comments on alternative approaches to organizing the ''prior authorization API'' certification criteria.

Comment: Several commenters stated that combining different functions under the single proposed ''prior authorization API—provider'' criterion, rather than allowing for modular certification of different functions, does not recognize that different systems may be involved in these transactions. They noted that the prior authorization process combines both administrative and clinical transactions depending on the step in the process. While clinical transactions may take place in EHRs, other administrative steps may take place in systems such as revenue cycle management systems. Commenters believed that by combining these functions under a single criterion, ASTP/ONC was assuming that an EHR would be performing each of the identified functions in the workflow specified in the proposed ''prior authorization API—provider'' criterion. Commenters stated that such an assumption would require combinations of products that may not exist at present, compelling collaboration among vendors in order to meet the workflow integration required for the criterion that does not currently exist in the market. Commenters stated that there are only a small number of EHR systems currently sold with a fully integrated revenue cycle management system, and that many healthcare providers prefer to combine EHR and RCM systems from different vendors. Other commenters noted that there are currently vendors in the market that specialize in only performing certain steps included as part of the electronic prior authorization workflow reflected in the proposed IGs. As a result of these observations, several commenters recommended that ASTP/ONC separately certify Health IT Modules to the functionality represented by each of the three proposed IGs.

Response: We appreciate commenters' feedback on our proposal for a single criterion to support the functionality represented by the three proposed IGs. We acknowledge that our proposal for a single criterion assumed that most Health IT Modules would be performing all of the functions specified by the CRD, DTR, and PAS IGs, and in instances where a developer of certified health IT did not support a functionality, the developer could use relied upon software. Comments received have persuaded us to revisit these assumptions and we agree that establishing multiple criteria could more effectively support a diverse

[475] *https://www.healthit.gov/sites/default/files/page/2022-03/2022-03-10_ePA_RFI_Recommendations_Report_Signed_508.pdf.*

[476] For more guidance on relied upon software, *see: https://www.healthit.gov/sites/default/files/relieduponsoftwareguidance.pdf.*

marketplace of developers, including those that specialize in only certain steps in the electronic prior authorization workflow. We further believe that such an approach would not inhibit certified health IT developers to support end-to-end workflows for providers as described in the CRD, DTR, and PAS IGs, as such developers could certify Health IT Module(s) to individual certification criteria reflecting different components of the prior authorization workflow.

Comment: A commenter suggested that ASTP/ONC allow developers to certify to both the complete workflow and components of the workflow, at least during an initial period as healthcare providers and gain an understanding of how they will comply with the certification requirements. For instance, the commenter suggested that a developer who only offers a solution focused on the functionality represented in the CRD IG should be able to certify to a criterion reflecting this functionality, while a second developer certifying to the complete workflow reflected in the CRD, DTR, and PAS IGs should be able to obtain certification reflecting those complete capabilities.

Response: We appreciate commenters' recommendation to certify both the complete workflow and individual criteria. However, we believe that an approach which certifies the complete workflow may constrain future needs to support dynamic workflows for prior authorization. We heard from commenters that multiple information systems may be involved in the prior authorization process, and while we reiterate that these criteria are intended for use by care providers and healthcare delivery organizations, systems certifying to these certification criteria need not be constrained only to clinical systems. For instance, and as is described in more detail later in this section, a Health IT Module certified to the criterion we are finalizing in 45 CFR 170.315(g)(32), which is required to support the DTR IG through cross-reference to 45 CFR 170.215(j)(2), may be part of an existing, deployed information system, or it may be a standalone information system that can be integrated with an existing system.

Comment: Several commenters supported our reference to the use of the ''relied upon software'' feature of the Certification Program in implementing the proposed ''prior authorization API—provider'' criterion. Commenters stated use of this flexibility would lead to cost savings and would eliminate the need for developers to build solutions from the ground up.

Response: We appreciate commenters' support for the relied upon software feature of the Certification Program. We agree this program element can support flexibility for developers to determine the best approach to developing Health IT Modules by leveraging partnerships with other vendors and products. However, we believe that this approach may be limited in its ability to support a dynamic health IT marketplace, which enables developers to certify to only those aspects of the electronic prior authorization workflow they believe best suits their circumstances.

Comment: Other commenters disagreed that the ''relied upon software'' element of the Certification Program would effectively address relevant issues. Specifically, commenters stated that this aspect of the program has compelled specific vendor collaboration and combinations of products that would not have otherwise occurred, and that such activities may displace combinations of products that have been developed in response to customer interest.

Response: We thank commenters for their views on the value of the relied upon software aspect of the Certification Program. We disagree that relied upon software has had a negative impact across the market for health IT products and services. Relied upon software has had the opposite impact by allowing developers with incomplete functionality to certify products under the Certification Program. Based on data from the CHPL as of May 1, 2025, about 60 percent of all Health IT Modules certified under the Certification Program since the 2015 Edition have used relied upon software to fulfill the requirements of one or more certification criteria.

However, we agree with commenters that relied upon software may not adequately address issues discussed in the HTI–2 Proposed Rule related to this topic (89 FR 63591). For example, in scenarios where a health care provider may already be using health IT products to support a specific exchange or interaction in the prior authorization workflow, it may be difficult for such a provider to find or use distinct health IT products to support the remaining interactions of the prior authorization workflow. In this scenario, there is no guarantee that a health IT developer would agree to use the provider's existing health IT product as relied upon software. As a result, we agree that additional flexibility within the Certification Program beyond relied upon software may be necessary to address certification for electronic prior authorization.

Comment: Many commenters recommended that ASTP/ONC allow developers to phase in availability of Health IT Modules meeting different parts of the electronic prior authorization workflow over time. Commenters stated that the workflow envisioned in the CRD, DTR, and PAS IGs is highly complex, and relies on advanced features such as CDS Hooks and Clinical Quality Language (CQL). Commenters noted that the Electronic Prior Authorization measures finalized for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category focused on the submission of a prior authorization request, suggesting that the functionality described in the PAS IG and the CRD IG will be the most immediately relevant to healthcare providers. Several commenters suggested that implementation of the CRD IG should be required first, followed by the DTR and PAS IGs. Several commenters identified the DTR IG as likely to include the most novel implementation challenges.

Response: We appreciate commenters recommendations regarding the sequencing and phased availability of Health IT Modules certified to electronic prior authorization workflows. We agree that the workflow envisioned in the CRD, DTR, and PAS IGs seeks to comprehensively address prior authorization processes, and that these IGs rely on advanced features such as CDS Hooks and Clinical Quality Language (CQL). We acknowledge that there may be potential benefits of a phased approach identified by commenters, for instance, beginning with implementation of the CRD and PAS IGs. This approach may allow health IT developers to focus more intensively on development of more advanced capabilities over a longer time period.

We note that, as discussed in section IX.*B*.4.b.(6)(f) of this final rule, we are not finalizing our proposal to include the ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34) in the Base EHR definition by a certain date. We are also not finalizing to include criteria in 45 CFR 170.315(g)(31)–(33) in the Base EHR definition. We are, therefore, not defining a specific date by which these criteria must be certified and provided to customers. Instead, developers may begin certification as soon as testing is available after the effective date of this final rule and work with their customers to implement in the manner most appropriate for their needs.

However, we note that requirements in other HHS, federal, state or local

programs for adoption and use of health IT certified to ONC health IT certification criteria may include dates impacting health IT developers' ability to sequence the rollout of certified health IT functionality to customers. For instance, developer timelines may be impacted by requirements to use technology certified to the finalized criteria for reporting of the Electronic Prior Authorization measures finalized for inclusion in the Medicare Promoting Interoperability Program and MIPS Promoting Interoperability performance category beginning with the EHR reporting period in CY 2027 and CY 2027 performance period/2029 MIPS payment year, respectively (89 FR 8926). We believe our approach of supporting certification as soon as possible after the effective date of the rule—without inclusion of a compliance timeline through the Base EHR definition—will allow for a transition period with implementation testing while also supporting timelines for use under other HHS programs.

After consideration of the public comments, we are finalizing an alternative structure for certification criteria for electronic prior authorization. Specifically, we are finalizing separate criteria in 45 CFR 170.315(g)(31), (g)(32), and (g)(33) to support the CRD, DTR, and PAS IGs, respectively, rather than finalizing a single criterion at 45 CFR 170.315(g)(34), as proposed. Finalizing separate certification criteria aligned with the capabilities described in each IG will support a more dynamic health IT marketplace by allowing Health IT Modules to demonstrate conformance to the three required IGs individually, in combination, or as a group. A more detailed discussion of how we are finalizing the proposals in 45 CFR 170.315(g)(34) as part of certification criteria in 45 CFR 170.315(g)(31) through (33) is provided below. As noted previously, we are finalizing the same versions of the IGs to support the criteria in 45 CFR 170.315(g)(31) through (33) as we identified in the HTI–2 Proposed Rule, with the important proviso that these standards are eligible for SVAP, thus enabling developers to certify Health IT Modules to these criteria using newer versions of these adopted standards.

(iii) Coverage Requirements Discovery

In the HTI–2 Proposed Rule, we proposed in 45 CFR 170.315(g)(34)(i) that the ''prior authorization API—provider'' certification criterion must support capabilities related to coverage discovery (89 FR 63588). We noted that these proposals were intended to facilitate the automation of both information exchange and prior authorization and reduce the need for provider-end manual intervention. We stated that Health IT Modules certified to this certification criterion would be able to request coverage information from a payer, for instance when a future encounter is being scheduled for a patient, and to initiate prior authorization electronically when a treatment decision has been made. We stated that these requirements would ensure that providers can request and receive a wide variety of information including updates to coverage information, alternative services or products, documentation requirements and rules related to coverage, forms, and templates to complete, and indications of whether prior authorization is required.

In 45 CFR 170.315(g)(34)(i), we proposed that a Health IT Module certified to the criterion must support capabilities to initiate and exchange information with payer systems as a client to support the identification of coverage requirements (89 FR 63588 and 63589). In 45 CFR 170.315(g)(34)(i)(A) we proposed that the Health IT Module must support the requirements described in the ''Privacy, Security, and Safety'' section of at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(1) (where we proposed to adopt the CRD IG version 2.0.1—STU 2). In 45 CFR 170.315(g)(34)(i)(B), we proposed that the Health IT Module must support capabilities in 45 CFR 170.315(j)(20) (where we proposed to adopt the ''workflow triggers for decision support interventions'' certification criterion) to enable workflow triggers to call decision support services, including support for ''appointment-book,'' ''encounter-start,'' ''encounter-discharge,'' ''order-dispatch,'' ''order-select,'' and ''order-sign'' CDS Hooks, according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(1) and requirements in 45 CFR 170.315(j)(20).

In 45 CFR 170.315(g)(34)(i)(C), we proposed that the Health IT Module must support the requirements applicable to ''CRD Clients'' in at least one of the versions of the implementation specification in 45 CFR 170.215(j)(1) including, as proposed in 45 CFR 170.315(g)(34)(i)(C)(*1*), the requirements in the ''CRD Client CapabilityStatement,'' and, as proposed in 45 CFR 170.315(g)(34)(i)(C)(*2*), support for the ''SHOULD'' requirements applicable to ''CRD Clients'' in Section 5.8 ''Additional Data Retrieval.'' We requested public input on whether to instead finalize a policy that these ''SHOULD'' requirements should be treated as ''SHALL'' requirements.

The following is a summary of the comments we received and our responses:

Comment: Several commenters offered general support for our requirements for the use of the CRD IG as the basis for the criterion elements in 45 CFR 170.315(g)(34)(i). Commenters noted that feedback from early implementations of the CRD IG have shown that the functionality reflected in the IG can provide substantial value in facilitating prior authorization workflows.

Response: We thank commenters for their support for our proposal to require support for the CRD IG.

Comment: Several commenters supported our proposal in 45 CFR 170.315(g)(34)(i)(C)(2) to require support for ''SHOULD'' requirements applicable to Coverage Requirements Discovery (CRD) Clients for additional data retrieval. These commenters stated that implementing a pre-fetch query functionality is critical for a CDS server to fully determine coverage requirements and reduce the need for manual intervention by clinicians.

Response: We thank commenters for their support.

Comment: Other commenters expressed concerns with our proposal to require support for ''SHOULD'' requirements applicable to CRD clients for additional data retrieval, and our discussion of treating these requirements as ''SHALL'' requirements. Commenters stated that the IG includes several ambiguous requirements, such as automatic parsing of clinical decision support (CDS) discovery endpoints and limited coverages returned in search based on payer client, and recommended that additional development time should be provided in order to resolve these ambiguities. Another commenter recommended that, while developers may choose to include such functionality in Health IT Modules, ASTP/ONC should not require implementation of these requirements for certification.

Response: We appreciate the comments regarding our proposal in 45 CFR 170.315(g)(34)(i)(C)(2) to require the ''SHOULD'' requirements applicable to ''CRD Clients'' in the ''Additional Data Retrieval'' section of the CRD IG. While we believe these capabilities may result in a more efficient and timely CRD workflow for users, we acknowledge and agree with the feedback that these requirements are currently optional in

the CRD IG and may not currently provide sufficient technical detail needed for implementation. As a result, we are not finalizing this proposed requirement. However, we encourage developers to consider implementation of these capabilities and encourage the standards community to continue to iterate upon and refine these capabilities in future versions of the CRD IG.

Comment: Regarding our proposal that a Health IT Module certified to the ''prior authorization API—provider'' support the six different hooks identified in the proposed rule, several commenters recommended that ASTP/ONC provide additional flexibility regarding what hooks developers are required to support. Commenters stated that the proposed requirements represented demands on Health IT Modules over and above the requirements in the IGs and recommended ASTP/ONC consider focusing on an initial core set of hooks that can expand over time as workflows develop.

Response: We thank commenters for their feedback on our proposal in 45 CFR 170.315(g)(34)(i)(B) to require support for the ''appointment-book'', ''encounter-start'', ''encounter-discharge'', ''order-dispatch'', ''order-select,'' and ''order-sign'' CDS Hooks. We appreciate commenter feedback requesting additional flexibility regarding the proposed requirements, particularly that not all Health IT Modules would be used in the workflows corresponding to the proposed CDS Hooks. Furthermore, we agree with commenters' recommendation to focus on a smaller set of hooks for initial implementation. We also acknowledge that many of the proposed CDS Hooks are indicated by the CDS Hooks IG as low maturity. We believe requiring only the ''order-sign'' CDS Hook will provide a relatively mature and impactful CDS Hook for initial baseline criterion requirements for provider systems. The ''order-sign'' CDS Hook is one of the ''primary hooks'' of the CRD IG and, according to the CDS Hooks IG, the most mature of the six CDS Hooks proposed. We encourage industry to explore opportunities to implement other CDS Hooks to reduce provider burden.

Comment: Several commenters noted that implementers are currently evaluating if a regular FHIR operation or a CDS hook could best execute the actions identified under the CRD IG. These commenters stated that if developers are required to certify Health IT Modules to CDS Hooks, opportunities for innovation and iteration on the IGs may be slowed, which are important given the evolving nature of the IG. Other commenters stated that they did not see a compelling need to require CDS Hooks as the only mechanism to invoke a payer service. Instead, the commenters recommended that ASTP/ONC define an operation definition that MAY be supported and only finalize requirements for the use of CDS Hooks as ''SHOULD'' requirements.

Response: We appreciate commenters' recommendations. We note that CDS Hooks is a central component within the CRD IG workflow, and we believe it is an important and extensible functionality for industry to pursue. We do not agree that requiring CDS Hooks will slow innovation on the IG; rather, the widespread use and deployment of CDS Hooks will result in more robust interoperability and dynamic information workflows to send and receive data in support of electronic prior authorization, among many other potential use cases. Where there may be opportunities to improve the CDS Hooks IG, such widespread deployment will allow for more rapid revision and improvement of the IG. While we are aware of alternatives to CDS Hooks to invoke a payer service, we note that only the CDS Hooks IG is cross-referenced in the CRD IG for this purpose. Thus, we are finalizing only the use of the CDS Hooks IG for this purpose to be consistent with the CRD IG. Also, we are finalizing a limited scope of ''SHOULD'' requirements with specific support requirements in 45 CFR 170.315(g)(31)(i)(B) to call decision support services including support for the ''order-sign'' CDS Hook.

Comment: Commenters noted that the triggers included in the CRD IG capability statement assume that an encounter has occurred. However, there are numerous scenarios in which the prior authorization workflow may be initiated in the absence of a patient encounter. Commenters recommended that ATSP/ONC finalize an expanded set of trigger events including those that are not dependent upon a patient encounter.

Response: We thank commenters for their input, but we decline to articulate a list of triggers necessary to initiate a prior authorization workflow at this time. We expect implementers to work with standards developers to refine aspects of the CRD IG, leveraging real-world experience, to achieve more consistent and effective implementation of coverage requirements discovery workflows. These refinements may include expanding the scenarios under which a prior authorization workflow must be initiated.

After consideration of the public comments, we are finalizing the proposed requirements in 45 CFR 170.315(g)(34)(i) as part of the ''provider prior authorization API—coverage requirements discovery'' certification criterion in 45 CFR 170.315(g)(31), with modifications. We describe how the proposed requirements map to the requirements we are finalizing below.

In general, we are finalizing technical requirements in 45 CFR 170.315(g)(31)(i) to require the capabilities associated with the ''CRD Client'' system actor defined in the CRD IG to enable users to request and receive coverage requirements. The regulation text we are finalizing in 45 CFR 170.315(g)(31) reorganizes, rephrases, and reduces the scope of the requirements proposed in 45 CFR 170.315(g)(34)(i).

We proposed to require in 45 CFR 170.315(g)(34)(i)(B) and 45 CFR 170.315(g)(34)(i)(B)(*1*) to require support for the capabilities in 45 CFR 170.315(j)(20) to enable workflow triggers to call decision support services, including support for ''appointment-book'', ''encounter-start'', ''encounter-discharge'', ''order-dispatch'', ''order-select,'' and ''order-sign'' CDS Hooks, according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(1) and requirements in 45 CFR 170.315(j)(20) of this section. We are finalizing with modification these requirements in 45 CFR 170.315(g)(31)(i)(B) to enable workflow triggers to call decision support services, to streamline the text, and limit the required CDS Hooks to only ''order-sign.''

We proposed in 45 CFR 170.315(g)(34)(i)(C) and 45 CFR 170.315(g)(34)(i)(C)(*1*) and (*2*) to require support for the requirements applicable to ''CRD Clients'' in at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(1), including the requirements in the ''CRD Client CapabilityStatement'' and the ''SHOULD'' requirements applicable to ''CRD Clients'' in Section 5.8 ''Additional Data Retrieval.''

We are finalizing requirements in 45 CFR 170.315(g)(31)(i)(C) to support all requirements and capabilities applicable to a ''CRD Client,'' with modification to combine and rephrase the proposed paragraphs of 45 CFR 170.315(g)(34)(i)(C) and 45 CFR 170.315(g)(34)(i)(C)(*1*) for more streamlined text and clarity. While not explicitly stated in the paragraph we are finalizing at 45 CFR 170.315(g)(31)(i)(C), Health IT Modules will be required to

support the ''CRD Client CapabilityStatement'' as part of supporting all required capabilities applicable to ''CRD Clients,'' according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(1) (where we are adopting the CRD IG version 2.0.1—STU 2). We are not finalizing proposals at 45 CFR 170.315(g)(34)(i)(C)(*2*) for reasons discussed in our response to comments.

We are finalizing 45 CFR 170.315(g)(31)(i)(A) to clarify required support for registration capabilities applicable to ''CRD Clients.'' This subparagraph clarifies a requirement proposed at 45 CFR 170.315(g)(34)(i)(C) for ''CRD Clients'' that is stated in the CRD IG but was not explicitly identified in the regulation text proposed at 45 CFR 170.315(g)(34). We note that a ''CRD Client'' must register with a ''CDS Service'' as a prerequisite to enable other required ''CRD Client'' FHIR API data capabilities. Registration requirements are described in the CDS Hooks and CRD IGs, thus we are finalizing the requirement in 45 CFR 170.315(g)(31)(i)(A) to remove potential ambiguity regarding required support for these critical capabilities in the Certification Program.

We clarify that for the purposes of this requirement, ''registration'' includes registration and configuration necessary to exchange data for the purposes of coverage requirements discovery using workflows in accordance with CDS Hooks and CRD IGs we are finalizing at 45 CFR 170.215(f) and 45 CFR 170.215(j), respectively. See the section ''Security and Safety'' in the CDS Hooks IG [477] and the section ''Enabling a CRD Server'' in the CRD IG [478] for additional details about the registration processes described in those IGs.

We are also finalizing a paragraph for documentation requirements for the ''provider prior authorization API—coverage requirements discovery'' criterion in 45 CFR 170.315(g)(31)(ii), which states that supported API server capabilities of ''CRD Clients'' from the CRD IG must include complete accompanying technical documentation. The requirements we are finalizing are based on the documentation requirements we proposed in the HTI–2 Proposed Rule at 45 CFR 170.404(a)(2)(i) and its subparagraphs (89 FR 63592 through 89 FR 63593).

In the HTI–2 Proposed Rule, we proposed to include additional documentation requirements in 45 CFR 170.404(a)(2)(i) and proposed that provisions of the API Condition and Maintenance of Certification requirements at 45 CFR 170.404, including the proposed documentation requirements in 45 CFR 170.404(a)(2)(i), would be applicable to the proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34) (89 FR 63592 through 63593).

However, we proposed the documentation requirements in 45 CFR 170.404(a)(2)(i) in tandem with proposals to remove similar language around documentation requirements from the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10). Under the narrow scope of this final rule, we are not finalizing any proposals in 45 CFR 170.315(g)(10), and therefore we are not finalizing the related documentation requirements in 45 CFR 170.404(a)(2)(i). Instead, we are finalizing references to ''complete accompanying technical documentation'' as part of the criteria in 45 CFR 170.315(g)(31)(ii) and 45 CFR 170.315(g)(33)(ii).

For the purposes of the requirement in 45 CFR 170.315(g)(31)(ii), we clarify that the following is expected to be included as part of complete accompanying technical documentation as applicable: (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns; (2) the software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s); and (3) all applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server. The expectation for technical documentation is consistent with what is currently required at 45 CFR 170.315(g)(10)(viii). Pursuant to the API Condition and Maintenance of Certification requirements at 45 CFR 170.404, which we are finalizing to apply to the ''provider prior authorization API—coverage requirements discovery'' criterion in section XI.*B*.4.b.(6)(c) of this final rule, the complete accompanying technical documentation required by 45 CFR 170.315(g)(31)(ii) must be publicly published as part of the Certified API Developer's complete business and technical documentation. We discuss revisions to 45 CFR 170.404 with implications for certified health IT developers that have Health IT Modules certified to 45 CFR 170.315(g)(31), (g)(32), and (g)(33) in section XI.*B*.4.b.(6)(d) of this final rule.

(iv) Documentation Templates and Rules

In 45 CFR 170.315(g)(34)(ii) we proposed requirements related to documentation and rules exchange (89 FR 63589). The DaVinci DTR and CRD IGs utilize Clinical Quality Language (CQL) to allow payers to inspect a patient's record for the necessary information related to the required documentation for a proposed item (such as durable medical equipment), medication, procedure, or other service. The DTR IG details the use of a payer provided Questionnaire resource and results from CQL execution to generate a QuestionnaireResponse resource containing the necessary information. We noted that this IG can allow payer APIs to specify how rules may be executed in a provider context so that documentation requirements are met, while at the same time reducing provider burden by reducing manual data entry.

We proposed in 45 CFR 170.315(g)(34)(ii) that a Health IT Module certified to the ''prior authorization API—provider'' certification criterion must support the ability to request and populate prior authorization documentation templates and rules from payer systems according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(2) (where we proposed to adopt the DTR IG version 2.0.1—STU 2).

We noted at 89 FR 63589 that ''Light'' DTR capabilities are applicable to EHRs that rely on a SMART on FHIR application to handle the form filling function of DTR. This requires the server to provide access to the specified resources to allow such an app to retrieve and edit QuestionnaireResponses and related resources. In 45 CFR 170.315(g)(34)(ii)(A)(*1*), we proposed the Health IT Module must support the capabilities included in the ''Light DTR EHR'' CapabilityStatement according to at least one versions of the implementation specification adopted in 45 CFR 170.215(j)(2) (where we proposed to adopt the DTR IG version 2.0.1—STU 2). In 45 CFR 170.315(g)(34)(ii)(A)(*2*)(*i*), we proposed that the Health IT Module must support functional registration of the ''DTR SMART Client'' according to the requirements included in 45 CFR 170.315(j)(1) (where we proposed to

[477] See *https://cds-hooks.hl7.org/#security-and-safety*.

[478] See *https://hl7.org/fhir/us/davinci-crd/STU2/foundation.html#enabling-a-crd-server*.

adopt a ''functional registration'' criterion). We also proposed in 45 CFR 170.315(g)(34)(ii)(A)(*2*)(*ii*) that the Health IT Module must support dynamic registration of the ''DTR SMART Client'' according to the requirements included in 45 CFR 170.315(j)(2) (where we proposed to adopt a certification criterion for ''dynamic registration'').

In 45 CFR 170.315(g)(34)(ii)(A)(*3*), we proposed that the Health IT Module must support launching the ''DTR SMART Client'' according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(2) (where we proposed to adopt the DTR IG version 2.0.1—STU 2) to allow providers to launch an app to complete documentation for prior authorization according to at least one of the versions of the implementation specification in 45 CFR 170.215(j)(2). In 45 CFR 170.315(g)(34)(ii)(A)(*3*)(*i*) we proposed that the Health IT Module must support authentication and authorization during the process of granting access to patient data to users according to the requirements in 45 CFR 170.315(j)(10) (where we proposed to adopt a certification criterion for ''SMART clinician access for EHR launch''). In 45 CFR 170.315(g)(34)(ii)(A)(*3*)(*ii*) we proposed that the Health IT Module must support asymmetric certificate-based authentication according to the requirements in 45 CFR 170.315(j)(11) for the ''Light DTR Client'' dynamically registered using the capabilities in 45 CFR 170.315(g)(34)(ii)(A)(*2*)(*ii*).

We stated that in contrast to ''Light DTR EHR'' capabilities, ''full'' DTR capabilities are relevant to EHRs that manage the form filling functions of DTR internally. In 45 CFR 170.315(g)(34)(ii)(B), we proposed that the Health IT Module must support the capabilities included in the ''Full DTR EHR'' CapabilityStatement according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(2) (where we proposed to adopt the DTR IG version 2.0.1—STU 2). Such EHRs need only support client capabilities for the Questionnaire Package, ValueSet Expand, and Next Question operations.

We requested comments on our proposals. The following is a summary of the comments we received and our responses:

Comment: We received numerous comments on our proposal in 45 CFR 170.315(g)(34)(ii) to require Health IT Modules certified to the ''prior authorization API—provider'' certification criterion to support both the capabilities included in the ''Light DTR EHR'' CapabilityStatement and the ''Full DTR EHR'' CapabilityStatement. Some commenters supported our proposal to finalize both requirements, stating that requiring all EHRs to comply with both sets of requirements will ensure market readiness, as some payers may not be ready to support the ''full'' DTR requirements initially and may need to rely upon a DTR SMART App in an EHR or practice management system to support implementation. Other commenters recommended that ASTP/ONC should allow developers to choose whether to support either the ''light'' or ''full'' DTR requirements, stating that a requirement to support both would be duplicative. Finally, numerous commenters recommended that ASTP/ONC, if it finalizes the criterion, should only require support for the ''full'' DTR capabilities. Commenters stated that the ''full'' DTR functionality has more potential for automation and improved performance, whereas implementation of ''light'' capabilities, while providing a faster path to adoption, may result in an inconsistent end-user experience. By contrast, commenters believed that requiring developers to implement the ''full'' DTR process would result in a superior user experience for clinicians and availability of the complete suite of functions including the ability to automate the completing of clinical templates. Moreover, commenters stated that the ''light'' functionality would not provide all of the information needed by payers and would not provide value to clinicians. Availability of the ''full'' DTR functionality would ultimately encourage increased adoption of prior authorization APIs.

Response: We thank commenters for their feedback on our proposal to require support for both ''Full DTR EHR'' and ''Light DTR EHR'' capabilities in the proposed ''prior authorization API—provider'' criterion. We agree with commenters that requiring support for ''Full DTR EHR'' capabilities would require certified API technology to support DTR capabilities that can reduce prior authorization burden through payer questionnaire retrieval and population. We also agree with commenters that ''Light DTR EHR'' capabilities alone would not result in substantial reduction of prior authorization burden and that requiring both ''Light DTR EHR'' and ''Full DTR EHR'' support simultaneously could burden developers with supporting a duplicative DTR workflow. Thus, we believe requiring support for the ''Full DTR EHR'' promotes industry adoption of substantial burden reduction capabilities from the DTR IG while also giving developers implementation flexibility. We note that under the ''Full DTR EHR'' requirements, health IT developers could develop the required DTR capabilities themselves or choose to integrate DTR apps with such capabilities into their Health IT Modules. For purposes of certification to DTR requirements, DTR apps could be integrated into certified health IT as ''relied upon software,'' which is permitted to be used by health IT developers to demonstrate compliance with certification criteria requirements.

After consideration of the public comment, we are finalizing the proposed requirements in 45 CFR 170.315(g)(34)(ii) as part of the ''provider prior authorization API—documentation templates and rules'' certification criterion in 45 CFR 170.315(g)(32), with modifications. Specifically, we are finalizing in 45 CFR 170.315(g)(32) that certified Health IT Modules must support all requirements and required capabilities applicable to a ''Full DTR EHR'' according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(2) (where we are adopting the DTR IG version 2.0.1—STU 2). We are not finalizing proposed requirements to support capabilities specific to a ''Light DTR EHR.''

As part of finalizing our proposal to require support for the capabilities included in the ''Full DTR EHR'' CapabilityStatement under the ''provider prior authorization API—documentation templates and rules'' criterion in 45 CFR 170.315(g)(32), we have made additional modifications to the language proposed in 45 CFR 170.315(g)(34)(ii). We are finalizing three separate paragraphs at 45 CFR 170.315(g)(32)(i)–(iii) to clarify and refine the requirements we initially proposed.

The paragraph we are finalizing in 45 CFR 170.315(g)(32)(iii) includes similar language to proposed 45 CFR 170.315(g)(34)(ii)(B) and requires support for all requirements and required capabilities applicable to a ''Full DTR EHR.'' This revised version of the proposed language provides clarity by rephrasing the requirement using plain language while maintaining the same scope. We note that while the ''Full DTR EHR'' CapabilityStatement artifact is not specifically referenced in the requirement language we are finalizing, health IT developers must support the capabilities required by the ''Full DTR EHR'' CapabilityStatement. Specifically, the requirement to support all requirements and required capabilities applicable to a ''Full DTR

EHR'' would also include support for the ''Full DTR EHR'' CapabilityStatement artifact. We also reiterate general Certification Program policy that all applicable conformance requirements expressed by a standard or implementation guide referenced in certification criteria are required to be supported for the purposes of certification unless otherwise specified. For example, for the 45 CFR 170.315(g)(32) criterion, all ''SHALL'' and ''Must Support'' requirements applicable to the ''Full DTR EHR'' system actor are required to be supported for the purposes of certification.

The paragraph we are finalizing in 45 CFR 170.315(g)(32)(i) specifies required support for registration capabilities applicable to a ''Full DTR EHR.'' This language clarifies a component of the requirement proposed at 45 CFR 170.315(g)(34)(ii)(B) that is included as part of support for requirements applicable to a ''Full DTR EHR'' in the DTR IG. Specifically, a ''Full DTR EHR'' must register with a ''DTR Payer Service'' as a prerequisite necessary to enable other required ''Full DTR EHR'' FHIR API data capabilities. Registration requirements for a ''Full DTR EHR'' are specified in the DTR IG, and we are finalizing requirements in 45 CFR 170.315(g)(32)(iii) to remove ambiguity that such registration requirements must be supported. See section ''Configuring App/EHR to Payer Connectivity'' in the DTR IG [479] for additional details about registration requirements for a ''Full DTR EHR.''

The paragraph we are finalizing in 45 CFR 170.315(g)(32)(ii) includes language to clarify a component of the requirement proposed at 45 CFR 170.315(g)(34)(ii)(B) to support requirements applicable to a ''Full DTR EHR.'' The paragraph at 45 CFR 170.315(g)(32)(ii) specifies required support for system authentication and authorization as a client in accordance with the ''Backend Services'' section of a version of the SMART App Launch IG adopted under 45 CFR 170.215(c). We include this language to clarify potential ambiguity in the DTR IG regarding ''Full DTR EHR'' requirements to support authentication and authorization in accordance with the SMART on FHIR Backend Services specification as well as to provide clarity and consistency to implementers regarding which versions of the SMART on FHIR Backend Services specification are available for the purposes of certification.

The ''Authenticating DTR client to payer API'' section of the DTR IG we are adopting in 45 CFR 170.215(j)(2) specifies the requirement for payers to require DTR EHRs to use SMART on FHIR Backend Services to authenticate to payer DTR API endpoints. As stated in the DTR IG in section ''Authenticating DTR client to payer API,'' [480] this requirement is framed to apply to the payer DTR API endpoint and does not require a specific version of the SMART on FHIR Backend Services specification. The language we are finalizing in 45 CFR 170.315(g)(32)(ii) clarify this element of the IG by (1) describing the effective requirement in the DTR IG explicitly, rather than implicitly through payer conformance requirements, to require the Health IT Module to support authentication and authorization according to SMART on FHIR Backend Services; and (2) requiring support for one of the versions of the SMART on FHIR Backend Services specification contained within the SMART App Launch implementation specifications adopted at 45 CFR 170.215(c).

(v) Prior Authorization Support

Finally, in 45 CFR 170.315(g)(34)(iii) we proposed that the ''prior authorization API—provider'' certification criterion must support capabilities related to the submission of a prior authorization request (89 FR 63588).

For the ''prior authorization API—provider'' certification criterion, we proposed in 45 CFR 170.315(g)(34)(iii)(A) that the Health IT Module must support the ability to submit a prior authorization request to a payer system according to at least one of the versions of the implementation specification adopted in 170.215(j)(3) (where we proposed to adopt the PAS IG version 2.0.1—STU 2). Specifically, we proposed in 45 CFR 170.315(g)(34)(iii)(A)(1) that the Health IT Module include support for the ''EHR PAS Capabilities'' CapabilityStatement according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(3).

We proposed in 45 CFR 170.315(g)(34)(iii)(A)(2) that the Health IT Module support the ability to include documentation created in 45 CFR 170.315(g)(34)(ii) in a prior authorization request to a payer system according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(3). We proposed in 45 CFR 170.315(g)(34)(iii)(A)(3) that the Health IT Module support the ability to consume and process a ''ClaimResponse'' according to at least one of the versions of the implementation specification adopted in 45 CFR 170.215(j)(3). Finally, we proposed in 45 CFR 170.315(g)(34)(iii)(A)(4) that the Health IT Module support subscriptions as a client according to the requirements in 45 CFR 170.315(j)(24) (where we proposed to adopt a ''subscriptions—client'' certification criterion) and an implementation specification in 45 CFR 170.215(j)(3), in order to support ''pended authorization responses.''

Comment: Several commenters highlighted specific technical issues with the PAS IG which commenters have identified as part of ongoing development work on the IG.

Response: We appreciate commenters' highlighting of these issues. We note that several of these issues have been resolved since the publication of the HTI–2 Proposed Rule. We acknowledge that, as with the other Burden Reduction IGs we are adopting in this section, the PAS IG continues to evolve. We appreciate the continued collaboration of interested parties across the standards development community in improving these specifications and will seek to utilize flexibility under the Certification Program to ensure updated versions of the implementation specifications are available for use by health IT developers in a timely manner.

After consideration of the public comments, we are finalizing the proposed requirements in 45 CFR 170.315(g)(34)(iii) as part of the ''provider prior authorization API—prior authorization support'' criterion in 45 CFR 170.315(g)(33), with modifications. The ''provider prior authorization API—prior authorization support'' criterion requires a Health IT Module to submit a prior authorization request as a client in accordance with at least one of the versions of the standard adopted in 45 CFR 170.215(j)(3) (where we are adopting the PAS IG version 2.0.1—STU 2). In comparison to proposed 45 CFR 170.315(g)(34)(iii) and its subparagraphs, the ''provider prior authorization API—prior authorization support'' criterion in 45 CFR 170.315(g)(33) has three categories of technical API requirements at and under 45 CFR 170.315(g)(33)(i).

The paragraph we are finalizing in 45 CFR 170.315(g)(33)(i)(C) and its subparagraphs describe requirements to

[479] *https://hl7.org/fhir/us/davinci-dtr/STU2/specification.html#configuring-appehr-to-payer-connectivity.*

[480] *https://hl7.org/fhir/us/davinci-dtr/STU2/specification.html#authenticating-dtr-client-to-payer-api.*

support prior authorization transactions as a client and include similar language to proposed 45 CFR 170.315(g)(34)(iii)(A) and its subparagraphs, with the exception of the proposed ability in 45 CFR 170.315(g)(34)(iii)(A)(2) to include documentation created in 45 CFR 170.315(g)(34)(ii) in a prior authorization request to a payer system, according to at least one of the versions of the implementation specifications adopted in 45 CFR 170.215(j)(3). That proposed requirement would have required the Health IT Module to support including documentation created using DTR IG capabilities in a prior authorization request to a payer system according to the PAS IG. We are not finalizing this proposed requirement in the ''provider prior authorization API—prior authorization support'' criterion since we are finalizing DTR IG capabilities in a distinct criterion in 45 CFR 170.315(g)(32). We anticipate that developers and implementers of certified health IT will combine capabilities of the CRD, DTR, and PAS IGs to reduce provider burden. This may occur because a certified health IT developer has chosen to certify to all three criteria at 45 CFR 170.315(g)(31) through (g)(33) or because a health IT developer with a Health IT Module certified to one or two of those criteria are working with other certified health IT developers' Health IT Modules to complete the electronic prior authorization workflow.

The paragraphs we are finalizing in 45 CFR 170.315(g)(33)(i)(A) and (B) specify required registration and authentication and authorization capabilities. Paragraph 45 CFR 170.315(g)(33)(i)(A) requires support for registration capabilities applicable to a client system and is a prerequisite capability required to enable authentication and authorization requirements we are finalizing in 45 CFR 170.315(g)(33)(i)(B). Paragraph 45 CFR 170.315(g)(33)(i)(B) requires system authentication and authorization as a client in accordance with the ''Backend Services'' section of at least one of the versions of the implementation specification adopted in 45 CFR 170.215(c).

These paragraphs clarify components of the requirement we proposed in 45 CFR 170.315(g)(34)(iii)(A) to support the ability to submit a prior authorization request to a payer system according to at least one of the implementation specifications adopted in 45 CFR 170.215(j)(3) (where we are finalizing adoption of the PAS IG version 2.0.1—STU 2). The PAS IG requires in section ''Privacy & Security'' that the provider system supports authentication to the payer system or an intermediary, and recommends servers (*e.g.,* payer systems) support the OAuth standard in a server to server capacity. While the PAS IG does not reference a specific version of the OAuth standard, the latest published version of the OAuth standard is OAuth 2.0 Authorization Framework (RFC 6749) [481] (OAuth 2.0) published October 2012. OAuth 2.0 is one of the foundational standards upon which the SMART Backend Services specification is based. Furthermore, the PAS IG requires all client (*e.g.,* provider) systems comply with the ''Security and Privacy'' section of the Da Vinci Health Record Exchange (HRex) IG, without specifying a version of that IG. The ''Security and Privacy'' section of the latest published version of the Da Vinci HRex IG,[482] published December 10, 2024, recommends OAuth server to server authentication as defined in the SMART Backend Services specification as one option when the identity of the requesting or receiving party is important.

Of the options recommended by the Da Vinci HRex IG, we believe the SMART Backend Services specification aligns most closely with the authentication recommendation from the PAS IG and is a specification already widely supported in a server capacity by developers of certified health IT in accordance with the requirements in the 45 CFR 170.315(g)(10) ''standardized API for patient and population services'' criterion. We believe clarifying a requirement for this otherwise optional authentication specification is necessary to establish a consistent baseline authentication and authorization mechanism in the Certification Program for provider systems to authenticate with and receive authorization from payer systems when using prior authorization transaction capabilities from the PAS IG.

We further note that according to our proposal in 45 CFR 170.315(g)(34)(ii)(B), Health IT Modules certified to 45 CFR 170.315(g)(34) would have been required to support the ''Full DTR EHR'' capabilities from the DTR IG (89 FR 63589 through 63590). As discussed in a previous comment response, supporting the SMART Backend Services specification as a client is part of implementing the ''Full DTR EHR'' capabilities from the DTR IG, and thus would have been required as part of the proposal at 45 CFR 170.315(g)(34)(ii)(B). Since we are finalizing DTR IG and PAS IG capabilities from the 45 CFR 170.315(g)(34) proposal in distinct criteria at 45 CFR 170.315(g)(32) and (33) respectively, we finalize paragraphs 45 CFR 170.315(g)(32)(ii) and 45 CFR 170.315(g)(33)(i)(B) in those criteria to establish consistent requirements to support the SMART Backend Services specification as a client.

In addition to the technical requirements we are finalizing at and under paragraph 45 CFR 170.315(g)(33)(i), we are also finalizing a paragraph for documentation requirements for the 45 CFR 170.315(g)(33) criterion in 45 CFR 170.315(g)(33)(ii). This paragraph requires that supported subscriptions client endpoint capabilities for the ''REST-Hook'' channel from the PAS IG must include complete accompanying technical documentation. These requirements complement existing requirements in the ''Transparency conditions'' at 45 CFR 170.404(a)(2) in lieu of finalizing the revisions to 45 CFR 170.404(a)(2)(i) and its subparagraphs that were proposed in the HTI–2 proposed rule.

For the purposes of this requirement, we clarify that the following is expected to be included as part of complete accompanying technical documentation as applicable: (1) API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns; (2) the software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s); and (3) all applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server. Pursuant to the API Condition and Maintenance of Certification requirements at 45 CFR 170.404, the documentation required by 45 CFR 170.315(g)(33)(ii) must be publicly published as part of the Certified API Developer's complete business and technical documentation. We discuss the finalization of including 45 CFR 170.315(g)(33) in the 45 CFR 170.404 API Condition and Maintenance of Certification requirements in section IX.*B*.4.b.(6)(d) of this final rule.

In summary, after consideration of the public comment, we are finalizing the following three certification criteria based on the ''prior authorization API—provider'' criterion we proposed in in 45 CFR 170.315(g)(34):

[481] *https://datatracker.ietf.org/doc/html/rfc6749.*

[482] *https://hl7.org/fhir/us/davinci-hrex/STU1.1/security.html.*

• Provider prior authorization API—coverage requirements discovery (45 CFR 170.315(g)(31)).
• Provider prior authorization API—documentation templates and rules (45 CFR 170.315(g)(32)).
• Provider prior authorization API—prior authorization support (45 CFR 170.315(g)(33)).

These criteria include additional modifications to the proposals for the ''prior authorization API—provider'' criterion that we are finalizing in response to public comments, and in order to streamline and clarify requirements in the final criteria. We have discussed these modifications in detail above.

(vi) Support for CMS Requirements

In the HTI–2 Proposed Rule (89 FR 63591) we noted that the ''prior authorization API—provider'' certification criterion proposed in 45 CFR 170.315(g)(34), if finalized, would support the availability of certified health IT that can enable health care providers to interact with the Prior Authorization APIs established pursuant to CMS payer API requirements, using certified health IT. CMS also finalized Electronic Prior Authorization measures for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability Performance Category in the CMS Interoperability and Prior Authorization Final Rule (89 FR 8926). These measures are intended to incentivize eligible hospitals, CAHs, and eligible clinicians to use Prior Authorization APIs to submit their prior authorization requests (89 FR 8946). We stated that if we finalized our proposal for the ''prior authorization API—provider'' certification criterion, adopting and using technology certified to this criterion would enable MIPS eligible clinicians, eligible hospitals and CAHs to complete the prior authorization request actions associated with these measures using certified health IT.

We also noted in the HTI–2 Proposed Rule that, at that time, CMS had not identified health IT certified to specific criteria to complete the actions specified for finalized Electronic Prior Authorization measures in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category (89 FR 63581 through 63582, 63591). We discussed how, if the proposed ''prior authorization API—provider'' certification criterion was finalized, we would work with CMS on appropriate steps within the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category to identify health IT certified to this criterion as an element of CEHRT necessary to report on the Electronic Prior Authorization measures. As CMS noted in the Interoperability and Prior Authorization Final Rule, use of health IT certified to support electronic prior authorization transactions can help to ensure that the actions associated with these measures are executed in a consistent fashion across the health care providers participating in these programs (89 FR 8926).

Comment: Commenters stated that enabling providers to interact with APIs that payers are developing will be important for the uptake of these payer APIs and realizing the potential benefits of electronic prior authorization. Commenters also believed that the availability of health IT certified to the ''prior authorization API—provider'' criterion would ensure that healthcare providers participating in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category will be able to meet requirements for reporting the Electronic Prior Authorization measures CMS has finalized.

Response: We thank commenters for their support and will collaborate with CMS on steps to identify the criteria in 45 CFR 170.315(g)(31), (32), and (33) that we are finalizing in this rule as necessary to support reporting of the Electronic Prior Authorization measures finalized for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.

Comment: Commenters expressed concerns about alignment between the Da Vinci CRD, DTR, and PAS IGs proposed for incorporation in the ''prior authorization API—provider'' criterion and the versions of the USCDI standard and US Core IG proposed for adoption in the HTI–2 Proposed Rule. Commenters stated that the proposed versions of the Da Vinci IGs have not yet been updated to reference proposed versions of the USCDI standard and US Core IG, creating potential misalignment across requirements. Commenters also expressed concerns about the timeline for adoption of updated versions of these standards relative to deadlines that have been established by CMS for establishment of APIs meeting the requirements in the Interoperability and Prior Authorization final rule by impacted payers.

Response: We appreciate commenters' concerns regarding alignment of CRD, DTR, and PAS IGs with USCDI and US Core IG versions. We agree that there are degrees of misalignment between Version 2.0.1 of the CRD, DTR, and PAS IGs with the versions of USCDI and the US Core IG we proposed for adoption in the HTI–2 Proposed Rule. We note that we are not finalizing USCDI Version 4 and US Core IG Version 7 as part of this final rule. Thus, developers will not encounter potential misalignment if they certify to criteria we are finalizing in this rule that reference the Da Vinci standards using USCDI Version 3 and US Core IG 6.1. Further, we note that the 2.1.0 versions of the CRD, DTR, and PAS IGs have been updated to cover USCDI Version 4 and US Core IG Version 7. Taken together, this means that developers certifying Health IT Modules to certification criteria that reference these IGs may do so using USCDI Version 3 and US Core IG Version 6 or, by using SVAP, certify using subsequent versions of USCDI and US Core IG (up to Version 7, currently) and avoid misalignment. Regarding CMS requirements for payer APIs, as we are not finalizing USCDI Version 4 and US Core IG Version 7 in this final rule, payers would not be subject to challenges related to misalignment based upon these proposed versions at this time. We will continue to work closely with CMS to manage issues of alignment across adopted standards.

Comment: We received numerous comments on issues related to CMS policies around prior authorization, including comments on the Prior Authorization API requirements finalized in the Interoperability and Prior Authorization final rule, and comments around other policies related to prior authorization that CMS could seek to advance as part of programs.

Response: We value these recommendations and will ensure that these inputs are shared with CMS. We will work together with CMS to further explore opportunities to address these issues.

(vii) Administrative Simplification Requirements Under HIPAA

We noted that, pursuant to the administrative simplification rules established under HIPAA, the Secretary must adopt electronic standards for use by ''covered entities,'' which is defined as including health plans, healthcare clearinghouses, and certain healthcare providers.[483] We noted that the two standards adopted for referral certification and authorization transactions under the HIPAA administrative simplification rules (45 CFR 162.1302) include: NCPDP Version

[483] For more information, *see https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification.*

D.0 for retail pharmacy drugs; and X12 Version 5010x217 278 (X12 278) for dental, professional, and institutional request for review and response for items and services. HHS has also proposed to adopt the X12 275 standard, which is used to transmit additional documentation to support the exchange of the additional information that is required for prior authorization, in the ''Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard'' proposed rule (87 FR 78438).

We stated that nothing in our proposed certification criteria related to electronic prior authorization would alter requirements for covered entities to use adopted HIPAA transaction standards. Moreover, the FHIR specifications we proposed to adopt for these certification criteria would not conflict with the use of the adopted HIPAA standard, and we stated we would expect covered entities using technology certified to these criteria to ensure compliance with applicable requirements.

We noted that in March 2021, the CMS National Standards Group (NSG), on behalf of HHS, approved an application [484] from an industry group of payers, providers, and vendors for an exception under 45 CFR 162.940 from the HIPAA transaction standards for Da Vinci payers and their trading partners when using the FHIR standard for prior authorization. Under this exception, the group tested a prior authorization exchange using the HL7 FHIR Da Vinci standard without the X12 278 standard to determine whether this alternative standard for prior authorization could improve efficiency. HHS provides information about requests for exceptions from standards to permit testing of proposed modifications on the CMS HIPAA administrative simplification website.[485]

On February 28, 2024, CMS NSG, on behalf of HHS, announced an application of enforcement discretion for HIPAA covered entities that implement FHIR-based Prior Authorization APIs as described in the CMS Interoperability and Prior Authorization Final Rule (89 FR 8758).[486] HHS stated that this action was in response to feedback received on multiple notices of proposed rulemaking and extensive stakeholder outreach and is intended to promote efficiency in the prior authorization process. Specifically, HHS stated that HIPAA Administrative Simplification enforcement action will not be taken against HIPAA covered entities that choose not to use the X12 278 standard as part of an electronic FHIR prior authorization process. We stated that HHS will continue to evaluate the HIPAA prior authorization transaction standards, including continuing to seek stakeholder input and evaluating the results of testing an all-FHIR-based transaction.

We received numerous comments on our discussion of the intersection between our proposals and standards adopted by CMS for administrative simplification transactions.

Comment: Several commenters raised concerns about the intersection between the proposed ''prior authorization API—provider'' criterion and the existing standards landscape for electronic prior authorization, which includes adoption and use of the X12 278 standard. Commenters stated that it is unclear how healthcare providers, if using Health IT Modules certified to the proposed ''prior authorization API—provider'' criterion, would be able to interact with health plans that continue to use the X12 278 standard. A commenter cited the 2023 CAQH Index Report, noting that while industry adoption of the X12 278 is low at 31 percent, it has increased from 13 percent in 2019. Commenters stated that they expect there will be a significant length of time beyond the January 1, 2027, compliance date for impacted payers when healthcare providers will continue to use the X12 278 standard. Commenters expressed concerns that adoption of these certified Health IT Modules would create a bifurcated approach between the use of X12 and FHIR approaches to completing prior authorization requests, and that physician practices would need to contract with intermediaries in order to continue to use the X12 278 standard where necessary. Commenters believed that covered entities would effectively be prohibited from using the mandated X12 transactions, particularly for the prior authorization submission step, and that under the proposals in the HTI–2 Proposed Rule and the final policies in the Interoperability and Prior Authorization final rule, ASTP/ONC and CMS would create a scenario in which covered entities have no option to use the legally mandated transaction standard. Commenters further argued that this approach seems contrary to the Congressional mandate set out in the HIPAA electronic healthcare transactions. Commenters encouraged ASTP/ONC to work with CMS to clarify the use of X12 transactions within electronic prior authorization workflows.

Response: We appreciate commenters' concerns regarding the intersection of different HHS policies addressing standards for electronic prior authorization. We continue to work closely with CMS to address ongoing regulatory strategy around such standards. While our finalization of certification criteria at 45 CFR 170.315(g)(31), (32), and (33) would support the availability of health IT enabling healthcare providers to conduct electronic prior authorization activities using the FHIR standards that we are adopting in this final rule, these final policies would not limit providers to exclusive use of technology using these standards for electronic prior authorization.

Comment: Commenters acknowledged the availability of enforcement discretion issued by CMS as discussed in the proposed rule (89 FR 63591 through 63592) and stated their appreciation for this flexibility. However, commenters raised concerns that this enforcement discretion could be revoked at any time. Commenters also noted that the administrative simplification exception provided for use of Da Vinci standards has been completed but the findings from the exceptions process have not yet been made available to the public and suggested that this would be an important resource for the public to be able to use when evaluating the proposed prior authorization approaches.

Response: We acknowledge commenters' concerns regarding reliance on CMS' enforcement discretion. We believe this enforcement discretion provides significant flexibility to healthcare providers and payers to pursue innovative approaches to electronic prior authorization at the present time. However, we continue to support CMS' efforts to establish long-term regulatory strategies in this area that support these goals. We note that the findings from the exception granted to the Da Vinci project are now

[484] *See https://confluence.hl7.org/display/DVP/Da+Vinci+HIPAA+Exception?preview=/113675673/113675685/Approval%20%232021031001.pdf.*

[485] Centers for Medicare & Medicaid Services (2022). Go-to-Guidance, Guidance Letters. Retrieved from *https://www.cms.gov/priorities/key-initiatives/burden-reduction/administrative-simplification/subregulatory-guidance/letters.*

[486] *See https://www.cms.gov/files/document/discretion-x12-278-enforcement-guidance-letter-remediated-2024-02-28.pdf.*

available.[487] We refer readers to the notice that appeared in the **Federal Register** on April 29, 2025, regarding the availability and location of the HL7 International Da Vinci Project Report (90 FR 17827). The report found that participants were able to successfully use standards-based FHIR APIs to conduct prior authorization transactions, and indicates that scaling adoption of this approach to information sharing is likely to deliver significant benefits to entities currently facing administrative burden associated with prior authorization processes. The findings from this report will continue to inform policy development and future implementation of the policies we are finalizing in this final rule.

Comment: Several commenters discussed whether the proposed certification criterion should also address exchange of prior authorization information using the X12 standard. Some commenters recommended that certified health IT should be required to support both an option using X12 as well as an option using FHIR. However, other commenters stated that inclusion of the X12 278 transaction as part of the proposed API would result in needless burden and cost for both providers and health plans, and that exchange partners should leverage the enforcement discretion provided by CMS to avoid mapping the X12 278 transaction as part of the electronic prior authorization API workflow.

Response: We did not propose, and are not finalizing, requirements for Health IT Modules certified to the certification criteria at 45 CFR 170.315(g)(31), (32), and (33) to demonstrate conformance or mapping to the X12 278 transaction. We agree with commenters that requiring all such Health IT Modules to include this functionality would increase costs and burden without an associated benefit, as healthcare providers may conduct electronic prior authorization activities without mapping requests to the X12 278 transaction at this time. However, this would not restrict health IT developers, payers, or other intermediaries, from providing for this mapping where such mapping may be necessary to complete electronic prior authorization transactions with payers via the X12 278 transaction.

Comment: Commenters noted that CMS has proposed to adopt the X12 275 standard and Consolidated Clinical Document Architecture (C–CDA) as relevant standards for healthcare attachments. Commenters expressed concern that there would be redundancy between this proposal, if finalized, and the proposed use of the Da Vinci FHIR PAS IG proposed for use in the ''prior authorization API—provider'' criterion. This IG references the Da Vinci Clinical Data Exchange (CDex) IG for attachments, rather than the X12 275 standard and C–CDA proposed by CMS. Commenters believed that these concurrent policies, if finalized, would create confusion for those implementing electronic prior authorization.

Response: We recognize that CMS has proposed the use of the C–CDA for attachment information accompanying the X12 275 transaction, including for prior authorization information, in the Administrative Simplification: Adoption of Standards for Health Care Attachments Transactions and Electronic Signatures, and Modification to Referral Certification and Authorization Transaction Standard proposed rule (87 FR 78438), which appeared in the **Federal Register** on December 21, 2022. This rule has not been finalized as of the publication of this final rule. We will continue to work with CMS on addressing any potential intersection between the policies in this rulemaking and policies which CMS may finalize in the future around HIPAA administrative simplification standards.

(d) Revision and Addition of API Condition and Maintenance of Certification Requirements

(i) Background

In the HTI–2 Proposed Rule, we made proposals to extend the applicability of the API Conditions of Certification in 45 CFR 170.404(a) and certain API Maintenance of Certification requirements in 45 CFR 170.404(b) to Certified API Developers with Health IT Modules certified to the criteria proposed for adoption in in 45 CFR 170.315(g)(7) through (10), 45 CFR 170.315(g)(20), 45 CFR 170.315(g)(30)–(36), and 45 CFR 170.315(j). In this final rule, we are only finalizing policies related to one of these proposed criteria, specifically the criterion in 45 CFR 170.315(g)(34). Therefore, in this section, we limit our focus to proposals from the HTI–2 proposed rule relevant to the proposed criterion in 45 CFR 170.315(g)(34). Specifically, we focus on proposals to amend the applicability of the following: the introductory text to 45 CFR 170.404, 45 CFR 170.404(b)(1), 45 CFR 170.404(b)(1)(i), and certain definitions in 45 CFR 170.404(c).

In addition to proposals in the HTI–2 Proposed Rule extending the applicability of 45 CFR 170.404, we also made proposals to update the requirements in 45 CFR 170.404. These proposals were made in tandem with proposals to update other elements of the Certification Program, including proposals to update to the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10), which we are not finalizing in this final rule. Accordingly, we are not finalizing any of the updates proposed to the requirements in 45 CFR 170.404 in the HTI–2 Proposed Rule, except for changes to the applicability of 45 CFR 170.404 with respect to the specific certification criteria that we are finalizing in this final rule.

However, we note that, with respect to proposals in the HTI–2 Proposed Rule to 45 CFR 170.404(a)(2)(i) regarding the technical documentation that a Certified API Developer must make available (89 FR 63592), we are finalizing related requirements within certification criteria being finalized in this rule in 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33). Our proposal in the HTI–2 proposed rule, if finalized, would have included language regarding technical documentation in 45 CFR 170.404(a)(2)(i), which would have been applicable to the proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34), pending the finalization of the proposals to expand the applicability of 45 CFR 170.404 to the criterion in 45 CFR 170.315(g)(34). We believe these technical documentation requirements are important to transparency around the APIs in the criteria we are finalizing in 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33) that are based on the 45 CFR 170.315(g)(34) proposal. Thus, we are finalizing a reference to complete accompanying technical documentation, as proposed in 45 CFR 170.404(a)(2)(i), within the text of the relevant certification criteria in 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33). We direct readers to the finalization of those criteria in this section for more information.

(ii) Proposals

In the HTI–2 Proposed Rule we proposed to add several proposed certification criteria to the existing list of criteria for which the requirements in 45 CFR 170.404 would apply, unless otherwise specified, which included the criterion in 45 CFR 170.315(g)(34). We stated that if our proposals were finalized, this would mean that the API Condition and Maintenance of Certification requirements would apply to developers of Health IT Modules certified to 45 CFR 170.315(g)(34). We stated we believe this approach is

[487] *See https://confluence.hl7.org/spaces/DVP/pages/113675673/Da+Vinci+HIPAA+Exception.*

essential to continue to fulfill the statutory requirements set forth in PHSA section 3001(c)(5)(D)(iv), in particular the statutory requirement that a developer of certified health IT has published application programming interfaces and allows health information from such technology to be accessed, exchanged, and used without special effort. As we described in the ONC Cures Act Final Rule (84 FR 7476 through 7477), we established the API Condition and Maintenance of Certification requirements to, among other outcomes, promote transparency and pro-competitive business practices among Certified API Developers in pursuit of a policy that would result in access, exchange, and use of EHI ''without special effort.'' We stated we believe that these same requirements should apply to developers of new API-related certification criteria, and that the proposals to reference additional API certification criteria in 45 CFR 170.404 (inclusive of the criterion in 45 CFR 170.315(g)(34)) would continue to adhere to our statutory charge to advance nationwide interoperability.

In the HTI–2 Proposed Rule, we proposed that the authenticity verification and registration requirements currently in 45 CFR 170.404(b)(1) should apply to Certified API Developers with a Health IT Module certified to one or more specified certification criteria, including the criterion proposed in 45 CFR 170.315(g)(34).

Similarly, we proposed in 45 CFR 170.404(b)(1)(i) that this provision should apply to an expanded set of specified certification criteria, which included proposed 45 CFR 170.315(g)(34). Under 45 CFR 170.404(b)(1)(i), a Certified API Developer is permitted to institute a process to verify the authenticity of API Users so long as such process is objective and the same for all API Users and completed within ten business days of receipt of an API User's request to register their software application for use with the Certified API Developer's Health IT Module certified to any of a set of specified certification criteria.

Finally, we proposed revisions to two key terms in 45 CFR 170.404(c). We proposed to revise *certified API technology* to mean the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria, including the criterion adopted in 45 CFR 170.315(g)(34). We noted that this revision would support our proposed application of requirements in 45 CFR 170.404 to the proposed APIs in 45 CFR 170.315(g) and the proposed modular API capabilities in 45 CFR 170.315(j). We also proposed to revise *Certified API Developer* to mean a health IT developer that creates ''certified API technology.'' We stated we believe this simplified definition for Certified API Developer will similarly support this term's application to the proposed API capabilities in 45 CFR 170.315(g) and proposed modular API capabilities in 45 CFR 170.315(j).

The following is a summary of the comments we received and our responses:

Comment: Commenters were mixed in their support for our proposals to add the ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34) to the API Conditions and Maintenance of Certification requirements in 45 CFR 170.404. While they supported the transparency requirements, some commenters stated they are duplicative of requirements in the Interoperability and Prior Authorization final rule which include similar transparency requirements. Other commenters noted concerns about applying Fees Conditions to these APIs. They noted that the prior authorization APIs are not simple query and retrieve functions. Rather, they are a complex, multi-step, bidirectional conversation between multiple parties. They claimed that prohibiting developers from generating revenue from these complex, orchestration-heavy APIs will significantly impact the willingness of vendors to build and supply these APIs, which will stymie innovation. They recommended that if we finalize the proposals, we should not apply the Fees Conditions to these APIs.

Response: We appreciate commenters' feedback. The regulations we are finalizing reflect a more targeted approach to apply requirements proposed in 45 CFR 170.404 to specific certification criteria in 45 CFR 170.315(g), including the certification criteria at 45 CFR 170.315(g)(31), (g)(32), and (g)(33) we are finalizing in this rule related to electronic prior authorization. For example, we believe that certified health IT developers with Health IT Modules certified to any of the criteria (g)(31) through (g)(33) ought to abide existing requirements at 45 CFR 170.404(a)(4) for openness and pro-competitive conditions. However, as we discuss further below, we believe that service base URL publication requirements at 45 CFR 170.404(b)(2) should not be applied to the criterion at 45 CFR 170.315(g)(32). We believe this targeted approach will address commenters who saw value in some of the requirements in 45 CFR 170.404, such as the transparency requirements, but were concerned with other requirements.

While we understand there are transparency requirements in the recent CMS Interoperability and Prior Authorization rule for specified payers, we do not believe our requirements for certified health IT developers subject to requirements at 45 CFR 170.404 are duplicative. Primarily, we believe there is no duplication because we are not, at this time, finalizing proposed requirements for Health IT Modules intended for use by payers covered by the CMS Interoperability and Prior Authorization rule. The requirements at 45 CFR 170.404(a)(2) for transparency are applicable to Certified API Developers with Health IT Modules certified in 45 CFR 170.315(g)(7) through (10), and, as we are finalizing in this rule, (g)(31), (g)(32), and (g)(33). These criteria are not intended for certification of health IT used by payers subject to the CMS Interoperability and Prior Authorization rule.

In regard to concerns with the fees conditions we acknowledge and agree that the electronic prior authorization criteria are not simple query and retrieve functions but rather complex, multi-step, bidirectional conversation between multiple systems. However, we disagree that the fee conditions would prohibit developers from generating revenue to a degree that would deter developers from building and supplying these APIs to customers. We note that several fees are explicitly permitted in 45 CFR 170.404(a)(3)(ii) through (iv) to recover costs associated with deployment, API usage, and value-added services. We refer interested parties to the finalized policies related to these permitted fees and the wider set of fees conditions at 45 CFR 170.404(a)(3) in the ONC Cures Act Final Rule (85 FR 25755).

Comment: Other commenters supported ASTP/ONC's extension of new capabilities to the Conditions of Certification and Maintenance of Certification requirements as a means of ensuring Health IT Modules not only implement capabilities, but continue to maintain these capabilities and ensure patients, providers, and payers are able to take advantage of their benefits.

Response: We thank commenters for their support.

After consideration of the public comment, we are finalizing our proposals, with modification. We are finalizing regulation text at 45 CFR 170.404 to include the phrase ''unless otherwise specified in this section,'' as proposed. This amendment enables the Certification Program to specify requirements in different subparagraphs

to pertain to different API-based certification criteria. Given that we are adopting in this final rule API-based certification criteria that require Health IT Module support for server capabilities at 45 CFR 170.315(g)(31) and client capabilities at 45 CFR 170.315(g)(32) and (33), not all requirements in 45 CFR 170.404 are relevant or would be appropriate for both types of capabilities. For example, the requirements at 45 CFR 170.404(b)(2) for publicly publishing FHIR endpoints belonging to a developer of certified health IT's customers is not relevant for Health IT Modules that support client capabilities, such as certified health IT that is certified to the criterion in 45 CFR 170.315(g)(32).

We are finalizing to add references to the certification criteria at 45 CFR 170.315(g)(31), (g)(32), and (g)(33) to the introductory text at 45 CFR 170.404. Consistent with prior discussion of finalizing multiple criteria to represent the capabilities we proposed in a single criterion in 45 CFR 170.315(g)(34), adding 45 CFR 170.315(g)(31), (g)(32), and (g)(33) to this introductory text would be equivalent to our proposal to include 45 CFR 170.315(g)(34) in the regulation text at 45 CFR 170.404. The addition of these references to the introductory text of 45 CFR 170.404 means that Health IT Modules certified to 45 CFR 170.315(g)(31), (g)(32), and (g)(33) are subject to all requirements listed in 45 CFR 170.404(a)(1) through (4), including fees conditions and openness and pro-competitive conditions, unless otherwise specified.

We are finalizing the addition of 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33) at 45 CFR 170.404(b)(1) and 45 CFR 170.404(b)(1)(i). This is similar to what we proposed in the HTI–2 Proposed Rule because the relevant API Condition and Maintenance of Certification requirements in 45 CFR 170.404 will apply to Health IT Modules certified to the new certification criteria for API technology being finalized in 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33) that reflect capabilities included in the originally proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(g)(34).

However, we are not finalizing to apply the API Condition and Maintenance of Certification requirements in 45 CFR 170.404(b)(1) to the new certification criterion in 45 CFR 170.315(g)(32) because the authenticity verification and registration for production use requirements under 45 CFR 170.404(b)(1) are not applicable to Health IT Modules certified to 45 CFR 170.315(g)(32). A Health IT Module certified to 45 CFR 170.315(g)(32) supports only client capabilities and is not publishing an API endpoint for applications to register with as part of supporting the ''Full DTR EHR'' capabilities in at least one of the IGs adopted at 45 CFR 170.215(j)(2).

We did not receive any substantive comments regarding our revisions to the definitions for the terms *certified API technology* and *Certified API Developer.* However, we are finalizing a revision to the key term as proposed for ''Certified API developer,'' by removing the duplicative references to criteria in the key term for ''certified API technology.'' We are also finalizing the key term for ''certified API technology,'' consistent with what we proposed by including capabilities of Health IT Modules that are certified to certification criteria adopted in 45 CFR 170.315(g)(31), (32), and (33). This will ensure consistent application of these key terms throughout regulation text in 45 CFR 170.404.

We are not finalizing any of the other proposals in the HTI–2 proposed rule for changes to the regulatory text at 45 CFR 170.404(a) and 45 CFR 170.404(b) at this time.

(e) Revisions to Real World Testing Requirements

The Cures Act requires, as Condition and Maintenance of Certification requirements under the Certification Program, that health IT developers successfully test the real world use of the technology for interoperability [488] in the type of setting in which such technology would be marketed. As discussed in the ONC Cures Act Final Rule, the objective of real world testing is to verify the extent to which certified health IT deployed in production contexts continues to demonstrate conformance to the full scope of applicable certification criteria and functions with the intended use cases as part of the overall maintenance of a health IT's certification (85 FR 25766).

In the HTI–2 Proposed Rule (89 FR 63594) we discussed that for reasons similar to our proposal to expand requirements in 45 CFR 170.404 to the proposed certification criteria in 45 CFR 170.315(g)(20), (g)(30) through (36), and 170.315(j), we proposed to revise the real world testing requirements in 45 CFR 170.405 by adding these proposed certification criteria in 45 CFR 170.405(a). Given that each of these proposed new certification criteria is focused on interoperability and data exchange, we stated we believe it is important that developers of certified health IT with Health IT Module(s) certified to these criteria participate in both Condition and Maintenance of Certification requirements. Per requirements in 45 CFR 170.405(b), we also proposed that developers of certified health IT with Health IT Modules certified to any one or more of the certification criteria in 45 CFR 170.315(g)(20), (g)(30) through (36), and 170.315(j) also submit annual real world testing plans as well as annual real world testing results, which applies to any one or more of the criteria referenced in 170.405(a). We noted that by including these criteria in 45 CFR 170.405(a) that health IT developers may voluntarily avail themselves of SVAP flexibility so long as they ensure that their annual real world testing plans and real world testing results submissions address all the versions of all the standards and implementation specifications to which each Health IT Module is certified. Under the narrow scope of this final rule, we are only finalizing policies based on our proposal to reference the criterion at 45 CFR 170.315(g)(34) (which was included in our proposal to reference criteria in (g)(30) through (36) in 45 CFR 170.405(a)), and our proposals to reference criteria in 45 CFR 170.315(j)(20) and 45 CFR 170.315(j)(24) (included in our proposal to reference criteria in 170.315(j) in 45 CFR 170.405(a)), to the real world testing requirements in 45 CFR 170.405.

The following is a summary of the comments we received and our responses:

Comment: Comments were mixed on the inclusion of certification criteria related to prior authorization as part of real world testing requirements at 45 CFR 170.405. Some commenters supported our proposal to include prior authorization criteria as part of real world testing because they believed real world testing requirements are critical to ensure products and standards facilitate the intended uses without negative, unintended uses. Other commenters did not believe that real world testing requirements should be applied to electronic prior authorization criteria, noting that payers are already required under the CMS Interoperability and Prior Authorization rule to report annual metrics.

Response: We thank commenters for their support and acknowledge those commenters who considered real world testing requirements at 45 CFR 170.405 duplicative of CMS requirements for impacted payers subject to the CMS

[488] Interoperability is defined in statute in section 3000 of the Public Health Service Act (as modified by section 4003 of the Cures Act) and defined in regulation at 45 CFR 170.102.

Interoperability and Prior Authorization rule. Respectfully, we disagree that requirements at 45 CFR 170.405 are duplicative of CMS requirements. Certification criteria established at 45 CFR 170.315(g)(31) through (33) are intended to support providers engaging in prior authorization workflows and real world testing requirements apply to Health IT Modules specified at 45 CFR 170.405(a) and the performance of these Health IT Modules in real-world clinical settings. These requirements do not overlap with the metrics CMS finalized for impacted payers to report on how payers are conducting prior authorization processes (89 FR 8889).

After consideration of public comments, we are finalizing updates to 45 CFR 170.405(a) to include the criteria in 45 CFR 170.315(g)(31), (g)(32), and (g)(33). We did not receive any comments regarding the proposed inclusion of criteria in 45 CFR 170.315(j)(20) and 45 CFR 170.315(j)(24) (which we are finalizing in this rule in 45 CFR 170.315(21)) as part of real world testing requirements at 45 CFR 170.405, and we are finalizing our proposal to include these criteria. We remind interested parties that inclusion of these criteria at 45 CFR 170.405(a) makes it possible for developers of certified health IT with Health IT Modules certified to these certification criteria to use SVAP to certify their Health IT Modules to newer versions of adopted standards referenced in these criteria.

(f) Addition of Criteria to the Base EHR Definition

In the HTI–2 Proposed Rule, we noted that the ''prior authorization API—provider'' certification criteria in 45 CFR 170.315(g)(34) pertains to certified Health IT Modules intended for use by healthcare providers. We stated we believe this certification criterion reflects fundamental capabilities, which would be appropriate for adoption by any healthcare provider using certified health IT. We noted that technology certified to the ''prior authorization API—provider'' criterion would enable a healthcare provider to conduct prior authorization requests and related interactions with payers that are widely used today.

We proposed to include the certification criterion 45 CFR 170.315(g)(34) to the set of certification criteria adopted by the Secretary that are necessary to meet the Base EHR definition. For the ''prior authorization API—provider'' certification criterion in 45 CFR 170.315(g)(34), we proposed that this criterion would be necessary to meet the Base EHR definition on and after January 1, 2027. We stated that this date is consistent with the Electronic Prior Authorization measures CMS finalized for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category, which program participants must report beginning with the CY 2027 EHR reporting period and CY 2027 performance period/2029 MIPS payment year, respectively (89 FR 8910).

The following is a summary of the comments we received and our responses:

Comment: A number of commenters supported our proposal to add the ''prior authorization API—provider'' to the Base EHR definition in 45 CFR 170.102, stating that developers must provide and support these Health IT Modules in order for clinicians to experience the benefits of electronic prior authorization. Some commenters also supported our proposal to add the ''prior authorization API—provider'' as of January 1, 2027, stating this would be necessary in order to align with CMS reporting requirements for the Electronic Prior Authorization measures finalized for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.

Response: We appreciate commenters' support.

Comment: Other commenters did not agree with our proposal to include the proposed ''prior authorization API—provider'' criterion in the Base EHR definition. These commenters stated that inclusion in the Base EHR definition would be premature, requiring the functionality as part of certified health IT before some providers are ready to use the functionality. Commenters recommended that ASTP/ONC only add the ''prior authorization API—provider'' criterion to the Base EHR definition once APIs based on the relevant standards have been widely adopted across payers.

Response: We appreciate commenters' concerns with our proposal to add the ''prior authorization API—provider'' criterion to the Base EHR definition at 45 CFR 170.102. We agree with commenters that healthcare providers' ability to use the functionality represented by these criteria is contingent upon payers implementing corresponding APIs that can exchange prior authorization information with healthcare providers. In addition, while CMS has finalized requirements for impacted payers to establish Prior Authorization APIs in the Interoperability and Prior Authorization final rule, it is possible that some healthcare providers that purchase a health IT product meeting the Base EHR definition would not submit prior authorization requests to any of the impacted payers under the CMS rule. We further agree that given current usage of these solutions, it may be more appropriate to add this criterion to the Base EHR definition once payer APIs meeting CMS' requirements have been widely implemented. Finally, we note that electronic prior authorization is not identified as a required capability for a ''qualified EHR'' under the definition of that term in section 3000 of the PHSA, which serves as the basis for the Base EHR definition as currently established by ASTP/ONC (77 FR 54262).

Comment: A number of commenters did not support our proposal to include the ''prior authorization API—provider'' criterion in the Base EHR definition as of January 1, 2027. Commenters that opposed this proposal noted that implementation of the capabilities reflected in the criterion will require a significant amount of development work for health IT developers, as well as substantial time to roll out new functionality to customers. Another commenter noted that the IGs we proposed to reference in the criterion contain ambiguous requirements, and that resolving this ambiguity will require additional development time, recommending that ASTP/ONC delay the deadline for inclusion in the Base EHR definition to January 1, 2028. Commenters acknowledged that the January 1, 2027, deadline was chosen in order to align with the January 1, 2027, deadline that CMS has finalized for impacted payers to establish the API requirements finalized in the Interoperability and Prior Authorization final rule. However, they contended that due to the challenges described in meeting this deadline, ASTP/ONC should work with CMS to delay these deadlines to January 1, 2028.

Response: We appreciate commenters' concerns regarding the proposed deadline of January 1, 2027, for inclusion of the ''prior authorization API—provider'' criterion in the Base EHR definition. We acknowledge that the proposed date of January 1, 2027 was intended to align with both CMS requirements for the implementation of Prior Authorization APIs by impacted payers, and that implementation of these electronic prior authorization capabilities may require novel development work for health IT developers.

As discussed previously, CMS has finalized that participants in the Medicare Promoting Interoperability

Program and the MIPS Promoting Interoperability performance category must report on the respective Electronic Prior Authorization measure included in these programs in an EHR reporting period in CY 2027 or the CY 2027 performance period/2029 MIPS payment year, respectively. The criteria we are finalizing in this rule in 45 CFR 170.315(g)(31), (32), and (33) specify requirements for certified Health IT Modules to enable eligible hospitals, CAHs, and eligible clinicians to interact with the payer Prior Authorization APIs from which these providers and clinicians must request prior authorization in order to complete the action specified in the measures. We will work with CMS to continue to monitor timelines related to the use of certified health IT in the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category.

After consideration of the public comment, we are not finalizing the proposed inclusion in the Base EHR definition of the ''prior authorization API—provider'' criterion. We further clarify that we are also not finalizing to add to the Base EHR definition the three electronic prior authorization criteria in 45 CFR 170.315(g)(31), (32), and (33) that we are finalizing in this rule based on the proposed ''prior authorization API—provider'' criterion. As a result of not finalizing any updates to the Base EHR definition, we are also not finalizing a date of January 1, 2027, for inclusion in the Base EHR definition.

(g) Additional Implementation Specifications for Provider, Patient, and Payer APIs

In the HTI–2 Proposed Rule, we proposed to adopt API implementation specifications, on behalf of the Secretary, in 45 CFR 170.215(k), (m), and (n), and make these specifications available for HHS use. At the same time, we proposed health IT certification criteria in 45 CFR 170.315(g)(30) through (36) which incorporated these implementation specifications into certification requirements under the Certification Program. In this final rule we are only finalizing criteria (at 45 CFR 170.315(31), (32), and (33)) based on the proposed ''prior authorization API—provider'' criterion in 45 CFR 170.315(34). However, as discussed in the proposed rule, these implementation specifications address certain use cases for exchange of health information independent of inclusion in a certified Health IT Module, and we therefore proposed to adopt these implementation specifications under PHSA section 3004 to make them available for HHS use.[489]

In the HTI–2 Proposed Rule (89 FR 63582), we proposed to adopt the HL7 FHIR® Da Vinci—Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2 (PDex US Drug Formulary IG) [490] in 45 CFR 170.215(m)(1) and incorporate it by reference in 45 CFR 170.299(g). We proposed to adopt this implementation specification under PHSA section 3004 and make it available for HHS use. We stated that this implementation specification can enable consumers, members, and patients to understand the costs and alternatives for drugs that have been prescribed, and to compare their drug costs across different insurance plans.

We proposed to adopt the HL7 FHIR Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.0.0—STU2 [491] in 45 CFR 170.215(k)(2)(i) and incorporate it by reference in 45 CFR 170.299(g) (89 FR 63582 and 63583). We proposed to adopt this implementation specification under PHSA section 3004 and make it available for HHS use. This implementation specification enables a payer to create a member's health history using clinical resources based on US Core profiles. We noted that a version 2.1.0 of the PDex IG was under development and available for interested parties to review at the time of the proposed rule.[492] We proposed as an alternative to adopt PDex IG version 2.1.0 if the standard is balloted and published before the issuance of this final rule. We noted several important enhancements in the PDex IG version 2.1.0 to align with the Interoperability and Patient Access Final Rule (85 FR 25522 through 25569) and the Interoperability and Prior Authorization Final Rule (89 FR 8768 through 8946). For example, we noted that version 2.1.0 supports US Core 6.1.0, which supports USCDI v3, as well as drops required support for aspects of prior authorization that are viewed as unnecessary or complicating to successful execution of the transaction in version 2.0.0 of the PDex IG. We also stated that version 2.1.0 includes an important use case for bulk data access based on the finalization of the Bulk Data Access IG as a required standard under the Payer API requirements finalized in CMS' rules. We stated that continued alignment among industry, government, and standards development organizations involved with the payer data exchange use cases is necessary and we stated that if PDex IG version 2.1.0 was balloted and published before issuance of this final rule, adoption of version 2.1.0 would support such alignment.

We further proposed to adopt the HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide version 2.0.0—STU 2 [493] in 45 CFR 170.215(k)(1)(i) and incorporate it by reference in 45 CFR 170.299(g) (89 FR 63583–63584). We proposed to adopt this implementation specification under PHSA section 3004 and make it available for HHS use. We stated that this implementation specification supports providing a set of resources that payers can display to consumers, primarily financial (claims and encounter) data, with some limited associated clinical data.

We proposed to adopt the HL7 FHIR Da Vinci Payer Data Exchange Plan Net implementation specification in 45 CFR 170.215(n)(1) and incorporate it by reference in 45 CFR 170.299(g) (89 FR 63592). We proposed to adopt this implementation specification under PHSA section 3004 and make it available for HHS use. Use of this implementation specification can enable third parties to develop applications through which consumers and providers can query the participants in a payer's network that may provide services that address their healthcare needs.

The following is a summary of the comments we received and our responses.

Comment: A commenter expressed support for our proposal to adopt the CARIN IG for Blue Button, stating that the IG brings value to consumers seeking to access their health information and to payers working to provide such access, and noting that the CARIN IG for Blue Button has already been identified as part of meeting federal requirements. Another commenter supported the use of the CARIN IG for Blue Button as well as the proposed Da Vinci PDex IG to support standardization and effective data exchange across payers, providers, and patients, noting that these implementation guides could enable better data access that will be beneficial for children and families with complex care and coverage circumstances. A

[489] See, for example, 89 FR 63582 for discussion of the proposed criterion at 45 CFR 170.315(g)(30) and the benefits of the IG proposed for adoption in 45 CFR 170.215(m).

[490] *See https://hl7.org/fhir/us/davinci-drug-formulary/STU2.0.1/.*

[491] *See https://hl7.org/fhir/us/davinci-pdex/STU2/.*

[492] *See https://build.fhir.org/ig/HL7/davinci-epdx/.*

[493] *See https://hl7.org/fhir/us/carin-bb/.*

commenter supported the adoption of the PDex US Drug Formulary IG. Several commenters expressed support for ASTP/ONC's proposal to adopt the PDex Plan Net IG, stating that this IG would help to improve the interoperability of provider directory information.

Response: We appreciate the support from commenters for these proposals.

Comment: Several commenters recommended adopting new versions of the IGs proposed in the HTI–2 Proposed Rule. Specifically, commenters recommended adopting the PDex IG version 2.1.0 and version 2.1.0 of the CARIN IG for Blue Button. A commenter recommended that ASTP/ONC work with CMS and standards development bodies to ensure that the most updated versions of the standards are adopted and to develop an ongoing versioning strategy.

Response: We appreciate commenters' recommendations regarding the adoption of newer versions of certain proposed specifications that have been released subsequent to the HTI–2 proposed rule.

We have been anticipating publication of version 2.1.0 of the PDex IG and described its many important benefits in the HTI–2 Proposed Rule.[494] Given the number of substantial and important updates included in the version 2.1.0 of the PDex IG, and the several commenters supportive of our alternative proposal to adopt 2.1.0, we believe there are strong reasons to finalize adoption of version 2.1.0. In addition to the benefits afforded by the newer version, finalization of the 2.1.0 version of the PDex IG will help avoid industry burden and sunk costs in comparison to our proposed adoption of version 2.0.0 of the IG, which was the version of the IG available at the time of the publication of the proposed rule. Finally, the 2.1.0 version of the PDex IG includes important updates to better implement requirements finalized by CMS in the Interoperability and Prior Authorization final rule. While CMS currently recommends use of the PDex IG in the final rule, CMS has stated that they may consider requiring this and other recommended standards in the future, similar to current requirements to use standards adopted in 45 CFR 170.215 and 45 CFR 170.213 (89 FR 8939 through 8941). We believe that adopting the 2.1.0 version of the IG at this time could support future CMS requirements.

Regarding updates to the other proposed standards, we note that an updated 2.1.0 version of the CARIN IG for Blue Button, which was also identified by commenters, was published on February 18, 2025. We agree with commenters that updated versions of these specifications may include important updates to align with newer versions of supporting standards, and ongoing changes that reflect the standards development community's efforts to incrementally improve these specifications. Unlike the PDex IG proposal, we did not propose an alternate proposal to adopt the CARIN IG for Blue Button version 2.1.0. We only proposed version 2.0.0. Accordingly, we believe it is most appropriate to adopt the versions of the CARIN IG and the other specifications that we proposed in the HTI–2 Proposed Rule. We note that ASTP/ONC will monitor future versions of these specifications.

After consideration of the public comment, we are adopting the following implementation specifications in 45 CFR 170.215 and incorporating them by reference in 45 CFR 170.299(g):

- HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US (45 CFR 170.215(k)(1)(i).
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1 (45 CFR 170.215(k)(2)(i)).
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU2 (45 CFR 170.215(m)(1)).
- HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU1.1 US (45 CFR 170.215(n)(1)).

We reiterate that at this time we are not finalizing the health IT certification criteria we proposed in the HTI–2 Proposed Rule that referenced these implementation specifications. Rather, as proposed, we are finalizing adoption of these implementation specifications under PHSA section 3004 for HHS use.

(7) Corrections for HTI–2 Final Rule

In **Federal Register** document 2024–29163 (89 FR 101772) final rule titled ''Health Data, Technology, and Interoperability: Trusted Exchange Framework and Common Agreement'' (HTI–2) (hereinafter referred to as the HTI–2 Final Rule), we identified certain technical and typographical errors following publication in the **Federal Register** on December 16, 2024.

a. Summary of Errors

In the ONC Cures Act Final Rule, we finalized 45 CFR 170.550(m) ''time-limited certification and certification status for certain 2015 Edition certification criteria,'' which provided that for five specific certification criteria, an ONC–ACB may only issue a certification to a Health IT Module and permit continued certified status for a specified time period (85 FR 25952). The five criteria with time-limited certification and certification status were ''drug-formulary and preferred drug list checks'' certification criterion (45 CFR 170.315(a)(10)), ''patient-specific education resources'' (45 CFR 170.315(a)(13)), ''data export'' certification criterion (45 CFR 170.315 (b)(6)), ''secure messaging'' certification criterion (45 CFR 170.315(e)(2)), and ''application access—data category request'' (45 CFR 170.315(g)(8)). Because the specified time periods for certification to these criteria have elapsed, we noted in the preamble of the HTI–2 Proposed Rule that we proposed to remove all of the certification criteria referenced in 45 CFR 170.550(m) in one action by removing 45 CFR 170.550(m) in its entirety (89 FR 63615 through 63616). In the HTI–2 Final Rule, we also removed and reserved these aforementioned certification criteria from the specific CFR locations in which they were adopted (89 FR 101776 through 101777). However, we inadvertently included a reference to 45 CFR 170.315(g)(2) to remove and reserve in the amendatory instructions for 45 CFR 170.315 (89 FR 101809) when it should read 45 CFR 170.315(g)(8). We also inadvertently omitted from amendatory instruction for 45 CFR 170.550(m) (89 FR 101810), an instruction to remove 45 CFR 170.550(m).

In the HTI–2 Final Rule (89 FR 101776) preamble, we intended to finalize as proposed removal and reservation of 45 CFR 170.315(g)(8). However, we erroneously included a reference to 45 CFR 170.315(g)(2) instead of 45 CFR 170.315(g)(8) in the amendatory instructions, which resulted in the removal of 45 CFR 170.315(g)(2) and retention of 45 CFR 170.315(g)(8) (89 FR 101809). We therefore add 45 CFR 170.315(g)(2) back into the CFR and remove 45 CFR 170.315(g)(8) to address this error. Section 170.315(g)(2) refers to automated measure calculation. The language to be inserted into the CFR is ''Automated measure calculation. For each Promoting Interoperability Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.''

In the HTI–2 Final Rule (89 FR 101776) preamble, we also intended to finalize as proposed the removal of 45

CFR 170.550(m). However, we omitted the amendatory language instructing the Office of the Federal Register to remove 45 CFR 170.550(m) in the regulatory text.

b. Waiver of Proposed Rulemaking, Comment Period, and Delay in Effective Date

Under 5 U.S.C. 553(b) of the Administrative Procedure Act (APA), the agency is required to publish a notice of the proposed rulemaking in the **Federal Register** before the provisions of a rule take effect. In addition, section 553(d) of the APA mandates a 30-day delay in effective date after issuance or publication of a rule. Sections 553(b)(B) and 553(d)(3) of the APA provide for exceptions from the notice and comment and delay in effective date requirements. Section 553(b)(B) of the APA provides an exception to the requirement that an agency publish a notice of proposed rulemaking in the **Federal Register** for good cause if the agency makes and incorporates a finding, to include a brief statement of reasons, that the notice and comment process are impracticable, unnecessary, or contrary to the public interest. In addition, section 553(d)(3) of the APA allows the agency to avoid the 30-day delay in effective date for good cause and where the agency includes a statement of support.

We believe this correction does not constitute a rule that would be subject to the APA notice and comment or delayed effective date requirements. This document corrects technical and typographical errors in the preamble and regulation text of the HTI–2 Final Rule, but it does not make substantive changes to the policies that were adopted in the HTI–2 Final Rule. As a result, this correction is intended to ensure that the information in the HTI–2 Final Rule accurately reflects the policies adopted in that document.

In addition, even if this were a rule to which the notice and comment procedures and delayed effective date requirements applied, we find that there is good cause to waive such procedures and requirements. Undertaking further notice and comment procedures to incorporate the corrections in this document into the HTI–2 Final Rule would be contrary to the public interest because it is in the public's interest for entities to receive accurate information regarding the relevant policies, and these corrections ensure the HTI–2 Final Rule reflects the policies laid out in the ONC Cures Act and HTI–2 Final Rules. This correction is intended solely to ensure that the HTI–2 Final Rule accurately reflects applicable law, and the policies finalized in the HTI–2 Final Rule. Therefore, we believe we have good cause to waive the notice and comment and effective date requirements.

(8) Incorporation by Reference

The Office of the Federal Register has established requirements for materials (for example, standards and implementation specifications) that agencies propose to incorporate by reference in the Code of Federal Regulations (79 FR 66267; 1 CFR 51.5(b)). Specifically, § 51.5(b)(2) requires agencies to discuss, in the preamble of a final rule, the ways that the materials they incorporate by reference are reasonably available to interested parties and how interested parties can obtain the materials; and summarize, in the preamble of the final rule, the material they incorporate by reference.

To make the materials we intend to incorporate by reference reasonably available, we provide a uniform resource locator (URL) for the standards and implementation specifications. In many cases, these standards and implementation specifications are directly accessible through the URLs provided. In most of these instances, access to the standard or implementation specification can be gained through no-cost (monetary) participation, subscription, or membership with the applicable standards developing organization (SDO) or custodial organization. Alternatively, a copy of the standards may be viewed for free at the U.S. Department of Health and Human Services, Office of the National Coordinator for Health Information Technology, 330 C Street SW, Washington, DC 20201. Please call (202) 690–7171 in advance to arrange inspection.

The National Technology Transfer and Advancement Act (NTTAA) of 1995 (15 U.S.C. 3701 *et seq.*) and the Office of Management and Budget (OMB) Circular A–119 require the use of, wherever practical, technical standards that are developed or adopted by voluntary consensus standards bodies to carry out policy objectives or activities, with certain exceptions. The NTTAA and OMB Circular A–119 provide exceptions to selecting only standards developed or adopted by voluntary consensus standards bodies, namely when doing so would be inconsistent with applicable law or otherwise impractical. As discussed in section III.A.1 of the HTI–2 Proposed Rule, we have followed the NTTAA and OMB Circular A–119 in proposing standards and implementation specifications for adoption, including describing any exceptions in the proposed adoption of standards and implementation specifications (89 FR 63514). Over the years of adopting standards and implementation specifications for certification, we have worked with SDOs, such as HL7, to make the standards we propose to adopt, and subsequently adopt and incorporate by reference in the **Federal Register**, available to interested parties. As described previously, this includes making the standards and implementation specifications available through no-cost memberships and no-cost subscriptions.

As required by § 51.5(b), we provide summaries of the standards we are adopting and incorporating by reference in the Code of Federal Regulations. We also provide relevant information about these standards and implementation specifications throughout the preamble.

We have organized the following standards and implementation specifications that we are adopting through this rulemaking according to the sections of the Code of Federal Regulations (CFR) in which they would be codified and cross-referenced for associated certification criteria and requirements that we are adopting.

(a) Vocabulary Standards for Representing Electronic Health Information—45 CFR 170.207

- *RxNorm, December 4, 2023, Full Update Release.*

URL: *https://www.nlm.nih.gov/research/umls/rxnorm/docs/rxnormarchive.html*

Access requires a user account and license agreement. There is no monetary cost for a user account and license agreement.

Summary: RxNorm, a standardized nomenclature for clinical drugs, is produced by the National Library of Medicine. RxNorm's standard identifiers and names for clinical drugs are connected to the varying names of drugs present in many different controlled vocabularies within the Unified Medical Language System (UMLS) Metathesaurus, including those in commercially available drug information sources. These connections are intended to facilitate interoperability among the computerized systems that record or process data dealing with clinical drugs.

(b) Application Programming Interface Standards—45 CFR 170.215

- *HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2, March 12, 2025.*

URL: *https://cds-hooks.hl7.org/STU2/*
This is a direct access link.

Summary: This HL7 FHIR® CDS Hooks Implementation Guide describes a ''hook'' based pattern for invoking clinical decision support (CDS) from within a clinician's workflow. The APIs described in the specification support synchronous, workflow-triggered CDS calls returning information and suggestions, and launching a user-facing SMART app when CDS requires additional interaction.

- *HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use, draft as of January 11, 2023.*

URL: *https://hl7.org/fhir/uv/subscriptions-backport/STU1.1/*
This is a direct access link.

Summary: The Subscription R5 Backport Implementation Guide enables servers running versions of FHIR earlier than R5 to implement a subset of R5 Subscriptions in a standardized way. During the development of FHIR R5, the Subscriptions Framework has gone through a significant redesign. Many implementers have expressed a need for functionality from the FHIR R5 version of Subscriptions to be made available in FHIR R4. The goal of publishing the Subscription R5 Backport Implementation Guide is to define a standard method of back-porting the R5 Subscriptions Framework for greater compatibility and adoption by systems leveraging an early version of FHIR (that is, FHIR R4).

- *HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1, June 18, 2025.*

URL:*https://hl7.org/fhir/us/davinci-pdex/STU2.1/*
This is a direct access link.

Summary: The Payer Data Exchange (PDex) Implementation Guide is provided for payers/health plans to enable them to create a Member's Health History using clinical resources (based on US Core Profiles established from FHIR R4) which can be understood by providers and, if they choose to, committed to their Electronic Medical Records (EMR) System.

- *HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2, January 8, 2024.*

URL:*https://hl7.org/fhir/us/davinci-crd/STU2/*
This is a direct access link.

Summary: The Da Vinci Coverage Requirements Discovery (CRD) Implementation Guide defines a workflow to allow payers to provide information about coverage requirements to healthcare providers through their provider systems at the time treatment decisions are being made. This will ensure that clinicians and administrative staff have the capability to make informed decisions and meet the requirements of the patient's insurance coverage.

- *HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2, January 11, 2024.*

URL:*https://hl7.org/fhir/us/davinci-dtr/STU2/*
This is a direct access link.

Summary: The Da Vinci Documentation Templates and Rules (DTR) Implementation Guide provides a mechanism for payers to express their documentation requirements computably in a way that allows clinicians and other EHR users to navigate and quickly specify the needed information in a context-specific way. The guide allows rules to be written in a way that supports automatically extracting existing EHR information for review/confirmation and adjusting the information prompted for based on what data is already known or entered, minimizing impact on provider time, while expediting subsequent payer interactions.

- *HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2, December 1, 2023.*

URL: *https://hl7.org/fhir/us/davinci-pas/STU2/*
This is a direct access link.

Summary: The Da Vinci Prior Authorization Support (PAS) Implementation Guide enables direct submission of prior authorization requests from EHR systems using FHIR. The implementation guide also defines capabilities around the management of prior authorization requests, including checking the status of a previously submitted request, updating a previously submitted request, and canceling a request. Direct submission of prior authorization requests from the EHR can result in faster prior authorization decisions, reducing costs for both providers and payers and improving patient experience.

- *HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US, November 28, 2022.*

URL: *https://hl7.org/fhir/us/carin-bb/STU2/*
This is a direct access link.

Summary: This implementation guide describes the CARIN for Blue Button® Framework and Common Payer Consumer Data Set (CPCDS), providing a set of resources that payers can display to consumers via a FHIR API. The CARIN for Blue Button IG was defined by the CARIN Alliance to meet the requirements in the CMS Interoperability and Patient Access final rule for impacted payers to make available claims and encounter data via a Patient Access API. This IG is primarily used to exchange financial (claims and encounter) data, with some limited associated clinical data.

- *HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2, December 1, 2023.*

URL: *https://hl7.org/fhir/us/davinci-drug-formulary/STU2.0.1/*
This is a direct access link.

Summary: This implementation guide defines a FHIR interface to a health insurer's drug formulary information for patients/consumers. The primary use cases for this FHIR interface enable consumers/members/patients to understand the costs and alternatives for drugs that have been prescribed, and to compare their drug costs across different insurance plans.

- *HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU1.1 US, April 4, 2022.*

URL: *https://hl7.org/fhir/us/davinci-pdex-plan-net/STU1.1/*
This is a direct access link.

Summary: This implementation guide defines a FHIR interface to access information about a health insurer's insurance plans, their associated networks, and the organizations and providers that participate in these networks. Publication of this data through a standard FHIR-based API will enable third parties to develop applications through which consumers and providers can query the participants in a payer's network that may provide services that address their healthcare needs.

C. Finalization of Interim Final Action With Comment Period on the Changes to the Fiscal Year 2025 Hospital IPPS Rates Due to Court Decision (CMS–1808–IFC)

In the interim final action with comment period (IFC) (CMS–1808–IFC), that appeared in the October 3, 2024 **Federal Register** (89 FR 80405) (hereinafter referred to as the FY 2025 IFC), CMS implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those

revisions, and made conforming changes to the hospital IPPS payment rates for FY 2025. These changes reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp.* v. *Becerra.* That IFC also made conforming changes to IPPS rates and factors used to determine certain payments under the LTCH PPS for FY 2025. In this section of this final rule, we are responding to the public comments that we received on the FY 2025 IFC and finalizing the interim final policies established therein.

1. Provisions of the Interim Final Action With Comment Period

a. Background

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to address 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). In the FY 2020 IPPS/LTCH PPS final rule, based on those public comments and the growing disparities between wage index values for high- and low-wage-index hospitals, we explained that those growing disparities are likely caused, at least in part, by the use of historical wage data to prospectively set hospitals' wage indexes. That lag between when hospitals increase wages and when those wage increases are reflected in the historical data creates barriers to hospitals with low wage index values being able to increase employee compensation, because those hospitals will not receive corresponding increases in their Medicare payment for several years (84 FR 42327). 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).[495] 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). As explained in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19396) and final rule (84 FR 42329), we indicated that the Secretary has authority to implement the low wage index hospital policy proposal under both section 1886(d)(3)(E) of the Act and section 1886(d)(5)(I) of the Act.

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.

In that same FY 2025 IPPS/LTCH PPS final rule (89 FR 69302), we also noted that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation in multiple courts, and that 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). We also stated that as of the date of that final rule's publication, the time to seek further review of the D.C. Circuit's decision in *Bridgeport Hospital* had not expired (see Fed. R. App. P. 40(a)(1)) and the government was evaluating the decision and considering options for next steps.

b. Revised IPPS Wage Index Values for FY 2025 and Transitional Payment Exception for Low Wage Hospitals Significantly Impacted by Those Revisions

After considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra*, in the FY 2025 IFC we recalculated the IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. Because we were now no longer applying the low wage index hospital policy in FY 2025, we also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts. (89 FR 80407 through 80408).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. 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. We stated in the FY 2025 IFC that for FY 2025, consistent with our past practice, we believe it is appropriate to establish a 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. Further, we discussed our current 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

[495] In the FY 2020 IPPS/LTCH PPS proposed rule, we agreed with respondents to a previous request for information who indicated that some current wage index policies create barriers to hospitals with low wage index values from being able to increase employee compensation due to the lag between when hospitals increase the compensation and when those increases are reflected in the calculation of the wage index. We noted that this lag results from the fact that the wage index calculations rely on historical data. We also agreed that addressing this systemic issue did not need to wait for comprehensive wage index reform given the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure (84 FR 19394 and 19395).

to offset the increase in total payments resulting from the application of that cap (89 FR 80407).

As discussed in the FY 2025 IFC (89 FR 80407 through 80408), some hospitals that benefitted from the low wage index hospital policy previously will experience decreases of 5 percent or more from their FY 2024 wage index to the FY 2025 wage index established in that IFC. Similar to how 42 CFR 412.64(h)(7) operates, in that IFC we applied a one-time, transitional adjustment to create a narrow transitional exception to the calculation of FY 2025 payments. The wage index cap policy at 42 CFR 412.64(h)(7) would have mitigated these FY 2025 decreases but would have done so in a budget neutral manner under our current regulations. Because section 1886(d)(5)(I) of the Act lacks any general budget neutrality requirement, we stated that we are not required by the statute to budget neutralize this transition policy. In some circumstances CMS has exercised discretion under section 1886(d)(5)(I) of the Act twice over—first to adopt an exception or adjustment, and then again to make that exception and adjustment budget neutral.[496] However, under the unique circumstances and due to the timing of the appellate court's decision so close to the beginning of FY 2025, we stated that we did not deem it appropriate to provide a second exception or adjustment that would budget neutralize the transition policy we were establishing in that IFC. 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. We stated that the agency's action in the FY 2025 IFC was intended to promote certainty regarding FY 2025 IPPS payments in light of the reasoning of *Bridgeport* and its application to the low wage index hospital policy in FY 2025, which would create ongoing confusion for hospitals extending into FY 2025 about the amount of their IPPS payments and would constitute an inefficient use of agency resources. We stated that in this instance, the lack of an opportunity prior to the effective date for interested parties to comment on the transition policy weighs in favor of an approach that does not adversely affect the significant majority of hospitals. Because section 1886(d)(5)(I) lacks any general budget neutrality requirement, we stated that we are not required by the statute to budget neutralize this transition policy. For these reasons, we declined to budget neutralize the transition policy in this case.

Therefore, in the FY 2025 IFC, we used our authority under section 1886(d)(5)(I)(i) of the Act to create a narrow transitional exception to the calculation of FY 2025 IPPS payments for low wage index hospitals significantly impacted by the removal of the low wage index hospital policy.[497] [498] The transitional exception policy established in that IFC applies to hospitals that benefitted from the FY 2024 low wage index hospital policy. For those hospitals, we compared the hospital's FY 2025 wage index established in the FY 2025 IFC to the hospital's FY 2024 wage index. If the hospital was significantly impacted by the removal of the low wage index hospital policy, meaning the hospital's FY 2025 wage index established in the FY 2025 IFC decreased by more than 5 percent from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2025 for that hospital is equal to the additional FY 2025 amount the hospital would be paid under the IPPS if its FY 2025 wage index were equal to 95 percent of its FY 2024 wage index.[499] For example, assume the FY 2024 wage index for a hospital that benefitted from the low wage index hospital policy was 0.7600, and the hospital's FY 2025 wage index established in the FY 2025 IFC was 0.7100. The hospital's FY 2025 wage index established in the FY 2025 IFC decreased by more than 5 percent from the hospital's FY 2024 wage index [that is, 0.7100 < 0.7220 where 0.7220 = (0.95 times 0.7600)]. The transitional payment exception for FY 2025 for this hospital is equal to the additional amount the hospital would be paid under the IPPS if its FY 2025 wage index were equal to 0.7220, which is 95 percent of 0.7600, its FY 2024 wage index.

Because the need to provide for payment stability and promote predictability is satisfied by the transitional payment exception under the FY 2025 IFC, we used our authority under section 1886(d)(5)(I)(i) of the Act to except hospitals that are eligible for this transition policy for the removal of the FY 2025 low wage index hospital policy for FY 2025 from the application of the wage index cap policy at 42 CFR 412.64(h)(7).

In addition, in the FY 2025 IFC (89 FR 80408), we discussed that 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. In the FY 2025 IFC (89 FR 80408), we stated that because we were no longer applying the low wage index hospital policy in FY 2025, we were 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 also discussed in that IFC, for FY 2025 we stated that we believe it is appropriate to establish a transition policy for low wage index hospitals significantly impacted by the removal of the low wage index hospital policy. 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 (87 FR 49435). As described previously, some low wage index hospitals experienced decreases of 5 percent or more in their FY 2025 wage index established in the FY 2025 IFC compared to their FY 2024 wage index, and we established a transitional payment exception to the calculation of FY 2025 IPPS payments for low wage index hospitals impacted by the removal of the low wage index hospital policy. In the FY 2025 IFC, we made a non-budget neutral equivalent exception under the capital IPPS.

Comment: Many commenters expressed opposition to ending the low wage index hospital policy. Several commenters recommended that CMS work with Congress and explore other mechanisms to address concerns with

[496] 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).

[497] We noted that the scope and magnitude of the transitional policy implemented in the FY 2025 IFC are much smaller than the low wage index hospital policy. As discussed in section VI. of the FY 2025 IFC (89 FR 80417), we estimated only 113 hospitals out of the over 3,000 hospitals paid under the IPPS would receive transitional exception payments, and the total payment impact of the transitional policy would be approximately $41 million.

[498] We noted that because creating an exception to the calculation of the FY 2025 payments is in this circumstance functionally equivalent to adjusting the FY 2025 payments, the transitional exception can be alternatively considered a transitional adjustment.

[499] We noted that we are not changing the FY 2025 wage index values under section 1886(d)(3)(E) for hospitals eligible for the transitional exception policy on the basis of the exception; the change is applied as a separate step only for purposes of determining the hospitals' FY 2025 IPPS payments.

the current wage index methodology or both. While a commenter stated that CMS was compelled to vacate the policy following the court ruling, this and other commenters described potential consequences of the policy ending, including hindered access to care, increased hospital closures, and recruitment challenges. Several commenters expressed specific concerns for rural hospitals with the removal of the low wage index hospital policy, noting that many rural hospitals will experience a lower wage index, which could lead to financial distress for rural hospitals and lack of access of care in rural areas. A commenter called for the FY 2025 IFC to be withdrawn and the removal of the low wage index hospital policy to be delayed.

Response: We appreciate the commenters' concerns regarding our recalculation of the FY 2025 wage index and removal of the low wage index hospital policy After considering the D.C. Circuit's decision, we recalculated the IPPS hospital wage index to remove the low wage index hospital policy for FY 2025. As discussed earlier, consistent with our past practice, to mitigate the negative financial impacts for FY 2025, we established a 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.

Comment: Some commenters supported increasing the wage index values of low wage hospitals but urged CMS to do so in a non-budget-neutral manner. Other commenters supported removal of the low wage index policy for FY 2025, with some recommending that CMS not implement the policy in the future.

Response: We appreciate commenters' support regarding the low wage index hospital policy. As discussed earlier, we recalculated the IPPS hospital wage index to remove the low wage index hospital policy for FY 2025 after considering the D.C. Circuit's decision in *Bridgeport Hosp.* v. *Becerra.* For the reasons explained in the FY 2025 IFC, we declined to implement the transition policy for low wage index hospitals significantly impacted by the removal of the low wage index hospital policy in a budget neutral manner for FY 2025.

Comment: Many commenters appreciated the transitional payment exception, with some commenters expressing concerns regarding the structure of the transition policy. While commenters supported the implementation of the transition policy in a non-budget neutral manner, many commenters called for other changes. Commenters suggested the transition policy should be extended beyond one year to give impacted hospitals time to adjust to the rescission of the policy, citing the short time period between the release of the FY 2025 IFC and the beginning of FY 2025. Other commenters stated that hospitals did not have a chance to prepare for the removal of the low wage hospital policy since it had been in place for four years and, per the FY 2025 IPPS/LTCH PPS final rule, was expected to be extended for at least three more years. Several commenters stated the transition policy should be based on the higher of the FY 2024 wage index or the FY 2025 wage index set forth the FY 2025 IPPS/LTCH PPS final rule, as corrected. Several commenters requested the transition be expanded to apply to more hospitals beyond those that will realize a more than 5 percent decrease in their wage index values.

Response: In the past, we 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. For the reasons explained earlier, we established a transition policy for FY 2025 low wage index hospitals significantly impacted by the removal of the low wage index hospital policy. For those hospitals, the transitional exception to the calculation of FY 2025 IPPS payments is based on whether the hospital's FY 2025 wage index established in the FY 2025 IFC decreased by more than 5 percent from the hospital's FY 2024 wage index. This comparison operates similarly to the wage index cap policy at 42 CFR 412.64(h)(7), which applies 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. Given the unique circumstances due to the timing of the appellate court's decision so close to the beginning of FY 2025, the transitional adjustment established in the FY 2025 IFC was implemented in a non- budget neutral manner.

Regarding FY 2026, we note elsewhere in this final rule, we are finalizing as proposed a transitional policy for hospitals that benefitted from the FY 2024 low wage index hospital policy that compares the hospital's FY 2026 wage index to the hospital's FY 2024 wage index that is being implemented in a budget neutral manner through an adjustment applied to the standardized amount for all hospitals. For a more detailed discussion of the FY 2026 transition policy, we refer readers to section III.F.7. of the preamble of this final rule.

We note that we received comments that were out of scope with regard to the provisions of the FY 2025 IFC. Therefore, we are not responding to these comments in this final rule.

After consideration of the public comments received, in this final rule, we are finalizing without modification the revised IPPS wage index values for FY 2025 after removal of the low wage index hospital policy, the removal of the low wage index budget neutrality factor from the FY 2025 standardized amounts, and the transitional payment exception for low wage index hospitals significantly impacted by the removal of the low wage index hospital policy for FY 2025 under our authority under section 1886(d)(5)(I)(i) of the Act. In addition, we are finalizing without modification that this transition policy is not implemented in a budget neutral manner for FY 2025. Lastly, we note we received no comments specific to the non-budget neutral equivalent exception under the capital IPPS and are finalizing without modification.

c. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2025

To reflect the removal of the low wage index hospital policy for FY 2025 following the appellate court decision in *Bridgeport Hosp.* v. *Becerra,* in the FY 2025 IFC (89 FR 80408 through 80411), we made changes to certain FY 2025 IPPS operating rates and factors due to implementation of the revised FY 2025 wage index and transitional payment exception for low wage index hospitals significantly impacted by the removal of the low wage index hospital policy. We present a summary of these changes in the discussion that follows. For additional details, we refer readers to the FY 2025 IFC (89 FR 80408 through 80411). As discussed later in this section, we did not receive any comments on these changes and are finalizing them without modification.

(1) Calculation of the Adjusted Standardized Amount for FY 2025

In the FY 2025 IFC (89 FR 80409), we discussed that based on the order of our FY 2025 budget neutrality calculations, the removal of the low wage index hospital policy and application of the transitional exception policy did not impact the calculation of the first five budget neutrality factors (that is, MS–DRG Reclassification and Recalibration Budget Neutrality Factor, Cap Policy MS–DRG Weights Budget Neutrality Factor, Wage Index Budget Neutrality Factor, Reclassification Budget Neutrality Factor, and the Rural Floor Budget Neutrality Factor). (We also

noted that the Rural Floor Budget Neutrality Factor is applied to the national wage indexes while the other budget neutrality adjustments are applied to the standardized amounts.) Under the provisions of the FY 2025 IFC, we no longer made a budget neutrality adjustment to the standardized amount for the low wage index hospital policy. Accordingly, in the FY 2025 IFC, we recalculated the cap policy for wage index budget neutrality factor and rural demonstration budget neutrality factor used for determining the standardized amounts for FY 2025 (89 FR 80409). We also calculated the FY 2025 outlier threshold to reflect the provisions of the FY 2025 IFC along with changes to those budget neutrality factors (89 FR 80409 through 80410). In addition, we updated the calculation of Factor 3 of the uncompensated care payment methodology for all DSH-eligible hospitals to reflect the updated information for the hospitals that are no longer projected to receive interim uncompensated care payments for FY 2025, revised the amount of the total uncompensated care payment calculated for each DSH-eligible hospital, and updated the list that we published for the FY 2025 IPPS/LTCH PPS final rule, as corrected, of hospitals that we identified to be subsection (d) hospitals and subsection (d) Puerto Rico hospitals projected to be eligible to receive interim uncompensated care payments for FY 2025 (see the discussion of Table 18 in the FY 2025 IFC (89 FR 80413 through 80414)).

In the FY 2025 IFC (89 FR 80409), we discussed that, because we applied the transitional exception for certain hospitals that benefitted from the low wage index hospital policy adjustment in a non-budget neutral manner, we first determined which hospitals would be eligible for this transition policy (that is, identified those that had received a higher wage index under the low wage index hospital policy in FY 2024). We then applied the transitional payment exception for eligible hospitals as described in section II.A. of the FY 2025 IFC. (As stated previously, hospitals eligible for the new transitional exception policy for FY 2025 are excepted from the wage index cap policy at 42 CFR 412.64(h)(7), which is budget neutral by design.)

The FY 2025 budget neutrality factors that we recalculated in the FY 2025 IFC were calculated using data described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69941 through 69948), with the FY 2025 IPPS/LTCH PPS final rule correction. In the FY 2025 IFC (89 FR 80409), we calculated a budget neutrality factor for the wage index cap policy at 42 CFR 412.64(h)(7) of 0.999166 in accordance with the existing methodology. As noted earlier, hospitals that are eligible for the transitional exception policy are excepted from the wage index cap policy at 42 CFR 412.64(h)(7) in FY 2025. (For additional details on the calculation of the wage index cap budget neutrality adjustment factor for FY 2025, refer to the FY 2025 IFC (89 FR 80409).)

In the FY 2025 IFC (89 FR 80409), we recalculated the budget neutrality factor for the rural community hospital demonstration program using the methodology described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69947 through 69948). However, when rounded to the sixth decimal, the factor (0.999811) did not change from the corrected factor as set forth in the FY 2025 IPPS/LTCH PPS correction.

The standardized amounts set forth in Tables 1A, 1B, and 1C for FY 2025 listed and published in section IV. of the FY 2025 IFC (89 FR 80414) (and available via the internet on the CMS website) reflect these factors.

We received no comments on the FY 2025 budget neutrality calculations and factors established in the FY 2025 IFC and are finalizing them in this final rule without modification.

(2) Outlier Payments

To calculate the FY 2025 outlier fixed-loss amount that reflects the provisions of the FY 2025 IFC, we used the methodology (data, factors, etc.) as described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69948 through 66962), as corrected, in conjunction with the wage index values, transitional payment exception policy for the removal of the low wage index hospital policy and other rates and factors established in the FY 2025 IFC (described previously).

In the FY 2025 IFC (89 FR 80410), we determined a threshold of $46,217 for FY 2025 and calculated total outlier payments of $4,354,709,696 and total operating Federal payments of $80,366,934,481. (For additional details on the outlier methodology and calculations for FY 2025, refer to the FY 2025 IFC (89 FR 80409 through 80410).) Accordingly, in that FY 2025 IFC, we established that for FY 2025, the outlier fixed-loss cost threshold is 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 Indian Health Service (IHS)/Tribal hospitals and Puerto Rico hospitals, and any add on payments for new technology, plus $46,217. In addition, in the FY 2025 IFC, we applied an outlier adjustment factor of 0.949 to the operating standardized amount based on the FY 2025 outlier threshold (as established in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69961)).

In the FY 2025 IFC (89 FR 80410), we discussed that 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. In the FY 2025 IFC, we projected that the threshold for FY 2025 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation (see 89 FR 69948 through 69953) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimated that capital outlier payments would equal 4.23 percent of capital payments based on the capital Federal rate established in section II.C. of the FY 2025 IFC (and which reflects our methodology to incorporate an estimate of capital outlier reconciliation as discussed in the FY 2025 IPPS/LTCH PPS final rule (see 89 FR 69953 through 69955)). The outlier adjustment factors applied to the operating standardized amount and capital Federal rate based on the FY 2025 outlier threshold established in the FY 2025 IFC are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.957704

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2025 capital outlier payments for capital outlier reconciliation, as discussed in the FY 2025 IPPS/LTCH final rule.

As described in the FY 2025 IFC (89 FR 80410), we applied the outlier adjustment factors to the FY 2025 payment rates after removing the effects of the FY 2024 outlier adjustment factors on the standardized amount.

We received no comments on the FY 2025 outlier calculations and factors established in the FY 2025 IFC and are finalizing them in this final rule without modification.

(3) FY 2025 Standardized Amounts

Tables 1A and 1B listed and published in section IV. of the FY 2025 IFC (and available via the internet on the CMS website) contain the national standardized amounts that apply to all hospitals, except hospitals located in Puerto Rico, for FY 2025. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section IV. of the FY 2025 IFC (and available via the internet on the CMS website). We also provided a table that illustrates the changes from the FY 2024 national standardized amounts to the FY 2025 national standardized amounts. (See 89 FR 80410 through 80411)

We received no comments on the FY 2025 standardized amounts established in the FY 2025 IFC and are finalizing them in this final rule without modification. As noted previously, the standardized amounts are set forth in Tables 1A, 1B, and 1C for FY 2025 listed and published in section IV. of the FY 2025 IFC (89 FR 80414) (and available via the internet on the CMS website).

d. Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2025

Similar to the discussion of the operating IPPS payment rates previously, the removal of the low wage index hospital policy and the establishment of a transitional exception policy in the FY 2025 IFC impacts the calculation of certain budget neutrality adjustment factors used for determining the capital Federal rate for FY 2025. As discussed previously, we also calculated the FY 2025 outlier threshold to reflect the provisions of that IFC along with the corresponding changes to the IPPS payment rates. Accordingly, in the FY 2025 IFC (89 FR 80411 through 80412), we established the following factors used for determining the capital Federal rate for FY 2025:

- The outlier payment adjustment factor.
- The portion of the budget neutrality adjustment factor for changes in the geographic adjustment factor (GAF) for the 5-percent cap on wage index decreases policy. (Under the provisions of the FY 2025 IFC, this factor would no longer reflect the low wage index hospital policy.)

In the FY 2025 IFC we discussed that, in general, these factors were calculated using the data and calculation methodology described in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69968 through 69971) with the FY 2025 IPPS/LTCH PPS final rule correction, except for the methodology for calculating the GAF budget neutrality factor which we modified to reflect the provisions of the IFC. We present a summary of these changes in the discussion that follows. For additional details, we refer readers to the FY 2025 IFC (89 FR 80411 through 80412). As discussed later in this section, we did not receive any comments on these changes and are finalizing them without modification.

(1) Outlier Payment Adjustment Factor

A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. In the FY 2025 IFC (89 FR 80411), we stated that based on the threshold discussed in section II.B. of that IFC, we estimated that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs will equal 4.26 percent of inpatient capital-related payments based on the capital Federal rate in FY 2025. We also stated that we estimate that taking into account projected capital outlier reconciliation payments will decrease the estimated percentage of FY 2025 capital outlier payments by 0.03 percent (as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69968). Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments will equal 4.23 percent (4.26 percent − 0.03 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2025. Accordingly, in the FY 2025 IFC (89 FR 80411), we applied an outlier adjustment factor of 0.9577 in determining the capital Federal rate for FY 2025. As we noted in the FY 2025 IFC, although the unrounded FY 2025 outlier adjustment factor was revised because of the removal of the low wage index hospital policy and transitional payment exception, after rounding this factor to 4 decimal places, the rounded factor was unchanged from the final rule.

We received no comments on the FY 2025 outlier adjustment factor established in the FY 2025 IFC and are finalizing it in this final rule without modification.

(2) Budget Neutrality Adjustment Factor for Changes in the GAF

The capital Federal rate is 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. In the FY 2025 IFC (89 FR 80412), we discussed that for FY 2025 we use a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of wage index changes on the GAFs. In the first step, we first 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 FY 2025 IFC, we stated that the provisions of the IFC did not impact this budget neutrality factor (0.9884). We also stated that the incremental adjustment factor for the FY 2025 MS–DRG reclassification and recalibration and for changes in the FY 2025 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy of 0.9854 is not impacted by the provisions of the FY 2025 IFC (89 FR 80412).

Due to the removal of the low wage index hospital policy (discussed previously and also referred to as the lowest quartile hospital wage index adjustment in the discussion of the 2-step methodology in the FY 2025 IPPS/

LTCH PPS final rule), in the FY 2025 IFC (89 FR 80412), we modified the second step of our 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of wage index changes on the GAFs. Specifically, we modified this budget neutrality factor to now ensure budget neutrality for changes to the GAFs due only to the 5-percent cap on wage index decreases policy. As discussed previously, we established a non-budget neutral transitional exception policy for hospitals that benefitted from the low wage index hospital policy during FY 2024. Hospitals that are eligible for the transitional exception policy are excepted from the wage index cap policy for FY 2025 under the provisions of the FY 2025 IFC. Therefore, due to the removal of the low wage index hospital policy, in the FY 2025 IFC (89 FR 80412), the second step of our calculation of the budget neutrality factor for changes in the GAFs in light of the effect of wage index changes on the GAFs only accounts for the application of the 5-percent cap on wage index decreases (for hospitals that did not receive the low wage index hospital policy adjustment in FY 2024). As described in that IFC, to achieve budget neutrality for the effects of the 5-percent cap on wage index decreases policy we calculated an incremental GAF budget neutrality adjustment factor of 0.9992.

We received no comments on the FY 2025 GAF budget neutrality adjustment factors established in the FY 2025 IFC and are finalizing them in this final rule without modification.

(3) Capital Federal Rate for FY 2025

In the FY 2025 IFC (89 FR 80412), as a result of factors established in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69971) with the FY 2025 IPPS/LTCH PPS final rule correction and the outlier adjustment factor and the budget neutrality factor for the effects of the 5-percent cap on wage index decreases established in that IFC (as discussed previously), we established a national capital Federal rate of $512.14 for FY 2025. We received no comments on the national capital Federal rate established in the FY 2025 IFC and are finalizing it in this final rule without modification. The national capital Federal rate for FY 2025 was calculated as shown in the following table.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2024 CAPITAL FEDERAL RATE AND THE FY 2025 CAPITAL FEDERAL RATE

	FY 2024	FY 2025	Change	Percent Change
Update Factor[1]	1.0380	1.0310	1.0310	3.10
GAF/DRG Adjustment Factor[1]	0.9885	0.9854	0.9854	-1.46
Cap Adjustment Factor[2]	0.9964	0.9992	1.0028	0.28
Outlier Adjustment Factor[3]	0.9598	0.9577	0.9978	-0.22
Capital Federal Rate	$503.83	$512.14	1.0165	1.65[4]

[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 2024 to FY 2025 resulting from the application of the 0.9854 GAF/DRG budget neutrality adjustment factor for FY 2025 is a net change of 0.9854 (or -1.46 percent).

[2] The cap 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 FY 2025 cap budget neutrality adjustment factor is 0.9992/0.9964 or 1.0028 (or 0.28 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 FY 2025 outlier adjustment factor is 0.9577/0.9598 or 0.9978 (or -0.22 percent).

[4] Percent change may not sum due to rounding.

e. High-Cost Outlier (HCO) Threshold for Site Neutral Payment Rate Cases Under the LTCH PPS for FY 2025

As discussed in the FY 2025 IFC (89 FR 80412 through 80413), in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69987), we established that the applicable HCO threshold for site neutral payment rate cases for FY 2025 is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. As discussed, the provisions of the FY 2025 IFC result in the recalculation of the IPPS fixed-loss amount for FY 2025. Therefore, in that IFC, for FY 2025 we established a fixed-loss amount for site neutral payment rate cases of $46,217, which is the same as the FY 2025 IPPS fixed-loss amount established in that FY 2025 IFC (and finalized in this final rule, as discussed previously). Accordingly, under this policy, for FY 2025, we 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 fixed-loss amount for site neutral payment rate cases of $46,217).

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 final rule. MedPAC recommendations for the IPPS for FY 2026 are addressed in Appendix B to this final 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*. We listed the data files available in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18405

through 18407). Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

XIII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501–3520 we are required to provide 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, 44 U.S.C. 3506(c)(2)(A) 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 final 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 final rule).

B. Collection of Information Requirements

1. ICRs for the Hospital Readmissions Reduction Program

In section VI.K. of the preamble of this final rule, we discuss updates to the Hospital Readmissions Reduction Program. Specifically, in this final rule, we are (1) modifying the six readmission measures in the program to include Medicare Advantage (MA) beneficiaries into the patient cohorts, and (2) modifying 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 these policies will not impact information collection burden. We believe that continuing to use these claims-based measures will 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 final rule, we discuss updates to the Hospital VBP Program. Specifically, we are modifying 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 finalized modifications will 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 assume any change in burden associated with the finalized modification to add MA beneficiaries into the patient cohorts. As finalized, the measure will 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 policy 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 final rule.

We also finalized removal of 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, there is no change in burden associated with the policy.

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, 2027), 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 final rule, we discuss updates to the HAC Reduction Program. Specifically, we are updating the Centers for Disease Control and Prevention's (CDC's) 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 update does not affect the amount of data hospitals are required to submit for these measures; therefore, we do not assume 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 final rule, we describe the burden changes regarding collection of information, under OMB control number 0938–1022.

For more detailed information on our finalized policies 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 final rule. We are modifying 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 are also modifying 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. These policies will not affect information collection burden.

We are removing 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 policies 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 are finalizing the use of the mean hourly wage for medical records specialists for the industry, ''general medical and surgical hospitals,'' which is $27.69.[500] 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 final rule for the Hospital IQR Program.

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 final 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 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 final rule, we discuss the modification of 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 modifications will include adding MA patients to the current cohort of patients and shortening the performance period from 3 years to 2 years. Because these measures will be calculated using MA encounter data and Medicare FFS claims that are already reported to the Medicare program for payment purposes, modifying these measures does not result in a change in burden associated with OMB control number 0938–1022.

c. Information Collection Burden Estimate for the 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 final rule, we are modifying 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 will 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 these modifications are designed to reduce the administrative burden associated with reporting these measures, they will 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 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 final rule, we are removing 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 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 will decrease the burden for all 3,050 IPPS hospitals by 509 hours annually at a savings of $28,188 (509 hours × $55.38).

e. Information Collection Burden Estimate for the 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 final rule, we are removing 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

[500] 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.*

information collection is approved under OMB control number 0920–1317 [501] (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 is completed by a Microbiologist with a wage rate of $58.60/hour and uploading of a CSV file is completed by an Information Technologist with a wage rate of $56.50/hour. Therefore, we estimate that this policy 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 Removal of the Screening 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 final rule, we are removing 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.[502] 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.[503] 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,[504] 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 will 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 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 final rule, we are removing 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 will 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 invited 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. We received no comments regarding these information collection requirements or the associated burden estimates and therefore, are finalizing without modification.

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 finalized in this final rule will 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 finalized in this final rule will 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 Impact Analysis (section I.K. of Appendix A of this final rule).

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[501] Available at *https://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=202501-0920-003*. Accessed February 26, 2025.

[502] Office of the Assistant Secretary for Planning and 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-department-health-human-services-regulatory-impact-analyses-conceptual-framework*.

[503] 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.

[504] 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-01: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 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	Finalized Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
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) x 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

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-1317 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	Finalized Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
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) x Change in Burden Hours (-27,450) = **-$1,608,570**							

*For purposes of this table, we state the maximum possible burden across all IPPS hospitals.

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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 final rule, we describe the burden changes regarding collection of information under OMB control number 0938–1175 for PCHs.

For more detailed information on our finalized policies for the PCHQR Program, we refer readers to section X.D. of the preamble of this final rule. We are removing 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 policies later in this section.

We are also modifying 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 policy will 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 are finalizing 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 final rule for the PCHQR Program.

b. Information Collection Burden Estimate for the 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 final rule, we are removing 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 estimate the removal of this measure will 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 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 final rule, we are removing the Screening for Social Drivers of Health measure beginning with the 2026 program year. 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 invited 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 received no comments regarding these information collection requirements or the associated burden estimates and therefore, are finalizing without modification.

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.[505] 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.[506] 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,[507] 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 will 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 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 final rule, we are removing 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 will 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 finalized in this final rule will 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 final rule).

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[505] Office of the Assistant Secretary for Planning and 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-department-health-human-services-regulatory-impact-analyses-conceptual-framework*.

[506] 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.

[507] 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

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 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	Finalized Annual burden (hours) across PCHs	Previously finalized annual burden (hours) across PCHs	Net difference in annual burden hours
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) x 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

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 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	Finalized Annual burden (hours) across PCHs	Previously finalized annual burden (hours) across PCHs	Net difference in annual burden hours
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) x Change in Burden Hours (-107) = **-$2,921**							

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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 estimated 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.5. of this final rule, we are finalizing our proposal to amend the LTCH QRP reconsideration request policy and process. As we noted in the FY 2016 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 final rule. We did not receive any public comments on the accuracy of the cost estimate assigned to this administrative burden.

a. Information Collection Burden Estimate for the 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 this final rule, we are finalizing our proposal 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 these modifications to this measure, we also are finalizing our proposal 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.

In estimating the change in information collection burden, we noted in the proposed rule (90 FR 18413) that 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. We estimated that our proposal 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 estimated 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 hours) and 0.10 hours per LTCH.

We estimated 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 estimated 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.

We have summarized the comments we received about modifying reporting requirements for the Patient/Resident COVID–19 Vaccination Measure in section X.E.3. of the preamble of this final rule and provided responses. We received public comments on the accuracy of the cost estimate assigned to this administrative burden, and provide a summary of those comments:

Comment: A few commenters stated that the burden estimate for this measure is not accurate, citing that it does not account for costs associated with the education/training of clinicians, reconciling patient vaccination status among the various sources, administering vaccinations, or providing payment for technological solutions to obtain a patient's COVID–19 vaccination status.

Response: We appreciate the commenters' feedback. Our current burden estimates do not include the cost of individual provider education and training needs, or those related to technological updates to software and hardware. Our burden estimates are doubled to provide for overhead and fringe benefits, which we believe accounts for the time it takes for staff to report items that are assessed as part of routine clinical care and medical charting in an LTCH.

After consideration of the public comments, we are finalizing 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.

b. Information Collection Burden Estimate for the Removal of Four Standardized Patient Assessment Data Elements Beginning With the FY 2028 LTCH QRP

In section X.E.4. of this final rule, we are finalizing our proposal 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 believed 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.[508] 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].

[508] U.S. Bureau of Labor Statistics' (BLS) May 2023 National Occupational Employment and Wage Estimates. *https://www.bls.gov/oes/current/oes_nat.htm.*

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 estimated 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) annually, or $182,330.100 ($552.39 × 330 LTCHs) for all LTCHs annually.

We have summarized the comments we received about removing four standardized patient assessment data elements collected under the SDOH category in section X.E.4 of this final rule and provided responses. We did not receive any comments about these specific estimates.

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 final 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 hours	-$7.01	-33 hours	-$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 hours	-$552.52	-2,601 hours	-$182,330.10
Total estimated change in burden for the FY 2028 LTCH QRP	-7.98 hours	-$545.51	-2,633.51	-$180,016.80

We invited public comments on the modification to information collection requirements for LTCH QRP beginning with the FY 2028 LTCH QRP.

We have summarized the comments we received about modifying reporting requirements for the Patient/Resident COVID–19 Vaccination Measure in section X.E.3. of this final rule, removing four standardized patient assessment data elements collected under the SDOH category in section X.E.4. of this final rule and amending the reconsideration policy and process in X.E.5. of this final rule and provided responses. After consideration of the public comments, we are finalizing these proposals as proposed.

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 final 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 finalized policies for the Medicare Promoting Interoperability Program, we refer readers to section X.F. of the preamble of this final rule. For the Medicare Promoting Interoperability Program, we are adopting 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 are modifying two measures: (1) the Safety Assurance Factors for Electronic Health Record Resilience (SAFER) Guides measure,

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, requiring eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required by the HIPAA Security Rule beginning with the EHR reporting period in CY 2026. We also finalized the definition of 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 are finalizing 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.[509] 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 final rule for the Medicare Promoting Interoperability Program.

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 final 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.

b. Information Collection Burden for the 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 final rule, we are adopting 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 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 final rule, we are modifying 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 and 59432 and 59433). In this final rule, because we are not finalizing an additional attestation, but instead modifying one that was previously finalized, this policy will not result in any changes to the information collection burden currently approved under OMB control number 0938–1278.

d. Information Collection Burden for the 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 final rule, we are modifying 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 by 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 policy compared to the currently approved burden estimate, we assume the currently approved burden estimate is sufficient to include the attestation and are not finalizing any changes to the information collection burden currently approved under OMB control number 0938–1278.

e. Information Collection Burden for the Policy 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

In section X.F.2. of the preamble of this final rule, we are defining 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 policy will not result in any changes to the information collection burden

[509] 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.*

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 final rule will 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 final rule).

8. ICRs for the Transforming Episode Accountability Model

In section XI.A. of the preamble of this final rule, we discuss testing the Transforming Episode Accountability Model (TEAM), finalized in the FY 2025 IPPS/LTCH PPS final rule (89 FR 68986), and finalized 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 final rule for TEAM need not be reviewed by the Office of Management and Budget.

Dr Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 30, 2025.

List of Subjects

42 CFR Part 412

Administrative practice and procedure, 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, and 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.

45 CFR Part 170

Computer technology, Electronic health record, Electronic information system, Electronic transactions, Health, Healthcare, Health information technology, Health insurance, Health records, Hospitals, Incorporation by reference, Laboratories, Medicaid, Medicare, Privacy, Reporting and record keeping requirements, Public health, Security.

For the reasons set out in the preamble, 42 CFR parts 412, 495, and 512 and 45 CFR part 170 are amended as follows:

Title 42—Public Health

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 60 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.

■ 4. 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]

■ 5. Section 412.90(j) is amended in by removing the date ''January 1, 2025''

and adding in its place the date ''October 1, 2025''.

§ 412.101 [Amended]

■ 6. 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]

■ 7. 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''.

■ 8. 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 60 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.

* * * * *

■ 9. Section 412.152 is amended by—
■ a. Revising and republishing the definition of ''Applicable period''; 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 reads 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.

(1) The applicable period for FY 2022 is the 3-year period from July 1, 2017 through June 30, 2020;

(2) Beginning with the FY 2023 program year, the applicable period is the 3-year period advanced by 1-year from the prior year's period from which data are collected in order to calculate excess readmission rations and adjustments under the Hospital Readmissions Reduction Program, unless otherwise specified by the Secretary; and

(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.

* * * * *

■ 10. 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 60 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]

■ 11. Section 412.160 is amended by removing the definition of ''Health equity adjustment bonus points.''

■ 12. Section 412.165 is amended by—

■ a. Removing paragraph (b)(5);

■ b. Redesignating 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 60 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.

■ 13. 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 60 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 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.

* * * * *

■ 14. 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 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 16. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 17. 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

■ 18. The authority citation for part 512 continues to read as follows:

Authority: 42 U.S.C. 1302, 1315a, and 1395hh.

■ 19. The heading for part 512 is revised to read as set forth above.

§ 512.500 [Amended]

■ 20. Section 512.500 is amended by removing and reserving paragraph (b)(18).

■ 21. Section 512.505 is amended by—

■ a. Removing the definition for ''ADI'';

■ b. Adding definitions for ''APC'' and ''CDI'' in alphabetical order;

■ c. Removing the definition for ''Decarbonization and Resilience Initiative'';

■ d. Revising the definition for ''Final normalization factor'';

■ e. Removing the definitions for ''Health equity goal'', ''Health equity plan'', ''Health equity plan intervention strategy'', and ''Health equity plan performance measure'';

■ f. Revising the definition for ''High-cost outlier cap'';

■ g. Adding definitions for ''Medicare ID'' and ''PECOS'' in alphabetical order;

■ h. Revising the definitions for ''Prospective normalization factor'' and ''Region'';

■ i. Adding a definition for ''Scaling factor'' in alphabetical order;

■ j. Revising the definition for ''TEAM participant'';

■ k. Adding a definition for ''Trend year'' in alphabetical order; and

■ l. 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.

* * * * *

TEAM participant means an acute care hospital that either—

(1) Initiates episodes and is paid under the IPPS and OPPS with a CCN primary address located in one of the mandatory CBSAs selected for participation in TEAM in accordance with § 512.515; or

(2) Makes a voluntary opt-in participation election to participate in TEAM in accordance with § 512.510 and is accepted to participate in TEAM by CMS.

* * * * *

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.

* * * * *

■ 22. 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 and OPPS 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).

23. 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.

* * * * *

■ 24. Section 512.540 is amended by revising paragraphs (a)(2) and (3), (b)(1) introductory text, and (b)(2) through (8) to 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) * * *

(1) *Calculation of the preliminary target price.* CMS calculates preliminary target prices based on average baseline episode spending for the region where the TEAM participant is located.

* * * * *

(2) *Baseline periods and associated performance years.* CMS uses the following baseline periods to determine baseline episode spending:

(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, 2023, 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.

(3) *Baseline episode spending weights.* CMS calculates the benchmark price as the weighted average of baseline episode spending, applying the following weights:

(i) Baseline episode spending from baseline year 1 is weighted at 17 percent.

(ii) Baseline episode spending from baseline year 2 is weighted at 33 percent.

(iii) Baseline episode spending from baseline year 3 is weighted at 50 percent.

(4) *Exclusion for high episode spending.* CMS applies a high-cost outlier cap to baseline episode spending at the 99th percentile of regional spending for each of the MS–DRG/HCPCS episode types specified in paragraph (a)(1)(ii) of this section for each baseline year individually.

(5) *Exclusion of incentive programs and add-on payments under existing Medicare payment systems.* Certain Medicare incentive programs and add-on payments are excluded from baseline episode spending by using, with certain modifications, the CMS Price (Payment) Standardization Detailed Methodology used for the Medicare spending per beneficiary measure in the Hospital Value-Based Purchasing Program.

(6) *Prospective normalization factor.* Based on the episodes in the most recent calendar year of the baseline period, CMS calculates a prospective normalization factor at the MS–DRG/HCPCS region level, which is a multiplier that ensures that the average of the total risk-adjusted benchmark price does not exceed the average of the total non-risk adjusted benchmark price, by doing the following:

(i) CMS applies risk adjustment multipliers, as specified in § 512.545(a)(1) through (3), to the most recent baseline year episodes to calculate the estimated risk-adjusted target price for all performance year episodes.

(ii) CMS divides the mean of the preliminary target price for each episode across all hospitals and regions by the mean of the estimated risk-adjusted target price calculated in § 512.540(b)(6)(i) for the same episode types across all hospitals and regions.

(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.

* * * * *

■ 25. Section 512.545 is amended by revising paragraphs (a), (e)(1)(i), and (f) introductory text to read as follows:

§ 512.545 Determination of reconciliation target prices.

* * * * *

(a) CMS risk adjusts the preliminary episode target prices computed under § 512.540 at the beneficiary level using a TEAM Hierarchical Condition Category (HCC) count risk adjustment factor, an age bracket risk adjustment factor, a beneficiary economic risk adjustment factor, and at the hospital level using a hospital bed size risk adjustment factor and a safety net hospital risk adjustment factor, and at the episode category-specific beneficiary level using factors specified in paragraphs (a)(6)(i) through (v) of this section.

(1) The TEAM HCC count risk adjustment factor uses five variables, representing beneficiaries with zero, one, two, three, or four or more CMS–HCC conditions based on a 180-day lookback period that ends on the day prior to the anchor hospitalization or anchor procedure.

(2) The age bracket risk adjustment factor uses four variables, representing beneficiaries in the following age groups as of the first day of the episode:

(i) Less than 65 years.

(ii) 65 to less than 75 years.

(iii) 75 years to less than 85 years.

(iv) 85 years or more.

(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.
(4) The hospital bed size risk adjustment factor uses four variables based on the TEAM participant's characteristics:
(i) 250 beds or fewer.
(ii) 251–500 beds.
(iii) 501–850 beds.
(iv) 850 beds or more.
(5) The safety net hospital risk adjustment factor is based on the TEAM participant meeting the definition of safety net hospital, as defined in § 512.505.
(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) [Reserved]
(X) 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) Prior post-acute care use.
(D) HCC 17: Cancer Metastatic to Lung, Liver, Brain, and Other Organs; Acute Myeloid Leukemia Except Promyelocytic.
(E) HCC 36: Diabetes with Severe Acute Complications.
(F) HCC 37: Diabetes with Chronic Complications.
(G) HCC 48: Morbid Obesity.
(H) HCC 125: Dementia, Severe.
(I) HCC 126: Dementia, Moderate.
(J) HCC 127: Dementia, Mild or Unspecified.
(K) HCC 151: Schizophrenia.
(L) HCC 155: Major Depression, Moderate or Severe, without Psychosis.
(M) HCC 199: Parkinson and Other Degenerative Disease of Basal Ganglia.
(N) HCC 224: Acute on Chronic Heart Failure.
(O) HCC 225: Acute Heart Failure (Excludes Acute on Chronic).
(P) HCC 226: Heart Failure, Except End-Stage and Acute.
(Q) HCC 238: Specified Heart Arrhythmias.
(R) HCC 253: Hemiplegia/ Hemiparesis.
(S) HCC 267: Deep Vein Thrombosis and Pulmonary Embolism.
(T) HCC 280: Chronic Obstructive Pulmonary Disease, Interstitial Lung Disorders, and Other Chronic Lung Disorders.
(U) [Reserved]
(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.

* * * * *

■ 26. Section 512.547 is amended by—
■ a. In paragraph (a) introductory text, removing the phrase ''Hospital Inpatient Quality Reporting Program and the Hospital-Acquired Condition Reduction Program'' and adding in its place ''Hospital Inpatient Quality Reporting Program, the Hospital-Acquired Condition Reduction Program, and the Hospital Outpatient Quality Reporting Program'';
■ b. In paragraph (a)(2) introductory text, removing the phrase ''years 2 through 5'' and adding in its place ''year 2'';
■ c. Adding paragraph (a)(3); and
■ d. Revising paragraphs (b)(1)(i)(B) introductory text and (b)(1)(i)(D).

The addition and revisions 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) * * *
(B) For the Hospital-Level Total Hip and/or Total Knee Arthroplasty (THA/TKA) Patient-Reported Outcome-Based Performance Measure (PRO–PM) (CMIT ID #1618) and the Information Transfer PRO–PM (CMIT ID # 1797):

* * * * *

(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.

* * * * *

■ 27. Section 512.550 is amended by revising paragraph (c) to read as follows:

§ 512.550 Reconciliation process and determination of the reconciliation payment or repayment amount.

* * * * *

(c) *Calculation of the reconciliation amount.* CMS compares the reconciliation target prices described in § 512.545 and the TEAM participant's performance year spending to establish a reconciliation amount for the TEAM participant for each performance year as follows:

(1) CMS determines the performance year spending for each episode included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS–DRG/HCPCS episode type using claims data that is available 6 months after the end of the performance year.

(2) CMS calculates and applies the high-cost outlier cap for performance year episode spending by applying the calculation described in § 512.540(b)(4) to performance year episode spending for each MS–DRG/HCPCS episode type.

(3) CMS applies the adjustments specified in § 512.545 to the preliminary

target prices computed in accordance with § 512.540 to calculate the reconciliation target prices for each MS–DRG/HCPCS episode type.

(4) CMS aggregates the reconciliation target prices computed in accordance with paragraph (c)(3) of this section for all episodes included in the performance year (other than episodes that have been canceled in accordance with § 512.537(b)) for each MS–DRG/HCPCS episode type.

(5) CMS subtracts the performance year spending amount determined under paragraphs (c)(1) and (2) of this section from the reconciliation target price amount determined under paragraph (c)(4) of this section for each MS–DRG/HCPCS episode type.

(6) CMS sums the values calculated under paragraph (c)(5) of this section across all MS–DRG/HCPCS episode types to determine the reconciliation amount.

(7) Exception for low volume hospitals: CMS caps the performance year spending amount for each MS–DRG/HCPCS episode type determined under paragraphs (c)(1) and (2) of this section to equal the reconciliation target price computed in accordance with paragraph (c)(3) of this section for episode categories where the TEAM participant did not meet the low volume threshold of at least 31 episodes during the 3-year baseline period. Low volume hospital episodes, including episode categories where CMS caps performance year spending, are included in the CQS, as calculated in § 512.547(b), and stop-loss/stop-gain thresholds, as applied at paragraph (e) of this section,

* * * * *

■ 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 512.564 is amended by revising paragraph (a) to read as follows:

§ 512.564 Referral to primary care services.

(a) A TEAM participant must include in hospital discharge planning a referral to an established supplier of primary care services, as recorded on admission to the hospital or hospital outpatient department, for a TEAM beneficiary, on or prior to discharge from an anchor hospitalization or anchor procedure. In the event an established supplier of primary care services is not recorded on admission to the hospital or hospital outpatient department, the TEAM participant must 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.

* * * * *

■ 31. 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]

■ 32. Section 512.598 is removed.

Title 45—Public Welfare

PART 170—HEALTH INFORMATION TECHNOLOGY STANDARDS, IMPLEMENTATION SPECIFICATIONS, AND CERTIFICATION CRITERIA AND CERTIFICATION PROGRAMS FOR HEALTH INFORMATION TECHNOLOGY

■ 33. The authority citation for part 170 continues to read as follows:

Authority: 42 U.S.C. 300jj–11; 42 U.S.C 300jj–14; 5 U.S.C. 552.

■ 34. Section 170.102 is amended by—revising and republishing the definition of ''Base EHR'' to read as follows:

§ 170.102 Definitions.

* * * * *

Base EHR means an electronic record of health-related information on an individual that—

(1) Includes patient demographic and clinical health information, such as medical history and problem lists;

(2) Has the capacity—

(i) To provide clinical decision support;

(ii) To support physician order entry;

(iii) To capture and query information relevant to healthcare quality;

(iv) To exchange electronic health information with, and integrate such information from other sources; and

(3) Has been certified to the certification criteria adopted by the Secretary in all of the following:

(i) Section 170.315(a)(1), (2), or (3); (a)(5) and (14), (b)(1), (c)(1), and (g)(7), (9), (10); and (h)(1) or (2).

(ii) Section 170.315(a)(9) or (b)(11) for the period up to and including December 31, 2024.

(iii) Section 170.315(b)(11) on and after January 1, 2025.

(iv) Section 170.315(b)(4) on and after January 1, 2028.

* * * * *

■ 35. Section 170.207 is amended by revising paragraph (d) to read as follows:

§ 170.207 Vocabulary standards for representing electronic health information.

* * * * *

(d) *Medications*—(1) *Clinical drugs*—(i) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, December 4, 2023, Full Update Release (incorporated by reference in § 170.299).

(ii) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, Full Update Release, July 5, 2022 (incorporated by reference, see § 170.299).

(iii) *Standard.* RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015, Full Release Update (incorporated by reference in § 170.299).

(2) *Standard. National Drug Codes.* The code set specified at 45 CFR 162.1002(b)(2) as referenced in 45 CFR 162.1002(c)(1) for the time period on or after October 1, 2015.

(3)–(4) [Reserved]

* * * * *

■ 36. Section 170.215 is revised and republished to read as follows:

§ 170.215 Application Programming Interface Standards.

The Secretary adopts the following standards and associated implementation specifications as the available standards for application programming interfaces (API):

(a) *API base standard.* The following are applicable for purposes of standards-based APIs.

(1) *Standard.* HL7® Fast Healthcare Interoperability Resources (FHIR®) Release 4.0.1 (incorporated by reference, see § 170.299).

(2) [Reserved]

(b) *API constraints and profiles.* The following are applicable for purposes of constraining and profiling data standards.

(1) *United States Core Data Implementation Guides*—(i) *Implementation specification.* HL7® FHIR® US Core Implementation Guide STU 3.1.1 (incorporated by reference in § 170.299). The adoption of this standard expires on January 1, 2026.

(ii) *Implementation Specification.* HL7® FHIR® US Core Implementation Guide STU 6.1.0 (incorporated by reference, see § 170.299).

(2) [Reserved]

(c) *Application access and launch.* The following are applicable for purposes of enabling client applications to access and integrate with data systems.

(1) *Implementation specification.* HL7® SMART Application Launch Framework Implementation Guide Release 1.0.0, including mandatory support for the ''SMART Core Capabilities'' (incorporated by reference, see § 170.299). The adoption of this standard expires on January 1, 2026.

(2) *Implementation specification.* HL7® SMART App Launch Implementation Guide Release 2.0.0, including mandatory support for the ''Capability Sets'' of ''Patient Access for Standalone Apps'' and ''Clinician Access for EHR Launch''; all ''Capabilities'' as defined in ''8.1.2 Capabilities,'' excepting the ''permission-online'' capability; ''Token Introspection'' as defined in ''7 Token Introspection'' (incorporated by reference, see § 170.299).

(d) *Bulk export and data transfer standards.* The following are applicable for purposes of enabling access to large volumes of information on a group of individuals.

(1) *Implementation specification.* FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1), including mandatory support for the ''group-export'' ''OperationDefinition'' (incorporated by reference, see § 170.299).

(2) [Reserved]

(e) *API authentication, security, and privacy.* The following are applicable for purposes of authorizing and authenticating client applications.

(1) *Standard.* OpenID Connect Core 1.0, incorporating errata set 1 (incorporated by reference, see § 170.299).

(2) [Reserved]

(f) *API-based workflow triggers.* The following are applicable for purposes of initiating calls to decision support services or initiating interactions that can be presented to users synchronously in their workflows.

(1) *Implementation specification.* HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2 (incorporated by reference in § 170.299).

(2) [Reserved]

(g) [Reserved]

(h) *API-based event notifications.* The following are applicable for the purposes of supporting proactive notifications from a server to a client when new information has been added or existing information has been updated.

(1) *FHIR Subscriptions: Implementation specification.* HL7® FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use (incorporated by reference in § 170.299).

(2) [Reserved]

(i) [Reserved]

(j) *Prior authorization*—(1) *Coverage requirements discovery*—(i) *Implementation specification.* HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(2) *Prior authorization documentation*—(i) *Implementation specification.* HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(3) *Prior authorization submission*—(i) *Implementation specification.* HL7 FHIR Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2 (incorporated by reference in § 170.299).

(ii) [Reserved]

(k) *Payer data exchange*—(1) *Blue button*—(i) *Implementation specification.* HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US (incorporated by reference in § 170.299).

(ii) [Reserved]

(2) *Payer data exchange*—(i) *Implementation specification.* HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1 (incorporated by reference in § 170.299).

(ii) [Reserved]

(l) [Reserved]

(m) *Drug formulary*—(1) *Implementation specification.* HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2 (incorporated by reference in § 170.299).

(2) [Reserved]

(n) *Directory information*—(1) *Implementation specification.* HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU 1.1 US (incorporated by reference in § 170.299).

(2) [Reserved]

■ 37. Section 170.299 is amended by adding paragraphs (g)(41) through (49) and (r)(10) to read as follows:

§ 170.299 Incorporation by reference.

* * * * *

(g) * * *

(41) HL7 FHIR® Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide, Version 2.0.1—STU 2, January 8, 2024, IBR approved for § 170.215(j).

(42) HL7 FHIR® Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide, Version 2.0.1—STU 2, January 11, 2024, IBR approved for § 170.215(j).

(43) HL7 FHIR® Da Vinci Prior Authorization Support (PAS) FHIR Implementation Guide, Version 2.0.1—STU 2, December 1, 2023, IBR approved for § 170.215(j).

(44) HL7 FHIR® CARIN Consumer Directed Payer Data Exchange (CARIN IG for Blue Button®) Implementation Guide, Version 2.0.0—STU 2 US, November 28, 2022, IBR approved for § 170.215(k).

(45) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Implementation Guide, Version 2.1.0—STU 2.1, June 18, 2025, IBR approved for § 170.215(k).

(46) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) US Drug Formulary Implementation Guide, Version 2.0.1—STU 2, December 1, 2023, IBR approved for § 170.215(m).

(47) HL7 FHIR® Da Vinci Payer Data Exchange (PDex) Plan Net Implementation Guide, Version 1.1.0—STU 1.1 US, April 4, 2022, IBR approved for § 170.215(n).

(48) HL7 FHIR® Subscriptions R5 Backport Implementation Guide, Version 1.1.0—Standard for Trial Use, draft as of January 11, 2023, IBR approved for § 170.215(h).

(49) HL7 FHIR® CDS Hooks Implementation Guide, Version 2.0.1—STU 2 Release 2, March 12, 2025, IBR approved for § 170.215(f).

* * * * *

(r) * * *

(10) RxNorm, December 4, 2023, Full Update Release, IBR approved for § 170.207(d).

* * * * *

■ 38. Section 170.315 is amended by—

■ a. Revising and republishing paragraph (b)(3);

■ b. Revising paragraph (b)(4);

■ c. Adding paragraph (g)(2);

■ d. Removing and reserving paragraph (g)(8);

■ e. Adding and reserving paragraphs (g)(11) through (30);

■ f. Adding paragraphs (g)(31) through (33);

■ g. Adding and reserving paragraph (i); and

■ h. Adding paragraph (j).

The revisions and additions read as follows:

§ 170.315 ONC Certification Criteria for Health IT.

* * * * *

(b) * * *

(3) Electronic prescribing. (i) [Reserved]

(ii) For technology certified subsequent to June 30, 2020:

(A)(*1*) For the time period up to and including December 31, 2027, enable a user to perform the prescription-related electronic transactions specified in paragraph (b)(3)(ii)(A)(*3*) of this section in accordance with the standards specified in § 170.205(b)(1) or (2).

(*i*) At a minimum, at least one of the versions of the standard adopted in § 170.207(d)(1).

(*ii*) The standard in § 170.207(d)(2) if using the standard in § 170.205(b)(2).

(*2*) On and after January 1, 2028, enable a user to perform the prescription-related electronic transactions specified in paragraph (b)(3)(ii)(A)(*3*) of this section in accordance with the standard specified in § 170.205(b)(2).

(*i*) At a minimum, at least one of the versions of the standard adopted in § 170.207(d)(1).

(*ii*) The standard in § 170.207(d)(2).

(*3*) The prescription-related electronic transactions are as follows:

(*i*) New prescriptions (NewRx).

(*ii*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(*iii*) Request and respond to cancel prescriptions (CancelRx, CancelRxResponse).

(*iv*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(*v*) Receive fill status notifications (RxFill).

(*vi*) Request and receive medication history (RxHistoryRequest, RxHistoryResponse).

(*vii*) Relay acceptance of a transaction back to the sender (Status).

(*viii*) Respond that there was a problem with the transaction (Error).

(*ix*) Respond that a transaction requesting a return receipt has been received (Verify).

(*x*) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse, PACancelRequest, PACancelResponse, and PANotification). These transactions are required if using the standard in § 170.205(b)(2).

(B) Enable a user to exchange race and ethnicity information when performing the following prescription-related electronic transactions, if using the standard in § 170.205(b)(2):

(*1*) Receive fill status notifications (RxFill).

(*2*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(*3*) Request to cancel prescriptions (CancelRx).

(*4*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(C) For the following prescription-related transactions, the technology must be able to receive and transmit the diagnosis or diagnoses that are the reason for prescription:

(*1*) Required transactions:

(*i*) New prescriptions (NewRx).

(*ii*) Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse).

(*iii*) Cancel prescriptions (CancelRx).

(*iv*) Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse).

(*v*) Receive fill status notifications (RxFill).

(*vi*) [Reserved]

(*vii*) Electronic prior authorization transactions (PAInitiationRequest, PAInitiationResponse, PARequest, PAResponse, PAAppealRequest, PAAppealResponse and PACancelRequest, PACancelResponse, PANotification). These transactions are required if using the standard in § 170.205(b)(2).

(*2*) [Reserved]

(D) [Reserved]

(E) Limit a user's ability to prescribe all oral liquid medications in only metric standard units of mL (that is, not cc).

(F) Always insert leading zeroes before the decimal point for amounts less than one and must not allow trailing zeroes after a decimal point when a user prescribes medications.

(4) *Real-time prescription benefit*—(i) *Send and receive information.* Enable a user to perform the following transactions using the XML format in accordance with at least one of the versions of the standards adopted in § 170.205(c); at a minimum, a standard adopted in § 170.207(d)(1); and the standard in § 170.207(d)(2), as follows:

(A) Request patient-specific prescription benefit information, estimated cost information, and alternative products, in accordance with the RTPBRequest transaction.

(B) Receive patient-specific prescription benefit information, estimated cost information, and alternative products in response to a request, in accordance with the RTPBResponse transaction.

(ii) *Display.* Display to a user in human readable format patient-specific prescription benefit information, estimated cost information, and alternative products, in accordance with at least one of the versions of the standard adopted in § 170.205(c).

* * * * *

(g) * * *

(2) *Automated measure calculation.* For each Promoting Interoperability Programs percentage-based measure that is supported by a capability included in a technology, record the numerator and denominator and create a report including the numerator, denominator, and resulting percentage associated with each applicable measure.

* * * * *

(8) [Reserved]

* * * * *

(11)–(30) [Reserved]

(31) *Provider prior authorization API—coverage requirements discovery.* Support the following capabilities to enable users to request and receive coverage requirements.

(i) *Coverage discovery.* Support the capability to initiate and exchange information as a ''CRD Client'' to enable the identification of coverage requirements according to at least one of the versions of the implementation specification adopted in § 170.215(j)(1), including the following:

(A) *Registration.* Support registration capabilities applicable to ''CRD Clients''.

(B) *CDS Hooks support.* Support the capabilities in paragraph (j)(20) of this section to enable workflow triggers to call decision support services including support for the ''order-sign'' CDS Hook.

(C) *CRD Client capabilities.* Support all requirements and required capabilities applicable to a ''CRD Client.''

(ii) *Documentation.* Supported API server capabilities of ''CRD Clients'' from an implementation specification

adopted in § 170.215(j)(1) must include complete accompanying technical documentation.

(32) *Provider prior authorization API—documentation templates and rules.* Support the capability for users to request and populate prior authorization documentation using templates and rules as a ''Full DTR EHR'' according to at least one of the versions of the implementation specification adopted in § 170.215(j)(2), including:

(i) *Registration.* Support registration capabilities applicable to a ''Full DTR EHR.''

(ii) *Authentication and authorization.* Support system authentication and authorization as a client in accordance with the ''Backend Services'' section of at least one of the versions of the implementation specification adopted in § 170.215(c).

(iii) *Full DTR EHR capabilities.* Support all requirements and required capabilities applicable to a ''Full DTR EHR.''

(33) *Provider prior authorization API—prior authorization support.* Support the following capabilities to enable users to submit prior authorization requests.

(i) *Prior authorization submission.* Support submitting a prior authorization request as a client in accordance with at least one of the versions of the implementation specification adopted in § 170.215(j)(3) including the following:

(A) *Registration.* Support registration capabilities applicable to a client system.

(B) *Authentication and authorization.* Support system authentication and authorization as a client in accordance with the ''Backend Services'' section of at least one of the versions of the implementation specification adopted in § 170.215(c).

(C) *Prior authorization transactions.* Support the ability to submit a prior authorization request as a client system including the following:

(*1*) Support the capabilities in the ''EHR PAS Capabilities'' Capability Statement.

(*2*) Support the ability to consume and process a ''ClaimResponse.''

(*3*) Support subscriptions as a client according to the requirements in paragraph (j)(21) of this section in order to support ''pended authorization responses.''

(ii) *Documentation.* Supported subscriptions client endpoint capabilities for the ''REST-Hook'' channel from implementation specifications adopted in § 170.215(j)(3) must include complete accompanying technical documentation.

* * * * *

(i) [Reserved]

(j) *Modular API capabilities.* The following technical outcomes and conditions must be met through the demonstration of application programming interface technology.

(1)–(19) [Reserved]

(20) *Workflow triggers for decision support interventions—clients.* Support the requirements applicable to a ''CDS Client'' according to at least one of the implementation specifications in § 170.215(f) including the following:

(i) *Registration.* Support registration capabilities applicable to ''CDS Clients''.

(ii) *Authentication and authorization.* Support authentication and authorization, including the following:

(A) Support for client authentication using JSON web tokens (JWT).

(B) Support for data access authorization of a ''CDS Service'' using access tokens.

(iii) *Workflow triggers.* Support the execution of decision support workflow triggers.

(iv) *Information exchange.* Send a decision support request to a ''CDS Service,'' including support for the following:

(A) *Resource access via API.* Support access to HL7 FHIR Resources via a RESTful API to support decision support intervention workflows according to the ''FHIR Resource Access'' section.

(B) *Receive and display response.* Support the receipt of a decision support response, including support for the display of the contents of a decision support response to an end-user.

(21) *Subscriptions—client.* Support subscriptions as a client according to at least one of the implementation specifications in § 170.215(h), including the following:

(i) Support the requirements in section ''Topic-Based Subscriptions—FHIR R4.''

(ii) Support the ''R4/B Topic-Based Subscription'' profile.

(iii) Support the accompanying client capabilities for the minimum requirements included in the ''R4 Topic-Based Subscription Server Capability Statement,'' including support for ''create,'' ''update,'' and ''delete'' interactions for Subscription Resources.

(iv) Receive subscription notifications according to section ''Topic-Based Subscriptions—FHIR R4,'' including support for consuming notifications via the ''REST-Hook'' channel as specified in the ''Channels'' section.

■ 39. Section 170.404 is amended by—

■ a. Revising the introductory text;

■ b. Revising paragraph (b)(1); and

■ c. Revising definitions for ''Certified API Developer'' and ''Certified API technology'' in paragraph (c).

The revisions read as follows:

§ 170.404 Application programming interfaces.

The following Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (10), and (31) through (g)(33) unless otherwise specified in this section.

* * * * *

(b) * * *

(1) *Authenticity verification and registration for production use.* The following apply to a Certified API Developer with a Health IT Module certified to one or more of § 170.315(g)(10), (31), and (33):

(i) *Authenticity verification.* A Certified API Developer is permitted to institute a process to verify the authenticity of API Users so long as such process is objective and the same for all API Users and completed within ten business days of receipt of an API User's request to register their software application for use with the Certified API Developer's Health IT Module certified to § 170.315(g)(10), (g)(31), and (g)(33).

(ii) *Registration for production use.* A Certified API Developer must register and enable all applications for production use within five business days of completing its verification of an API User's authenticity, pursuant to paragraph (b)(1)(i) of this section.

* * * * *

(c) * * *

Certified API Developer means a health IT developer that creates ''certified API technology.''

Certified API technology means the capabilities of Health IT Modules that are certified to any of the API-focused certification criteria adopted in § 170.315(g)(7) through (10), and (31) through (33).

§ 170.405 [Amended]

■ 40. Section 170.405 is amended in paragraph (a), by removing the phrase ''(g)(7) through (10), and (h) must'' and adding in its place the phrase ''(g)(7) through (10), (g)(31) through (33), (h), and (j)(20) and (21) must''.

■ 41. Section 170.550 is amended by—

■ a. Adding paragraph (g)(6); and

■ b. Removing paragraph (m).

The addition reads as follows:

§ 170.550 Health IT Module certification.

* * * * *

(g) * * *

(6) Section 170.315(b)(4) if the Health IT Module is presented for certification to the certification criteria in § 170.315(b)(3).

* * * * *

Robert J. 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 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 figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final 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 final 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 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 final rule for further discussion of the MDH program.

As discussed in section V.B.2. of the preamble of this final 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 making 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 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 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 final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. 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 using for determining the prospective payment rates for FY 2026.

In summary, the 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 final rule for a complete discussion on the FY 2026 inpatient hospital update. The table that follows shows these four scenarios:

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
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.825	−0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.475	0	−2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.7	−0.7	−0.7	−0.7
Applicable Percentage Increase Applied to Standardized Amount	2.6	0.125	1.775	−0.7

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 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 final 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 final 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 transition for the discontinuation of the low wage index hospital policy (as described in section III.F.7. of the preamble of this final 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 Public Law 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Public Law 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 applying 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 applying a uniform, national budget neutrality adjustment to the FY 2026 wage index for the rural floor.

For FY 2026, we are continuing 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 final 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 discontinuing the low wage index hospital policy. Because we are discontinuing 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 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 finalizing to rebase and revise the national labor-related and nonlabor-related shares (based on the 2023-based hospital IPPS market basket discussed in section IV.B.3. of the preamble of this final 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 final rule, as proposed, we are finalizing 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, as proposed, we are applying 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 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 final 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 calculating 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 using the 2023-based IPPS operating and capital market baskets for FY 2026. As discussed in section VI.B. of the preamble of this final 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 reducing the FY 2026 applicable percentage increase (which for this final rule is based on IGI's second quarter 2025 forecast of the 2023-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2025 forecast of the IPPS hospital market basket percentage increase (as discussed in appendix B of this final rule), the forecast of the hospital market basket percentage increase for FY 2026 for this final rule is 3.3 percent and the forecast of the productivity adjustment for FY 2026 for this final rule is 0.7 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 final rule for a complete discussion on the 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 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 FY 2026 update factors is set forth in appendix B of this final 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 final 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 adjusting 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 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 removing 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 not removing 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), as we proposed, we are including 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, as we proposed, we included 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 applying 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 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 final rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.L. of the preamble of this final 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.

To do this for FY 2026 (as we did in the last 12 fiscal years), as we proposed, we are including the 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 considered 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 including 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 final rule and later in this section, we are continuing 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 including estimated uncompensated care payments in this comparison.

As discussed elsewhere in this final 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. In the proposed rule we stated that 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 also stated that 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. As of the time of the development of this final rule, the MDH program has not been extended by law into FY 2026. Therefore, for purposes of this final rule's calculations, we computed payments under the Federal national rate (not including 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate as applicable) for the total payments for these hospitals in the budget neutrality discussed in this section. and we accounted for uncompensated care payments in the computation of total payments under the Federal rate.

• As proposed, we included 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 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. 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 final 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 making 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 final rule, as we proposed, 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 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 FY 2026 relative weights (before applying the 10-percent cap), consistent with our policy in section V.I. of the preamble to this final rule, we are applying the 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 applying 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 final rule for a complete discussion on the adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this final rule, for a complete discussion of the 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 budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are applying 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 FY 2026 budget neutrality factors.

b. 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 final 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 final 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 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 FY 2026 relative weights before applying the 10-percent cap, and the FY 2025 pre-reclassified wage data, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously); and
- Aggregate payments using the FY 2025 labor-related share percentages, the FY 2026 relative weights after applying the 10-percent cap, and the FY 2025 pre-reclassified wage data, and applied the same proxy FY 2026 hospital readmissions payment adjustments and proxy FY 2026 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2026 relative weights, consistent with our proposal in section V.I. of the preamble to this final rule and our historical policy, and as discussed in the preceding section, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the 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 budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we are applying 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 FY 2026 budget neutrality factors.

c. Updated Wage Index—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 adjusting 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 final rule.

To compute a 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 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 hospital readmissions payment adjustment and the proxy hospital VBP payment adjustment (as described previously).
- Aggregate payments using the FY 2026 relative weights and the FY 2026 pre-reclassified wage indexes, applied the 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 MS–DRG reclassification and recalibration budget neutrality adjustment factor before the 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 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 FY 2026 budget neutrality factors.

Comment: A commenter requested that CMS explain how it applies budget neutrality for a reduction to the labor-related share and show the related adjustment to the standardized amount as it does for all budget neutral provisions. The commenter questioned whether CMS first applies budget neutrality as a change to the national labor-related share including hospitals with a wage index less than 1.0 and then applies the 62 percent labor-related share without budget neutrality. The commenter stated that if so, they requested that CMS apply an alternative methodology that ensures that the decrease in payments for high-wage hospitals requires a positive budget neutrality adjustment to the standardized amount.

Response: The calculation of the FY 2026 wage index budget neutrality factor is the same as every fiscal year except for FY 2026 we also include the change of the labor share on each side of the comparison. Specifically, as explained in the previous comparison, we 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 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). We do not assign hospitals a labor share of 62 percent in the calculation of the wage index budget neutrality factor.

d. Reclassified Hospitals—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 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 2026 labor-related share percentage, the FY 2026 relative weights, and the 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 hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments using the FY 2026 labor-related share percentage, the FY 2026 relative weights, and the FY 2026 wage data after such reclassifications, and applied the same proxy hospital readmissions payment adjustments and the proxy 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 final 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 final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this 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 FY 2026 budget neutrality factors.

The 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 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 final rule.

e. 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 final 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 calculated 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 FY 2026 rural Puerto Rico wage index is calculated based on the average of the 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 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 national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2026 budget neutrality factors.

As further discussed in section III.G.2. of this final 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 final rule for a complete discussion regarding the imputed floor.

f. Permanent Cap Policy for Wage Index—Budget Neutrality Adjustment

As noted previously, in section III.G.6. of the preamble to this final 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 FY 2026 labor-related share percentages, the FY 2026 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments with the 5-percent cap using the FY 2026 labor-related share percentages, the FY 2026 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

g. 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 final 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 finalizing to discontinue the low wage index hospital policy. Because we are discontinuing 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 final rule, we are finalizing as proposed 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 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 transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the FY 2026 labor-related share percentages, the FY 2026 relative weights, and applied the proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments (as described previously).
- Aggregate payments with the transition for the discontinuation of the low wage index hospital policy, the 5-percent cap using the FY 2026 labor-related share percentages, the FY 2026 relative weights, and applied the same proxy hospital readmissions payment adjustments and the proxy hospital VBP payment adjustments applied previously.

This FY 2026 budget neutrality adjustment factor was applied to the standardized amount.

We note, Table 2 associated with this final rule contains the wage index by provider before and after applying 5 percent cap and the transition for the discontinuation of the low wage index hospital policy.

h. Rural Community Hospital Demonstration Program Adjustment

In section VI.N. of the preamble of this final 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 final 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 Pub. L. 108–173. For FY 2026, based on the latest data for this final 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 $47,586,847. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, 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 Final FY 2026 budget neutrality factors. We refer readers to section VI.N. of the preamble of this final 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 FY 2026 budget neutrality factors, as discussed in the previous sections.

SUMMARY OF FY 2026 BUDGET NEUTRALITY FACTORS

MS-DRG Reclassification and Recalibration Budget Neutrality Factor	0.998580
Cap Policy MS–DRG Weights Budget Neutrality Factor	0.999897
Wage Index Budget Neutrality Factor	1.001531
Reclassification Budget Neutrality Factor	0.956835
* Rural Floor Budget Neutrality Factor	0.973976
Cap Policy Wage Index Budget Neutrality Factor	0.999397
Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor	0.999726

SUMMARY OF FY 2026 BUDGET NEUTRALITY FACTORS—Continued

Rural Demonstration Budget Neutrality Factor	0.999552

*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. 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 an 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).)

Comment: One commenter objected to the new criteria adopted in CR 13566 without first going through notice and comment rulemaking.

Response: We responded to a similar comment in the FY 2025 IPPS/LTCH final rule (89 FR 69949). Similar to our response in that final rule, CMS established the outlier reconciliation regulation under § 412.84(i)(4) effective for discharges on or after August 8, 2003 which makes all hospital outlier payments subject to reconciliation. CMS has not modified the outlier regulation. The instructions CMS has issued via CR 13566 have set forth an enforcement policy that determines when MACs will identify additional hospitals for reconciliation referral. They do not change the legal standards that govern the hospitals.

We explained that we believe the new criteria balance current administrative feasibility with the goal of expanding the scope of cost reports identified for outlier reconciliation approval to increase the accuracy of outlier payments. These new criteria for identifying hospital cost reports that MACs should be referred for outlier reconciliation approval are in addition to the original criteria for reconciliation described previously. We refer the reader to the FY 2025 IPPS/LTCH final rule for a complete discussion regarding the new criteria adopted in CR 13566.

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 believe a methodology that incorporates an

[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*.

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 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, in the proposed rule, 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, in the proposed rule 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, in the proposed rule we used the latest quarterly PSF update (December 2024 for the proposed rule).

As previously explained, 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 proposed rule for the FY 2026 outlier fixed-loss cost threshold, we evaluated the use of the most recent available data at the time of the proposed rule (as described previously) using the 5-step methodology as set forth in the FY 2025 IPPS/LTCH PPS final rule. As we explained in the proposed rule, we found that using the most recent available data under our 5-step methodology appeared 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 the 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 the proposed rule (as described previously), the ratio calculated under Step 4 of the methodology was 0.095654 percent (($79,574,408/$83,189,787,222) × 100), which, when rounded to the second digit, was +0.1 percent. We stated that under Step 5 of the methodology, this percentage amount would be used to adjust the outlier target for FY 2026. This would have meant that for FY 2026, we would have incorporated 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 was 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 at the time of the proposed rule (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 previously, 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). In the

[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).

proposed rule, we stated that using the FY 2020 cost report data and PSF values described previously under our methodology would be the first time that the percentage of operating outlier reconciliation dollars to total Federal operating payments from Step 4 was a positive value (and would have the effect of an increase to the outlier threshold). In the proposed rule we stated that 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 proposed 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 stated that 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 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 proposed 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 proposed to target an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2026. Therefore, for FY 2026, we proposed 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 the Addendum to the proposed rule, we provided the FY 2026 proposed outlier threshold as calculated for the 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 was 0.949 (1 − 0.051).

We noted, in the FY 2026 proposed rule, consistent with our historical practice, we planned to evaluate the updated data available at the time of the development of the final rule (such as the March 2025 HCRIS extract of the FY 2020 cost report). We stated that 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 invited 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.

Comment: One commenter supported the proposal to hold the data constant from the FY2025 IPPS/LTCH PPS final rule.

Response: We appreciate the support for the proposal to hold constant the outlier reconciliation estimate. For this final rule, we evaluated the updated data available at the time of the development of this final rule (specifically, the March 2025 HCRIS extract of the FY 2020 cost report). Using the most recent available data for this final rule, the ratio calculated under Step 4 of the methodology would be 0.0937 percent (($77,958,731/$83,200,772,713) × 100), which, when rounded to the second digit, is +0.09 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 5.1 percent [5.1 percent − (0.09 percent)]. This positive 0.09 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).

As discussed earlier, 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 for this final rule (described previously), similar to the proposed rule, 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. Similar to the proposed rule, for this final rule, 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.

After considering the comments received and based on our evaluation using the updated data available at the time of the development of this final rule which continues to show that that data may be an anomaly, we are finalizing as proposed. Specifically, for purposes of incorporating an estimate of outlier reconciliation into the outlier fixed-loss cost threshold calculation for FY 2026, we are holding the data constant and using 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 continue to 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. We are using this percentage to adjust the 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 finalizing 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 targeting an outlier threshold at an amount higher than 5.1 percent for outlier payments for FY 2026. Therefore, for FY 2026, we are incorporating 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 outlier threshold as calculated for this final 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 final operating outlier offset to the standardized amount is 0.949 (1—0.051).

(b) 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 are establishing 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 reducing 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, in the proposed rule 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, in the proposed rule 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 allowed 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 the estimate, we used the latest quarterly PSF update (December 2024) for the proposed rule.

As previously explained, 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 in the proposed rule, 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 explained in the proposed rule, we found that using the most recent available data under our 5-step methodology appeared to produce anomalous results that may not provide an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year. (We noted, for the hospitals identified in Step 1b (hospitals that would be referred for outlier reconciliation approval under the new criteria), for the 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

[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)

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 previously).

For the proposed rule, the estimated percentage of FY 2026 capital outlier payments otherwise determined using the shared outlier threshold was 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 at the time of the proposed rule (described previously), the total in Step 2 was $1,529,376, which was a positive amount. The percentage calculated in Step 4 was a positive 0.021188 percent (($1,529,376/$7,218,168,555) × 100), which, when rounded to the second digit, was +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 the FY 2026 proposed rule we would have increased the estimated percentage of FY 2026 aggregate capital outlier payments by 0.02 percent. This positive 0.02 percentage point was 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 at the time of the proposed rule (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 previously mentioned, 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). In the proposed rule, 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 stated in the proposed rule that 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 proposed 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 the 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 was 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 stated that we believed 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 the Addendum of the proposed rule, we incorporated the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the proposed capital Federal rate based on the estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2026.

We noted in the proposed rule, for the FY 2026 final rule, consistent with our historical practice, we planned 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 stated that 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 invited 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.

Comment: As previously mentioned, we received one comment supporting our proposal to hold the data constant from the FY 2025 IPPS/LTCH PPS final rule.

Response: We appreciate the support for the proposal to hold constant the outlier reconciliation estimate. For this final rule, we evaluated the updated data available at the time of the development of this final rule (specifically, the March 2025 HCRIS extract of the FY 2020 cost report). Using the most recent available data for this final rule, similar to the proposed rule, the total in Step 2 is $1,500,253, which is a positive amount. The percentage calculated in Step 4 is a positive 0.020782 percent (($1,500,253/$7,219,087,289) × 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 this final rule 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). 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). Similar to the proposed rule, for this final rule 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.

After considering the comments received and based on our evaluation using the updated data available at the time of the development of this final rule which continues to show that that data may be an anomaly, we are finalizing as proposed. Specifically, 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 holding the data constant and using 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 final rule, taking into account projected capital

payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation amounts from Steps 2a and 2b. (89 FR 69955).

outlier reconciliation under our methodology would decrease the estimated percentage of FY 2026 aggregate capital outlier payments by 0.03 percent. This percentage amount is being 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 of this final rule, we incorporated 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.

(2) 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 FY 2026 outlier threshold, we simulated payments by applying 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 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 using 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 FY 2026 relative weights, consistent with our policy discussed in section IV.I. of the preamble to this final rule, we applied the 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 proposed to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2026, we proposed 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 the 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 the FY 2026 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We proposed 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 the FY 2026 IPPS/LTCH PPS proposed rule, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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, in the proposed rule, 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 the 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 the 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 Pub. L. 108–173.
- Incorporating our policy (described in section III.6. of the preamble of this final 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 final 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, the 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 final 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 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 proposed 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 proposed 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 proposed to include estimated FY 2026 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed 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.

Comment: A commenter requested that CMS apply trims when calculating charge inflation as it does under the LTCH PPS to ''remove all claims from providers whose growth in average charges was a statistical outlier''.

Response: We responded to a similar comment in the FY 2024 IPPS/LTCH PPS final rule (88 FR 59351). As we explained in that final rule, there are many more providers and claims under the IPPS compared to the LTCH PPS. When we analyzed the LTCH PPS claims data, a single LTCH provider had substantial increases in its charges with average charges per case of approximately $10 million which significantly influenced the charge inflation factor. Since there are fewer hospitals and claims under the LTCH PPS, the potential for a single provider to influence the charge inflation factor is much more significant. We are not aware of a similar situation with a hospital having such high average charges under the IPPS. Therefore, we believe it is not necessary to apply the same trim to hospitals included in the IPPS charge inflation factor. We refer the reader to the FY 2024 IPPS/LTCH final rule for our complete response.

Comment: Commenters supported the proposed decrease in the high-cost outlier threshold from the FY 2025 threshold.

Response: We appreciate the commenters' feedback. We note that the FY 2026 final rule's fixed-loss threshold is lower than the proposed rule's fixed-loss threshold.

Comment: A commenter requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. This commenter explained that high charge cases have a significant impact on the threshold. The commenter stated that it examined the data to understand the factors that drove a doubling of the threshold between FY 2016 and FY 2025, and stated that it observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold. If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the commenter stated that the impact of this population of cases on the threshold will likewise increase. Thus, the commenter recommended that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs. One commenter requested that CMS release greater detail on how the fixed loss threshold is calculated, with particular attention to the treatment of extreme cases. The commenter recommend CMS remove statistical outliers from the calculation, as is done when extreme cases appear in the data used to calculate the MS–DRG relative weights.

Response: We responded to a similar comment in prior rulemaking, most recently in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69959–69960). As we explained in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526) and other prior rulemaking, the methodology used to calculate the outlier threshold includes all claims to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We continue to believe excluding these cases would artificially lower the threshold. We continue to believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate.

Also, as we explained in the FY 2024 IPPS/LTCH final rule (88 FR 59352), in response to commenter's recommendation that CMS consider whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs, we believe the current calculation of outlier payment meets these goals. If a case has high charges that once reduced to cost significantly exceed the payment plus the threshold, then the case will receive a larger outlier payment reflective of the higher costs. Therefore, we believe the current payment system provides such a mechanism.

With regard to the commenter that requested that CMS release greater detail on how the fixed loss threshold is calculated, with particular attention to the treatment of extreme cases, we believe we have provided detailed information regarding how the fixed loss threshold is calculated. Also, for the reasons stated earlier, including cases with high charges lends more accuracy to the threshold. We welcome more specific information from the commenter with regard to the detail the commenter is requesting.

Comment: A commenter noted the final fixed-loss threshold established by CMS has consistently been lower than the threshold set forth in the proposed rule, and the variance between the proposed and final thresholds has generally exceeded 4 percent. The commenter emphasized that this demonstrates that CMS must ordinarily use the most recent data to appropriately calculate the outlier threshold.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer readers to that rule for our response. We reiterate that CMS' historical policy is to use the best available data when setting the payment rates and factors in both the proposed and final rules. Sometimes there are variables that change between the proposed and final rule as result of the availability of more recent data, such as the charge inflation factor and the CCR adjustment factors that can cause fluctuations in the threshold amount. Other factors such as changes to the wage indexes and market basket increase can also cause the outlier fixed loss cost threshold to fluctuate between the proposed rule and the final rule each year. We use the latest data that is available at the time of the development of the proposed and final rules, such as the most recent update of MedPAR claims data and CCRs from the most recent update of the PSF.

Comment: A few commenters believe Congress required CMS to calculate the standardized amount using the ''average standardized amount computed for the previous fiscal year under paragraph (2)(D) or this subparagraph'' (with the subparagraph referring to section 1886(d)(3)(A) of the Act). The commenters believe that CMS should use the FY 1985 standardized amount before it was adjusted to offset projected outlier payments under section 1886(d)(3)(B) of the Act and the neutrality provisions of sections 1886(d)(3)(C)(i) and (e)(1)(B) of the Act. The commenters believe that the FY 1986 IPPS rates reduced the standardized rate in that year and all subsequent years, including the time-period at issue here. To correct this error, the commenters believe CMS should either adjust the standardized amount or adjust the standardized amount and the MS–DRG weights.

Response: We appreciate the commenters' concerns. We note that this issue was raised and addressed during the FY 1986 IPPS rulemaking process. In setting the standardized amount for FY 1986, we explained at the time that the ''latest measure is more accurate than the earlier measurements used to compute the previously published factors because of the availability of more complete and later data, [and] its use should result in a more precise approximation of the amounts that should have been paid in FY 1984 and FY 1985, if we had been able to achieve budget neutrality accurately.'' 50 FR at 35697. We declined to engage in ''retroactive implementation of revised budget neutrality adjustments'' for FYs 1984 and 1985 because doing so ''would not comport with the basic principle of prospectivity of the prospective payment system.'' Id. But we ''converted these factors prospectively by adjusting the FY1986 rates accordingly.'' Id.

We further disagreed with those earlier commenters that ''the prior years' standardized rates before budget neutrality should serve as the basis for updating the FY 1986 rates.'' Id. We stated that ''section 1886(d)(3)(A) and (C) of the Act does not explicitly require that the update factor apply to the FY 1985 payment rate prior to the adjustments for budget neutrality in FY 1985.'' Id.

We understand that commenters now express disagreement with those decisions made after notice and comment nearly forty years ago. However, we do not believe it is appropriate to address these concerns again now, particularly in light of the fact that we

did not solicit comments on the issue of revisiting the FY 1986 adjustment. It would be inappropriate to revise a long-standing decision made following notice and an opportunity for comment without providing notice that we were considering revisions of the issue.

Comment: A commenter requested that CMS make a reduction to the outlier threshold due to the proposed productivity adjustment of 0.8 percent, so that there is compatibility with the 2025 threshold.

Response: As noted previously, section 1886(d)(5)(A)(iv) of the Act states that outlier payments may not be less than 5 percent nor more than 6 percent of the total payments projected or estimated to be made based on DRG prospective payment rates for discharges in that year. We believe that the commenter's suggestion to make a reduction to the FY 2026 outlier fixed-loss cost threshold due to the productivity adjustment would be inconsistent with the statute as such a threshold would not result in a projection of outlier payments that are not less than 5 percent nor more than 6 percent of projected total payments for FY 2026.

After consideration of the public comments we received and for the reasons discussed, we are finalizing to use the same methodology we proposed, without modifications, to calculate the final outlier threshold for FY 2026.

For the FY 2026 final outlier threshold, we used the March 2024 MedPAR file of FY 2023 (October 1, 2022 through September 30, 2023) charge data (released in conjunction with the FY 2025 IPPS/LTCH PPS final rule) and the March 2025 MedPAR file of FY 2024 (October 1, 2023 through September 30, 2024) charge data (released in conjunction with this FY 2026 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $ 86,123.88 ($596,284,630,184/6,923,569 cases) from October 1, 2022 through September 31, 2023, to the average covered charge per case of $ 90,864.64 ($628,751,420,329/6,919,649 cases) from October 1, 2023 through September 31, 2024. This rate-of-change was 5.5 percent (1.05505) or 11.3 percent (1.11313) 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, we are establishing the FY 2026 outlier threshold using hospital CCRs from the March 2025 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the final rule. We applied 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 replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned 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 did not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2026, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section).

For this final rule, as we have done since FY 2014 (with the exception of FYs 2022 and 2023, as discussed in the FY 2022 and FY 2023 IPPS/LTCH PPS proposed and final rules), we are adjusting the CCRs from the March 2025 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2024 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2025 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 methodology noted earlier, for this final rule, we calculated a March 2024 operating national average case-weighted CCR of 0.251988 and a March 2025 operating national average case-weighted CCR of 0.240921. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2024 operating national average case weighted CCR from the March 2025 operating national average case-weighted CCR and then dividing the result by the March 2024 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.956081.

We used the same methodology earlier to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2024 capital national average case-weighted CCR of 0.017642 and a March 2025 capital national average case-weighted CCR of 0.016453. We then calculated the percentage change between the two national capital case weighted CCRs by subtracting the March 2024 capital national average case-weighted CCR from the March 2025 capital national average case-weighted CCR and then dividing the result by the March 2024 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.932604.

As discussed previously, for purposes of estimating the final outlier threshold for FY 2026, we used a wage index that reflects the policies discussed in this final rule. This includes the following:

- Application of the rural and imputed floor adjustment.
- The frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.
- The 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 final 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 transition for the discontinuation of the low wage index hospital policy (as described in section III.F.7. of the preamble of this final rule).

As stated previously, if we did not take the above into account, our estimate of total FY 2026 payments would be too low, and, as a result, the outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.14 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).

- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.
- Based on the policy finalized, as previously described, we used the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the 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 finalizing to incorporate an estimate of FY 2026 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, we are finalizing 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 incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.14 percent [5.1 percent − (− .04 percent)]. Under this approach, we determined a threshold of $ 40,397 and calculated total outlier payments of $4,457,496,335 and total operating Federal payments of $82,262,071,135. 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 incorporated 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 methodology for incorporating an estimate of outlier reconciliation in the

determination of the outlier threshold, the threshold would be $40,714. We are finalizing 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 $40,397.

(3) Other 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 3.84 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 reduce the FY 2026 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2026 outlier threshold are as follows:

	Operating standardized amounts	Capital Federal rate *
National	0.949	0.957704

* The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2025 capital outlier payments for capital outlier reconciliation, as discussed in the FY 2025 IPPS/LTCH final rule.

We are applying 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 1.263 or capital CCRs greater than 0.132 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 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 statewide average capital CCRs. As previously stated, the 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 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 5.17 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 final rule. We will provide an estimate of actual FY 2025 outlier payments in the FY 2027 IPPS/LTCH PPS proposed rule.

5. 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 applying to all hospitals, except hospitals located in Puerto Rico, for FY 2026. The 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 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 applying 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 standardized amounts reflecting the applicable percentage increases for FY 2026.

The 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 FY 2026 national standardized amounts. The second through fifth columns display the changes from the FY 2025 standardized amounts for each 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 FINAL 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%): $4,790.03; 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%): $4,790.03; 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%): $4,790.03; 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.
FY 2026 Update Factor	1.026	1.00125	1.01775	0.993.
FY 2026 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap.	0.998580	0.998580	0.998580	0.998580.
FY 2026 Cap Policy MS–DRG Weight Budget Neutrality Factor.	0.999897	0.999897	0.999897	0.999897.
FY 2026 Wage Index Budget Neutrality Factor	1.001531	1.001531	1.001531	1.001531.
FY 2026 Reclassification Budget Neutrality Factor	0.956835	0.956835	0.956835	0.956835.
FY 2026 Cap Policy Wage Index Budget Neutrality Factor.	0.999397	0.999397	0.999397	0.999397.
Transition for the Discontinuation of the Low Wage Index Hospital Policy Budget Neutrality Factor.	0.999726	0.999726	0.999726	0.999726.
FY 2026 RCH Demonstration Budget Neutrality Factor.	0.999552	0.999552	0.999552	0.999552.
FY 2026 Operating Outlier Factor	0.949	0.949	0.949	0.949.
National Standardized Amount for FY 2026 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (66.0/34.0).	Labor: $4,456.72; Nonlabor: $2,295.89.	Labor: $4,349.21; Nonlabor: $2,240.51.	Labor: $4,420.88; Nonlabor: $2,277.43.	Labor: $4,313.38; Nonlabor: $2,222.05.
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: $4,186.62; Nonlabor: $2,565.99.	Labor: $4,085.63; Nonlabor: $2,504.09.	Labor: $4,152.95; Nonlabor: $2,545.36.	Labor: $4,051.97; Nonlabor: $2,483.46.

B. 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 labor-related and nonlabor-related shares that we are using 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. 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 final rule, we are applying 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 applying 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 final 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 the FY 2026 IPPS/LTCH PPS proposed rule, we proposed 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 2023-based IPPS market basket. We note, as described in section IV. of the preamble of this final rule, effective beginning FY 2026, we are finalizing to rebase and revise the IPPS market basket to reflect a 2023 base year. We also are finalizing to recalculate the labor- related share for discharges occurring on or after October 1, 2025, using the final 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

We stated in the proposed rule that 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 proposed 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. We stated we were interested in and solicited 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.

Comment: A commenter supported CMS' proposal to maintain the current COLA methodology temporarily while we evaluate alternative approaches. The commenter requested that CMS utilize a more sensitive adjustment to reflect cost variation across Alaska. The commenter stated that tying Alaska's COLA to a single urban index does not reflect higher costs in more remote areas. The commenter also requested that CMS reconsider the 25% cap on COLA adjustments and engage with providers during the development of the new methodology.

Response: We appreciate the commenter's support for our proposal and may consider the commenter's suggestions for future rulemaking.

After consideration of the public comment we received, we are finalizing our proposal 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 COLA factors for FY 2026.

FY 2026 COST-OF-LIVING ADJUSTMENT (COLA) FACTORS: ALASKA AND HAWAII HOSPITALS

Area	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

C. Calculation of the 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 final 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 × 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 final 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 final 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 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 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
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3

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
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	−0.825	−0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	−2.475	0	−2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.7	−0.7	−0.7	−0.7
Applicable Percentage Increase Applied to Standardized Amount	2.6	0.125	1.775	−0.7

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 final 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 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 final 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 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. 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 used 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 Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2026

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2026. In particular, we explain why the FY 2026 capital Federal rate will increase approximately 2.35 percent, compared to the FY 2025 capital Federal rate. As discussed in the impact analysis in Appendix A to this rule, we estimate that capital payments per discharge will increase approximately 3.2 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 update factor for FY 2026 under that framework is 2.8 percent based on a projected 2.8 percent increase in the 2023-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a 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 final rule, we describe the policy adjustments that we applied 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, as proposed, the 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 final 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, as proposed, we are making 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, as proposed, we are not making 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 final rule, as proposed, we are continuing 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 using 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, as proposed, we are making 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 2.8 percent capital update factor under the capital update framework for FY 2026, as shown in the following table.

FY 2026 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.8
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	2.8

*The capital input price index represents the 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, as proposed, we continue to incorporate the impact of estimated operating outlier reconciliation payment amounts into the outlier threshold model. (For more details on our methodology 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 final rule.)

For FY 2025, we estimated that outlier payments for capital-related PPS payments will 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 will equal 3.87 percent of inpatient capital-related payments based on the capital Federal rate in FY 2026. Using the methodology outlined in section II.A.4.i. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments will 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 will equal 3.84 percent (3.87 percent—0.03 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2026. Accordingly, we applied an outlier adjustment factor of 0.9616 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 will 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 FY 2026 outlier adjustment of 0.9616 is a 0.41 percent change from the FY 2025 outlier adjustment of 0.9577. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2026 is 1.0041 (0.9616/0.9577) so that the outlier adjustment will increase the FY 2026 capital Federal rate by approximately 0.41 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.F.5. of the preamble of this final 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. (We note, after consideration of public comments, we are finalizing the provisions of the FY 2025 IFC without modification, as discussed in section XI.C. of the preamble of this final rule.)

As discussed in section III.F.5. of the preamble of this final rule, for FY 2026 and subsequent fiscal years, as proposed, we are discontinuing the low wage index hospital policy and associated budget neutrality adjustment. In addition, as discussed in section IIII.F.6. of the preamble of this final 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 FY 2026 wage index. Therefore, in addition to our permanent 5-percent wage index cap policy at 42 CFR 412.64(h)(7), as proposed, we are establishing 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 will be implemented in a budget neutral manner. Specifically, 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 are establishing a transitional payment exception for FY 2026 for that hospital that will 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 this finalized policy, we are making a budget neutral equivalent exception under the capital IPPS. In this section, we refer to this finalized 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 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 changes, we augmented our historical methodology for computing the budget neutrality factor for changes in the GAFs.

Specifically, we used a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. In the first step, we 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 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 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 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 2-step calculation of the 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 FY 2026 GAFs without incorporating the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9934 for FY 2026.

Next, we compared estimated aggregate capital Federal rate payments based on the FY 2026 GAFs with and without the 5-

percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2026 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the FY 2026 GAFs (both with and without the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy). (We note, for this calculation the 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 transition for the discontinuation of the low wage index hospital policy on the FY 2026 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9989.

The budget neutrality factor for the 5-percent cap on wage index decreases policy and the 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 budget neutrality factor for the 5-percent cap on wage index decreases policy and the 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 budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the 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 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 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 FY 2026 GAFs without the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. The incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 0.9984. Next, we compared estimated aggregate capital Federal rate payments based on the 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 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 FY 2026 GAFs without the 5 percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy. The 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 FY 2026 MS–DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we applied an incremental budget neutrality adjustment factor of 0.9983 (0.9984 × 0.9999) for FY 2026 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The incremental adjustment factor for the FY 2026 MS–DRG reclassification and recalibration (0.9983) and for changes in the FY 2026 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (0.9934) is 0.9918 (0.9983 × 0.9934). 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 transition for the discontinuation of the low wage index hospital policy on the FY 2026 GAFs, as described previously, we calculated a budget neutrality adjustment factor of 0.9989 for FY 2026. We refer to this budget neutrality factor for the remainder of this section as the cap/transition adjustment factor.

We applied the 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 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 incremental GAF/DRG adjustment factor of 0.9918 accounts for the MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for changes in the GAFs that result from 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 cap/transition adjustment factor of 0.9989 accounts for changes that result from the 5-percent cap on wage index decreases policy and the 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 establishing an update of 2.8 percent in determining the FY 2026 capital Federal rate for all hospitals. As a result of this final update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $524.15 for FY 2026. The national capital Federal rate for FY 2026 was calculated as follows:

- The FY 2026 update factor is 1.028; that is, the update is 2.8 percent.
- The FY 2026 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and 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 0.9918.
- The 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 transition for the discontinuation of the low wage index hospital policy is 0.9989.
- The FY 2026 outlier adjustment factor is 0.9616.

We are providing the following chart that shows how each of the factors and adjustments for FY 2026 affects the computation of the FY 2026 national capital Federal rate in comparison to the FY 2025 national capital Federal rate. The FY 2026 update factor has the effect of increasing the capital Federal rate by 2.8 percent compared to the FY 2025 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal

rate by 0.82 percent. The FY 2026 cap/transition budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.02 percent compared to the FY 2025 capital Federal rate. The FY 2026 outlier adjustment factor has the effect of increasing the capital Federal rate by 0.41 percent compared to the FY 2025 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 2.35 percent, compared to the FY 2025 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2025 CAPITAL FEDERAL RATE AND THE FY 2026 CAPITAL FEDERAL RATE

	FY 2025	FY 2026	Change	Percent change
Update Factor [1]	1.0310	1.0280	1.0280	2.80
GAF/DRG Adjustment Factor [1]	0.9854	0.9918	0.9918	-0.82
GAF Cap/Transition Adjustment Factor [2]	0.9992	0.9989	0.9998	-0.02
Outlier Adjustment Factor [3]	0.9577	0.9616	1.0041	0.41
Capital Federal Rate	$512.14	$524.15	1.0235	[4] 2.35

[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 0.9918 GAF/DRG budget neutrality adjustment factor for FY 2026 is a net change of 0.9918 (or −0.82 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 FY 2026 GAF Cap/Transition budget neutrality adjustment factor is 0.9989/0.9992 or 0.9998 (or −0.02 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 FY 2026 outlier adjustment factor is 0.9616/0.9577 or 1.0041 (or 0.41 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the 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 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 fixed-loss amount of $40,397.

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 final rule, we are using the IPPS operating and capital market baskets that reflect a 2023 base year. For a complete discussion of the rebasing of the IPPS operating and capital market baskets, we refer readers to section IV. of the preamble of this final rule.

2. Forecast of the CIPI for FY 2026

Based on IHS Global Inc.'s (IGI) second quarter 2025 forecast, for this final rule, we are forecasting the 2023-based CIPI to increase 2.8 percent in FY 2026. This reflects a projected 3.4 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 3.6 percent increase in other capital expense prices in FY 2026, partially offset by a projected 0.2 percent decline in vintage-weighted interest expense prices in FY 2026. The weighted average of these three factors produces the forecasted 2.8 percent increase for the 2023-based CIPI in FY 2026.

As proposed, we are using the more recent data available to determine the FY 2026 increase in the 2023-based CIPI for this final rule.

Comment: A commenter supported the continued application of a prospective methodology for capital-related payments adjusted by the DRG weight. The commenter stated that the agency should assess whether this approach captures the rising costs associated with necessary infrastructure investments—particularly those related to climate resiliency, cybersecurity modernization, and structural upgrades to accommodate infection control. The commenter stated that many of these costs are long-term in nature and cannot be met through base operating rate adjustments alone.

Response: The CIPI reflects the structure of capital costs for IPPS hospitals and the associated prices for capital inputs used in providing Medicare services in IPPS hospitals. As stated in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18247 through 18252), the 2023-based IPPS capital input price index cost weights are based on the Medicare cost report data from Worksheet A–7. The Medicare cost report capital cost data reflects all allowable capital-related costs for land and depreciable assets, with additional recognition of costs for capital-related items and services that are legally obligated by an enforceable contract (See CMS Pub. 15–1, chapter 28, § 2806). The Medicare cost report does not allow us to separately identify detailed costs for infrastructure investment costs that the commenter mentioned; however, we believe these costs could meet the definition of Medicare-allowable capital-related costs and thus be reflected in the base year cost weights. (See section IV of the preamble of this final rule for additional details on the rebasing and revising of the hospital market baskets for acute care hospitals.)

IV. 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 the FY 2026 IPPS/LTCH PPS proposed rule, based on IGI's 2024 fourth quarter forecast, we estimated that the proposed 2023-based IPPS operating market basket percentage increase for FY 2026 was 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 would 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 was 3.2 percent, in accordance with the applicable regulations at 42 CFR 413.40. We also proposed that if more recent data became 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.

More recent data has become available. Based on IGI's second quarter 2025 forecast, we estimate that the 2023-based IPPS operating market basket percentage increase for FY 2026 is 3.3 percent (that is, the estimate of the market basket rate-of-increase). Accordingly, the FY 2026 rate-of-increase percentage that we will apply 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 3.3 percent, which is based on IGI's second quarter 2025 forecast.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.3 percent 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 IX. of the preamble and section V. of the Addendum of this final 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. Changes to the Payment Rates for the LTCH PPS for FY 2026

A. LTCH PPS Standard Federal Payment Rate for FY 2026

1. Overview

In section IX. of the preamble of this final 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 final 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 final 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 FY 2026 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2026, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2026, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2026 LTCH PPS standard Federal payment rate, as we proposed, we are applying 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 final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 2.7 percent (that is, the most recent estimate of the 2022-based LTCH market basket increase of 3.4 percent less the productivity adjustment of 0.7 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are applying an update factor of 1.027 to the FY 2025 LTCH PPS standard Federal payment rate of $49,383.26 to determine the 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 establishing an annual update to the LTCH PPS standard Federal payment rate of 0.7 percent (or an update factor of 1.007). This update reflects the annual market basket update of 3.4 percent reduced by the 0.7 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 applying an area wage level budget neutrality factor to the FY 2026 LTCH PPS standard Federal payment rate of 1.0021275, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section), and 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 establishing an LTCH PPS standard Federal payment rate of $50,824.51 (calculated as $49,383.26 × 1.027 × 1.0021275) 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 establishing an LTCH PPS standard Federal payment rate of $49,834.74 (calculated as $49,383.26 × 1.007 × 1.0021275) for FY 2026.

B. 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 FY 2026 LTCH PPS standard Federal payment rate wage index values that will 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. 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, 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 continuing 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. 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18664), consistent with our historical practice, we proposed 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 proposed 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 was 69.2 percent. The portion of capital-related costs that is influenced by the local labor market was estimated to be 46 percent (that was, 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 was 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 proposed 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 also proposed that if more recent data became 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 would use such data, if appropriate, to determine the FY 2026 LTCH PPS labor-related share.

Comment: A few commenters expressed appreciation and support for the proposed FY 2026 labor-related share of 73.1 percent, which represents a 0.3 percentage point increase over last year's 72.8 percent. The commenters stated that health care providers continue to face workforce challenges that were exacerbated during the COVID–19 pandemic and an increased labor-related share will help reimbursement rates to recognize that pressure. However, some commenters expressed concern that the proposed 0.3 percentage point increase to the labor-related share does not sufficiently account for the dramatic increases in labor costs that LTCHs are incurring.

Several commenters opposed CMS' proposal to increase the labor-related share to 73.1 percent for FY 2026. A commenter

stated that this change—especially coming on top of last year's notable increase from 68.5 percent to 72.8 percent—will adversely affect hospitals in areas with below-average wage indices. The commenter stated that keeping the labor-related share at its current level (72.8 percent)—or lower—would help avoid further penalizing hospitals in low-wage areas and would help mitigate the growing disparity between high-wage and low-wage regions. Therefore, the commenter believed the labor-related share for LTCHs should remain aligned with, or below, that of other inpatient providers to ensure fairness and protect rural and community LTCHs from disproportionate payment cuts.

Response: The total difference between the proposed FY 2026 labor-related share using the 2022-based LTCH market basket (73.1 percent) and the FY 2025 labor-related share (72.8 percent) is a result of incorporating more recent data regarding expected price pressures facing LTCHs. We believe incorporating these more recent data in the LTCH market basket is appropriate, resulting in a corresponding increase in the labor-related share, and appropriately identifies the portion of an LTCH's standard Federal payment rate to be adjusted by the applicable LTCH wage index. This methodology is consistent with the determination of the labor-related share since the implementation of the LTCH PPS.

After consideration of public comments, we are finalizing the FY 2026 labor-related share using the most recently available data. Based on IHS Global Inc.'s second quarter 2025 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, & Repair Services; and All Other: Labor-Related Services is 69.0 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 second quarter 2025 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 finalizing a total labor-related share for FY 2026 of 72.9 percent (the sum of 69.0 percent for the labor-related share of operating costs and 3.9 percent for the labor-related share of capital-related costs).

4. 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, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2026 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final 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.

Comment: A commenter opposed CMS's use of unadjusted FY 2022 cost report data for determining the applicable area wage index values for the FY 2026 LTCH PPS standard Federal payment rate. The commenter noted that pandemic-driven labor costs, especially contract labor, were unusually high and not representative of future conditions. The commenter argued that using unmodified data from this period will distort wage index values and the data should be adjusted to account for pandemic-related anomalies.

Response: We thank the commenter for the feedback regarding the use of adjusted data in calculating the applicable wage index values for the FY 2026 LTCH PPS standard Federal payment rate. Similar to the FY 2025 wage index (89 FR 69266 through 69268), it is not readily apparent how any changes due to the COVID–19 PHE differentially impacted the wages paid by individual hospitals. Even if changes due to the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data to account for the effects of the COVID–19 PHE.

We have not identified any significant issues with the FY 2022 wage data based on our audits. As is standard practice, the Medicare Administrative Contractors (MACs) audited the data, and no major concerns were reported across hospitals. The commenter did not provide specific examples or data to show that certain providers or CBSAs were disproportionately affected by the PHE or contract labor costs. The concerns raised appear to be generalized without evidence of specific distortions in the FY 2022 wage data. Furthermore, even if CMS applied a uniform adjustment to contract labor salaries and hours, it would proportionally affect both area and national average hourly wages (AHW), leaving the wage index—which is a relative measure—essentially unchanged. Lastly, FY 2022 remains the most recent year for which audited wage data is available. FY 2023 wage data has not yet been audited and is therefore not suitable for use in setting the FY 2026 wage index.

Taking all of these factors into account, we believe the FY 2022 wage data is the best available wage data to use for FY 2026. Therefore, as we proposed, consistent with our historical practice, we are using the most recent data available to determine the final applicable area wage index values for the FY 2026 LTCH PPS standard Federal payment rate in this final rule.In addition, as we proposed, we computed the FY 2026 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the 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. As we proposed, we also continued 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, as we proposed, we continued 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 used to determine the FY 2026 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the 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, 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 used to determine the FY 2026 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for rural North Dakota (CBSA 35). Consistent with our existing methodology, we calculated the FY 2026 wage index value for CBSA 35 as the average of the wage index values for all CBSAs that are contiguous to the rural counties of the State (that is, 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 final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: A commenter stated that while they support the permanent cap on LTCH PPS wage index decreases policy, they urge CMS to implement this policy in a non-budget-neutral manner. to address financial strain that LTCHs continue to face.

Response: Implementation of this policy in a budget neutral manner is consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner. Consistent with this requirement, we continue to believe that changes to area wage level adjustments, including the 5-percent cap on the decrease on an LTCH's wage index, should not result in any change in estimated aggregate LTCH PPS payments. Furthermore, we also continue to anticipate that, in the absence of wage index policy changes beyond an annual update of the wage data, most LTCHs will experience year-to-year wage index declines less than 5 percent in any given year, and that the overall budget neutrality adjustments associated with the cap on wage index decreases will therefore be relatively small and will not create volatility in LTCH PPS payments. We expect 17 LTCHs to receive the 5-percent cap in FY 2026.

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 final rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

6. 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 an 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 area wage level budget neutrality factor. Specifically, as we proposed, we determined 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 FY 2026 wage index values (including the application of the 5-percent cap on wage index decreases) and the FY 2026 labor-related share of 72.9 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the 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 FY 2026 updates to the area wage level adjustment (calculated in Step 2) to determine the 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 FY 2026 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2026 LTCH PPS standard Federal payment rate after the application of the FY 2026 annual update.

As we proposed, we used 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 final rule, using the steps in the methodology previously described, we determined a FY 2026 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0021275. Accordingly, in section V.A. of this Addendum, we applied the area wage level adjustment budget neutrality factor of 1.0021275 to determine the FY 2026 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. 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 the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18236), we proposed to update the labor-related share of the IPPS market basket. In section V.C. the Addendum of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18448), we presented a table for comparison purposes between 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 and the COLA factors utilized for FYs 2022 through 2025.

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18449), we also proposed maintaining the current COLA factors for FY 2026 to be consistent with the approach proposed under the IPPS as discussed in section II.B.2. the Addendum of the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18438). We believed that 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.

We solicited public comments on the proposal regarding maintaining the current COLA factors under the LTCH PPS for FY 2026. We received no comments on this proposal and are finalizing the use of the current COLA factors for FY 2026 without modification. We also summarize comments regarding the proposed COLAs under the IPPS in section II.B.2. of the Addendum of this final rule. 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 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 finalized FY 2026 COLA factors.

FY 2026 Cost-of-Living Adjustment Factors: Alaska and Hawaii Under the LTCH PPS

Area	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

FY 2026 COST-OF-LIVING ADJUSTMENT FACTORS: ALASKA AND HAWAII UNDER THE LTCH PPS—Continued

Area	COLA
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. 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. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the best available data to determine the LTCH total CCR ceiling for FY 2026 in this final rule. Specifically, in this final rule, we used our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2025 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are establishing an LTCH total CCR ceiling of 1.348 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. (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).)

We did not receive any public comments on our proposals and are finalizing our proposals as described previously.

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 final

rule, as we proposed, we are using our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2025 update of the PSF. As we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will 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).

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, as we proposed, we are continuing 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 using 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, 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 March 2025. 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 March 2025 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 used the national average total CCR for rural IPPS hospitals for rural Connecticut, Massachusetts, and North Dakota in Table 8C. We note that there were no LTCHs located in these rural areas as of March 2025.

We did not receive any public comments on our proposals. We are finalizing our proposals as described previously.

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 12594; April 26, 2024) with an update to the outlier reconciliation criteria.

3. 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. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18450 through 18452), we discussed our proposed methodology for determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 and proposed an outlier fixed-loss amount of $91,247. This proposed fixed-loss amount was approximately $14,000 higher than the fixed-loss amount for FY 2025 ($77,048). In the proposed rule, we sought comments on the proposed fixed-loss amount and stated that we would consider these comments when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 in the final rule. In this section, we first summarize and respond to the comments received. Later in this section, after consideration of the comments received, we present the detailed application of our finalized methodology and the resulting fixed-loss amount.

Comment: Like previous years, several commenters objected to the methodology we proposed to use to calculate the charge inflation factor we proposed to apply when determining the FY 2026 fixed-loss amount. These commenters requested that CMS return to the methodology employed prior to FY 2022 in which the charge inflation factor was set equal to the market basket update. Some commenters stated that returning to this methodology would provide greater stability and predictability to the fixed-loss amount. Several commenters asserted that the proposed charge inflation methodology has led to unnecessary increases in the fixed-loss amount in prior years and in this year's proposed rule. A few commenters stated that returning to the market basked based methodology would result in a fixed-loss amount of approximately $51,000 for FY 2026.

Response: We appreciate the feedback and suggestions that commenters provided on the proposed charge inflation factor. As we did in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69981), we acknowledge that in recent years and in FY 2026, the calculated fixed-loss amount would have been lower if we had estimated charge inflation based on the market basket update. However, while the market basket methodology would have yielded lower fixed-loss amounts, we estimate the methodology would have resulted in high cost outlier payments that significantly exceeded the statutory target compared to the current methodology. Therefore, we continue to believe using a charge inflation factor based on actual growth rates in charges from historical claims data rather than one based on quarterly market basket update values leads to better accuracy in calculating the fixed-loss amount that would result in actual outlier payments meeting the statutory target.

Comment: Some commenters objected to the use of FY 2023 cost report data in the determination of the FY 2026 fixed-loss amount. These commenters stated that these data were significantly impacted by the COVID–19 pandemic and reflect LTCH utilization trends that are unlikely to be repeated in FY 2026. Examples provided by commenters included differences in patient acuity during the COVID–19 pandemic, levels of COVID–19 hospitalizations, and changes in vaccination and immunity rates. Commenters specifically objected to the CCRs that CMS proposed to use in determining the fixed-loss amount, stating that these CCRs were derived from FY 2023 cost report data and reflect elevated costs incurred by LTCHs during the COVID–19 pandemic. A commenter specified that nursing costs significantly increased during the COVID–19 pandemic. The commenter stated that these costs have since stabilized and will not be representative of nursing costs in FY 2026. Another commenter described significant increases in both labor and supply cost incurred by LTCHs during the pandemic. However, this commenter stated that these costs remain elevated due to distortions in the labor force and supply chains caused by the pandemic. Commenters requested that CMS use modified FY 2023 cost report data or pre-pandemic cost report data when determining the fixed-loss amount for FY 2026.

Like previous years, some commenters urged CMS to exclude dialysis patients from the FY 2024 claims data when determining the fixed-loss amount. Commenters again presented evidence demonstrating that the cost of treating dialysis patients in LTCHs has risen in recent years. The commenters also provided explanations for these cost increases. As an example, some commenters stated that the withdrawal of dialysis services provided by lower-cost third-party providers has forced LTCHs to internalize these services at a higher expense. Commenters stated that the costs for dialysis services would continue escalating through FY 2026 at a rate faster than CMS's ratesetting methodology can accommodate. The commenters believe that removing these cases would ensure that these cases do not skew the calculation of the fixed-loss amount.

Similar to last year, a commenter encouraged CMS to incorporate claims data from FY 2025 into the calculation of the fixed-loss amount for FY 2026. This commenter stated that incorporating additional months of data into the ratesetting model would improve the accuracy of the fixed-loss amount calculation.

Response: We thank the commenters for their feedback regarding the FY 2023 cost report data used in calculating the fixed-loss amount to account for COVID–19 impacts. As discussed later in this section of the Addendum, we obtain CCRs used in determining the fixed-loss amount from the most recently available Provider Specific File (PSF). The PSF generally contains CCR data from an LTCH's most recently settled or tentatively settled cost report, whichever is from the latest cost reporting period. We agree with commenters that the majority of CCRs obtained from the most recently available PSF used in this final rule were derived from FY 2023 cost reports. However, we do not believe the commenters provided sufficient evidence to support why LTCH costs relative to charges in FY 2023 would differ significantly from LTCH costs relative to charges in FY 2026. While commenters discussed levels of costs in FY 2023, they did not provide information on levels of charges or the relationship between costs and charges in FY 2023. We also note that the most recently available LTCH cost-to-charge ratios (of which the majority are from FY 2023 cost reports) are lower, on average, compared to pre-pandemic levels, and as such, it appears LTCHs on average increased their charges even more than the increases in costs experienced due to the COVID–19 pandemic in FY 2023. Commenters did not provide any reasons why LTCH charges would not continue to rise or fall relative to increases or decreases in costs. As discussed in more detail later in this section of the Addendum, our current methodology already applies an adjustment factor to the most recently obtained CCRs that accounts for historical changes in the relationship between costs and charges for LTCHs. However, for the reasons discussed previously, we disagree with commenters that any further adjustment to the CCRs is appropriate for determining the FY 2026 fixed-loss amount.

We thank the commenters for the suggestion to exclude dialysis claims when calculating the fixed-loss amount. The comments provided evidence supporting the belief that the costs of treating dialysis patients reflected in the FY 2024 claims data would further increase in FY 2026. For this reason, we believe removing these claims from the calculation of the fixed-loss amount would lessen the accuracy of our payment model which sets a FY 2026 fixed-loss amount that results in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

We thank the commenters for the suggestion to use more recent claims data for calculating the fixed loss amount in this final rule. As discussed later in this section, we are using more recent claims data than we used in the proposed rule. Specifically, we are using the March 2025 update of the FY 2024 MedPAR file to calculate the fixed loss amount in this final rule. At the time of developing this final rule, this was the most recent full year of publicly available claims data. We continue to believe it is most appropriate to use one full year of publicly available claims data in our ratesetting calculations. The use of one full year of publicly available claims data is consistent with our historical practice and is not susceptible to the seasonality issues affiliated with using partial year data. We note the commenter did not provide any suggestions on how CMS could adjust partial year data for seasonality effects. For these reasons, we are not adopting commenters' suggestion to incorporate claims from the first part of FY 2025 in our calculation of the fixed-loss amount for FY 2026.

Comment: Like previous years, several commenters stated that CMS needs to update its high-cost outlier policy to better account for the effects of the dual rate LTCH PPS payment structure on outlier payments. Several commenters stated that under the dual rate payment structure, the majority of LTCH standard Federal payment rate cases have become concentrated in only a few MS–LTC–DRGs. The commenters stated that there is great variation in patient severity and costs among the cases grouped to these MS–LTC–DRGs which they believe leads to many of them qualifying for outlier payments, and that this pattern is contributing to the proposed increase in the fixed-loss amount. Commenters again highlighted standard Federal payment rate cases grouped to base MS–LTC–DRGs 189 and 207. These two base MS DRGs, which accounted for over 40 percent of standard Federal payment rate cases in FY 2024, are not subdivided based on the presence or absence of a complication or comorbidity (CC) or a major complication or comorbidity (MCC). Commenters requested that CMS refine certain MS–LTC–DRGs by creating subgroups within these base MS–DRGs based on the presence or absence of CCs and MCCs, which they believe would increase LTCH PPS payment accuracy thereby reducing the outlier payments made to cases grouped to such MS–LTC–DRGs. A commenter suggested that CMS use LTCH claims data, rather than IPPS claims data, when determining changes to the MS–LTC–DRG classifications. The commenter believes that the LTCH claims data would support splitting certain MS–LTC–DRG that the current IPPS data does not justify.

Response: We continue to appreciate commenters' suggestions on possible refinements to certain MS LTC–DRGs, in particular the concerns regarding the absence of CC or MCC subgroups within certain high-volume MS–LTC–DRGs, and commenters' thoughts on the impact this may have on LTCH PPS outlier payments. In the FY 2025 IPPS/LTCH PPS final rule, we stated that we would like to have the opportunity to explore and analyze such adjustments more before making this type of change. At this time, we have not found evidence that the MS–LTC–DRG structure is a major driver in the recent increases to the fixed-loss amount. We also note that commenters did not provide quantitative analysis of their own that would support this conclusion. For these reasons, we are not adopting any of the changes to the MS–LTC–DRGs suggested by commenters in this final rule. However, we may consider these comments for future rulemaking.

Comment: Like previous years, commenters expressed concern with the impact of the LTCH PPS dual rate payment system on the claims data CMS uses for calculating the fixed-loss amount. Commenters again asserted that because CMS only uses cases that would have been paid the standard Federal rate, the claims dataset used in the calculation is smaller and on average has a higher acuity than the claims datasets CMS used prior to the start of the dual rate payment structure. The commenters believe this change has led to fluctuations in the fixed-loss amount. To offset the decrease in standard Federal rate claims, commenters recommended that CMS use all LTCH claims, including those paid at the site neutral payment rate, to determine the fixed-loss amount. Commenters again stated that CMS should reconsider whether the statutory outlier payment target of 7.975 percent is still an appropriate target for LTCH PPS standard Federal rate cases under the dual rate payment system. One commenter stated that CMS should use its authority to implement methodological changes that will prevent large increases in the fixed loss amount caused by the dual rate payment system and the 7.975 percent criterion.

Response: We thank the commenters for this feedback. Section 1886(m)(7) of the Act directs the Secretary to establish a fixed-loss amount for LTCH PPS standard Federal payment rate cases that would result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, we are not adopting the commenter's suggestion to modify the 7.975 percent target or include cases in our payment model other than those paid the standard Federal payment rate (or would have been paid at the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of those discharges).

Comment: Several commenters urged CMS to factor into the calculation of the fixed-loss amount a projection of the amount of outlier dollars CMS estimates it will recoup through outlier reconciliation. Commenters expressed that this is especially important given the instructions CMS issued to MACs in CR 13566, which commenters stated will increase the number of LTCHs subject to outlier reconciliation in FY 2026. Commenters also stated that not including a projection of reconciled outlier dollars in the fixed-loss amount calculation is contrary to what CMS does in other payment systems, including the IPPS. Commenters stated that CMS's failure to account for recouped outlier dollars would cause CMS to set the fixed-loss amount at an artificially high level that will not represent the actual amount of outlier payments to LTCHs after outlier reconciliations are done as part of the settlement of FY 2026 cost reports.

Response: We thank the commenters for this feedback. We agree with commenters that incorporating an estimate of reconciled

outlier dollars for the fiscal year into our methodology for determining the fixed-loss amount for that fiscal year would improve its accuracy. However, at the time of writing this final rule, we are unable to determine an appropriate estimate and predictor of outlier reconciliation for the upcoming fiscal year.

It is difficult to predict the specific LTCHs that will have CCRs and outlier payments reconciled in any given year as there are many different variables that determine whether a specific case will be eligible for an outlier payment, including the CCR, the estimated costs of the case, the payment amounts, and the fixed-loss amount itself. Historically, under the IPPS, in general an outlier reconciliation adjustment to the IPPS fixed-loss threshold has been computed using the percentage of total outlier reconciliation dollars to total Federal payments for a historical cost report data year. Rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we adopted a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports as we believe such an approach would be a more feasible and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year (84 FR 42623 through 42623). It stands to reason that any such adjustment to the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases would encounter similar considerations or would be computed in a similar manner.

The LTCH PPS payments (including outlier payments and reconciled outlier payments) are reported on Worksheet E3, Part IV of the cost report. However, this worksheet does not separately list outlier payments or reconciled outlier payments for only standard Federal payment rate cases. We believe an accurate outlier reconciliation adjustment would require historical outlier and reconciled outlier payment data from cases that were paid the standard Federal payment rate (or would have been paid at the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of those discharges). Furthermore, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69948 through 69955), CMS modified its historical methodology for incorporating outlier reconciliation in the IPPS fixed-loss threshold to account for the additional hospitals that will be reconciled under the new criteria outlined in CR 13566. The modified methodology incorporates supplemental outlier payment data provided to CMS from MACs for IPPS hospitals that would have been identified for reconciliation had the new criteria been in place during that historical cost reporting period. CMS did not request these data from MACs for LTCHs, and due to system limitations, the MACs would need sufficient lead time to produce these supplemental data for LTCHs.

For these reasons, we are unable to adopt the commenters' suggestion. We note that the commenters did not specifically address how to project outlier reconciliation for the upcoming fiscal year, but we welcome recommendations or suggestions on how to account for the potential impact of reconciliation in the determination of the fixed-loss amount for LTCH PPS standard Federal payment rate cases. We intend to explore the data challenges discussed previously as we continue to consider the feasibility of including outlier reconciliation in the determination of the fixed-loss amount or LTCH PPS standard Federal payment rate cases and may consider this issue for future rulemaking.

Comment: In general, commenters expressed concern that the proposed fixed-loss amount would result in three consecutive years of large increase to the fixed-loss amount. The commenters stated that these increases create instability and uncertainty for LTCHs and negatively impact their ability to serve the sickest patients. Commenters believe that the proposed increase to the outlier fixed-loss amount would have negative financial impacts on LTCHs. Some commenters warned the increase would reduce access to LTCH care, increase ''backups'' at IPPS hospitals, and cause some LTCHs to close. Commenters expressed that the proposed increase in the fixed-loss amount would make reimbursement insufficient compared to the costs of treatment and would make admitting the most medically complex patients untenable for LTCHs. A commenter stated that CMS must account for patient access to LTCH services when setting HCO thresholds.

Commenters provided a variety of recommendations for CMS to consider when determining the fixed-loss amount in this final rule. Some commenters advocated for CMS to adopt a modified version of the alternative approach to determining the FY 2025 fixed-loss amount that CMS discussed and considered in the FY 2025 IPPS/LTCH PPS proposed rule appendix (89 FR 36644). In that FY 2025 proposed rule, CMS considered providing a non-budget neutral, one-year transition to the full increase to the fixed-loss amount by setting the amount equal to an average of the 2024 fixed-loss amount and the calculated FY 2025 fixed-loss amount. The commenters urged CMS to consider this approach for FY 2026, but requested that CMS phase in the increase to the fixed-loss amount over a longer period, such as three or four years. One commenter requested that CMS set the FY 2026 fixed-loss amount equal to the FY 2023 fixed-loss amount. Another commenter similarly requested that CMS set the FY 2026 fixed-loss amount equal to the FY 2025 fixed-loss amount.

Several commenters requested that CMS adopt a non-budget neutral cap on annual increases to the fixed-loss amount. Some commenters stated that this cap would be similar to the cap policies CMS already applies to the LTCH PPS wage index and MS–LTC–DRG relative weights. A commenter requested that the cap be 5 percent while another stated that the cap should be set equal to the annual market basket percent increase. Some commenters stated that in combination with setting the charge inflation factor equal to the market basket update when determining the FY 2026 fixed-loss amount, CMS should also adopt in a non-budget neutral manner a freeze on the fixed-loss amount for future years beginning in FY 2027.

Response: We thank the commenters for the feedback. As discussed in greater detail later in this section, with the use of more recent data available for this final rule, our proposed methodology for determining the fixed-loss amount results in a fixed-loss amount of $78,936, which is significantly lower than the fixed-loss amount of $91,247 that we proposed and similar to the FY 2025 fixed-loss amount of $77,048. At this time we do not believe it is necessary or appropriate to use our adjustments authority to adjust outlier payments by using an alternative methodology to set the fixed-loss amount that would not result in total estimated outlier payments being projected to be equal to the statutory target of 7.975 percent in section 1886(m)(7) of the Act. We understand the comments on the impact the fixed-loss amount has on LTCH finances and access to care under the LTCH PPS and will continue to consider those issues for future rulemaking.

After consideration of the comments received, we are finalizing our proposed methodology for determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 without modification. In this section of this Addendum, we present the detailed application of our finalized methodology.

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) Charge Inflation Factor for Use in Determining the 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, as we proposed, we computed a charge inflation factor based on the most recently available data. Specifically, we used the March 2025 update of the FY 2024 MedPAR file and the March 2024 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 March 2025 update of the FY 2024 MedPAR file and the March 2024 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 $303,404 ($12,753,897,528/42,036 cases) from FY 2023 to the average covered charge per case of $342,229 ($14,779,859,933/43,187 cases) from FY 2024. This rate-of-change was 12.7965 percent, which results in a 1-year charge inflation factor of 1.127965, and a 2-year charge inflation factor of 1.272305 (calculated by squaring the 1-year factor). We inflated the billed charges obtained from the FY 2024 MedPAR file by this 2-year charge inflation factor of 1.272305 when determining the 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, as we proposed, we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the March 2025 PSF as the most recently available PSF and the March 2024 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 March 2025 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 March 2025 update of the FY 2024 MedPAR file, we identified their CCRs from both the March 2024 PSF and March 2025 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 finalized Version 43 of the GROUPER) to calculate case-weighted average CCRs. Based on this data, we calculated a March 2024 national average case-weighted CCR of 0.235922 and a March 2025 national average case-weighted CCR of 0.220240. We then calculated the national

CCR adjustment factor by dividing the March 2025 national average case-weighted CCR by the March 2024 national average case-weighted CCR. This results in a 1-year national CCR adjustment factor of 0.933527. When calculating the 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 March 2025 PSF or whose CCR was missing in the March 2025 PSF. For all other providers, we multiplied their CCR from the March 2025 PSF by the 1-year national CCR adjustment factor of 0.933527. We note that the March 2025 PSF national average case-weighted CCR was 2.8 percent lower than the December 2024 PSF national average case-weighted CCR. We also note that the 1-year national adjustment CCR adjustment factor calculated in this final rule is 1.7 percent lower than the 1-year national adjustment CCR factor that we proposed. The incorporation of more recent cost-to-charge ratio data into our payment model was the primary driver of the reduction in the fixed-loss amount calculated in this final rule compared to the fixed-loss amount calculated in the proposed rule.

(3) Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2026

In this final rule, for FY 2026, using the best available data and the steps described previously, we calculated a 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 payment rates and policies for these cases presented in this final rule). Consistent with our historical practice, we use the best available LTCH claims data and CCR data 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 March 2025 update of the FY 2024 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2025 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 establishing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2026 of $78,936 that will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2026 payments for such cases. As such, we will 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 adjusted LTCH PPS standard Federal payment rate payment and the fixed-loss amount for LTCH PPS standard Federal payment rate cases of $78,936).

4. 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 final rule, we used FY 2024 data in the FY 2026 LTCH PPS 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, as we proposed, we are establishing 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 IPPS fixed-loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $40,397, which is the same 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 will 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 fixed-loss amount for site neutral payment rate cases of $40,397).

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, as we proposed, we are continuing this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the 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, as we proposed, we are applying 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 HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

We did not receive any public comments on our proposals regarding HCO payments for site neutral payment rate cases and are finalizing these proposals as described previously, without modification.

E. 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).

As discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18453), for FY 2026, based on the most recent data available at that time, we proposed 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 proposed 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.

We did not receive any public comments in response to our proposal, and as such are finalizing this proposal. However, as we proposed, we are determining the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in this final rule using more recent data.

For FY 2026, as discussed in greater detail in section IV.E.2.b. of the preamble of this final 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 62.14 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 46.61 percent (the product of 75 percent and 62.14 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 71.61 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 + 46.61 percent = 71.61 percent).

Therefore, for FY 2026, consistent with our proposal, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 will include an applicable operating Medicare DSH payment amount that is equal to 71.61 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.

F. Computing the 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 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 FY 2026 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2026 of $50,824.51, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2026, applying our 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 FY 2026 LTCH PPS wage index value of 1.0228 (as shown in Table 12A listed in section VI. of this Addendum). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2026 of 0.9443 (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 Federal prospective payment for this Medicare patient case in FY 2026, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2026 LTCH PPS standard Federal payment rate ($50,824.51) by the labor-related share (72.9 percent) and the wage index value (1.0228). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (27.1 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9443) to calculate the total adjusted LTCH PPS standard Federal payment for FY 2026 ($48,791.30). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$50,824.51
Labor-Related Share	× 0.729
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $37,051.07
Wage Index (CBSA 16984)	× 1.0228
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $37,895.83
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($50,824.51 × 0.271)	+ $13,773.44
Adjusted LTCH PPS Standard Federal Payment Amount	= $51,669.27
MS–LTC–DRG 189 Relative Weight	× 0.9443
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $48,791.30

VI. Tables Referenced in This Final Rule Generally Available Through the Internet on the CMS Website

This section lists the tables referred to throughout the preamble of this final 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 final 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 final 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 final rule, we are making available separate tables listing the ICD–10–CM codes or ICD–10–PCS codes that would be used to identify cases relevant to the Breakthrough Device-designated indication for the RECELL® Autologous Cell Harvesting Device for purposes of the new technology add-on payment for FY 2026, in Table 10 associated with this final 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 final rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final 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 Final Rule Home Page'' or ''Acute Inpatient -Files- for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2026 Final Rule
Table 3.—Wage Index Table by CBSA—FY 2026 Final Rule
Table 4A.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2026 Final Rule
Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2026 Final Rule
Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2026 Final 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.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2026
Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2026
Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2026
Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2026
Table 6I.—Complete MCC List—FY 2026
Table 6I.1.—Additions to the MCC List—FY 2026
Table 6J.—Complete CC List –FY 2026
Table 6J.1.—Additions to the CC List—FY 2026
Table 6J.2.—Deletions to the CC List—FY 2026
Table 6K.—Complete CC Exclusions List—FY 2026
Table 6P.—ICD–10–CM and ICD–10–PCS Codes for 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 MS–DRG changes or other analyses). These tables are referred to throughout section II.C. of the preamble of this final rule.
Table 8A.—FY 2026 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)—FY 2026 Final Rule
Table 8B.—FY 2026 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals—FY 2026 Final Rule
Table 10.—Relevant ICD–10 Codes for Certain FY 2026 New Technology Add-On Payments
Table 16.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2026
Table 18.—FY 2026 Medicare DSH Uncompensated Care Payment Factor 3

The following LTCH PPS tables for this FY 2026 final 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.—FY 2026 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)—FY 2026 Final Rule
Table 11.—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—FY 2026 Final Rule
Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2025, through September 30, 2026—FY 2026 Final Rule
Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2025, through September 30, 2026—FY 2026 Final Rule

TABLE 1A—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 FINAL RULE

Hospital submitted quality data and is a meaningful EHR user (update = 2.6 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.125 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.775 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.7 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,456.72	$2,295.89	$4,349.21	$2,240.51	$4,420.88	$2,277.43	$4,313.38	$2,222.05

TABLE 1B—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 FINAL RULE

Hospital submitted quality data and is a meaningful EHR user (update = 2.6 percent)		Hospital submitted quality data and is NOT a meaningful EHR user (update = 0.125 percent)		Hospital did NOT submit quality data and is a meaningful EHR user (update = 1.775 percent)		Hospital did NOT submit quality data and is NOT a meaningful EHR user (update = −0.7 percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,186.62	$2,565.99	$4,085.63	$2,504.09	$4,152.95	$2,545.36	$4,051.97	$2,483.46

TABLE 1C—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 FINAL RULE

	Rates if wage index greater than 1		Hospital is a meaningful EHR user and wage index less than or equal to 1 (update = 2.6 percent)		Hospital is NOT a meaningful EHR user and wage index less than or equal to 1 (update = 0.125 percent)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National [1]	Not Applicable	Not Applicable	$4,186.62	$2,565.99	$4,085.63	$2,504.09

[1] For FY 2026, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D—CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2026 FINAL RULE

	Rate
National	$524.15

TABLE 1E—LTCH PPS STANDARD FEDERAL PAYMENT RATE—FY 2026 FINAL RULE

	Full update (2.7 percent)	Reduced update * (0.7 percent)
Standard Federal Rate	$50,824.51	$49,834.74

* 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 final 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 final 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 changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, and the decisions 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 changes will 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. Update to the IPPS Payment Rates

As discussed in section IV. of the preamble of this final rule, we are finalizing our proposal 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 2023-based IPPS market basket, we calculated a labor-related share of 66.0 percent, which we will use for discharges occurring on or after October 1, 2025. The 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 final 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 of this final rule, we are updating the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 2.6 percent (that is, a 3.3 percent market basket percentage increase with a reduction of 0.7 percentage point for the productivity adjustment). We are also updating the hospital-specific rates by the applicable percentage increase (including the market basket percentage increase and the productivity adjustment).

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 will receive an applicable percentage increase of 1.775 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 will receive an applicable percentage increase of 0.125 percent which reflects a three-quarter percent reduction of the market basket update for being identified as not a EHR meaningful 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 will receive an applicable percentage increase of -0.70 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. 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. 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 final 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 discontinuing the low wage index hospital policy and are no longer applying a low wage index budget neutrality factor to the standardized amounts. As discussed in section III.F.7. of the preamble of this final rule, we are using 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 is being implemented in a budget neutral manner. This transitional exception policy applies to hospitals that benefitted from the FY 2024 low wage index hospital policy and compares the hospital's FY 2026 wage index to the hospital's FY 2024 wage index. If the hospital's FY 2026 wage index is decreasing by more than 9.75 percent from the hospital's FY 2024 wage index, then the transitional payment exception for FY 2026 for that hospital will 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 are making 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 final 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 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 are using 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 final 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 final 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 final rule, we proposed 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. Update to the LTCH PPS Payment Rates

The update to the LTCH PPS standard Federal payment rate for FY 2026 is discussed in section IX.C. of the preamble of this final rule. For FY 2026, we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate of 2.7 percent (that is, the 3.4 percent market basket increase with a reduction of 0.7 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 an update of 0.7 percent for FY 2026, 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 Provisions—Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this final 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 finalized within this final rule 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.

6. Finalization of the IFC on the Changes to the FY 2025 Hospital IPPS Rates Due to Court Decision (CMS–1808–IFC)

In section XI.C. of the preamble of this final rule, we finalize the provisions of the FY 2025 IFC published in the October 4, 2025 **Federal Register** (89 FR 80405), which implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those revisions, and made conforming changes to the hospital IPPS payment rates for FY 2025. These changes reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp.* v. *Becerra.* That IFC also made conforming changes to IPPS rates and factors used to determine certain payments under the LTCH PPS for FY 2025.

7. ONC Health IT Certification Program Updates

In section IX.*B.* of the preamble of this final rule, ASTP/ONC finalizes provisions of the HTI–2 proposed rule published on August 5, 2024 (89 FR 63498), which update the ONC Health IT Certification Program in accordance with our statutory responsibilities under the Health Information Technology for Economic and Clinical Health (HITECH) Act and 21st Century Cures Act. These updates advance HHS policy goals to strengthen interoperability, reduce burden for health IT developers and users, improve health data exchange, and support transparency to empower patients to make well-informed healthcare decisions. These final policy provisions result in monetary costs for developers of certified health IT and health IT providers purchasing or upgrading certified health IT. These costs are offset by downstream efficiencies such as cost savings resulting from improvements to automation, reduction of manual effort required to conduct prior authorizations, improved operational workflow, and support for more timely and transparent clinical decision-making. These finalized provisions are needed to promote a more patient-centered healthcare system.

B. Overall Impact

We have examined the impacts of this final 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 changes for FY 2026 acute care hospital operating and capital payments will redistribute amounts in excess of $100 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, will result in an estimated $5.0 billion increase in FY 2026 payments, primarily driven by the net effect of 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, the expiration of the MDH program, and new technology add-on payment changes. 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 $83 million in FY 2026 relative to FY 2025.

Our operating payment impact estimate includes the 2.6 percent applicable percentage increase to the standardized amount (reflecting the 3.3 percent market basket rate-of-increase reduced by the 0.7 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 final 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 final rule will 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 final 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 final rule will 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 changes will ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the final policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2026, on various hospital groups. We estimate the effects of individual 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 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 3,033 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 1,381 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 final rule. The impact of the 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 final rule, we are announcing 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 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 update 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, will increase by 4.3 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 changes on the operating and capital prospective payment systems. This section primarily deals with the 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 changes in this final rule. However, there are other 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 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 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 payments under the capital IPPS, and the impact of 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 changes:

- The estimated effects of 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 applicable percentage increase of 2.6 percent (that is, a 3.3 percent market basket rate-of-increase with a reduction of 0.7 percentage point for the productivity adjustment), and the applicable percentage increase (including the market basket rate-of-increase and the productivity adjustment) to the hospital-specific rates.
- The effects of the 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 changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values due to the effects of the incorporation of updated wage data from hospitals' cost reporting periods, the update to the labor and non-labor share percentages, and the changes in wage index reclassifications.
- The total estimated change in payments based on the FY 2026 policies relative to payments based on FY 2025 policies.

To illustrate the impact of the 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 4.6 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 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 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 final rule for a complete discussion of the FY 2026 inpatient hospital update, including the four possible applicable percentage increases. For purposes of the simulations shown later in this section, we modeled the 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 previously and in section VI.B. of the preamble of this final rule and these hospitals are identified in the impact file posted in conjunction with this final 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 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 applicable percentage increases discussed in section VI.B. of the preamble of this final rule.

2. Impact Analysis of Final Changes on Payments for IPPS Operating Costs and Uncompensated Care Payments

Table I displays the results of our analysis of the 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 CHANGES ON PAYMENTS FOR IPPS OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2026

	Number of hospitals [1]	FY 2026 outlier payments (1) [2]	FY 2026 hospital rate update (2) [3]	MDH expiration (3) [4]	FY 2026 uncompensated care payments (4) [5]	FY 2026 weights and DRG changes with application of recalibration budget neutrality (5) [6]	FY 2026 wage index (6) [7 8 9]	All FY 2026 changes (7) [10]
All Hospitals	3,033	0.3	2.5	−0.1	1.7	0.0	−0.1	4.3
By Geographic Location:								
Urban hospitals	2,372	0.4	2.5	−0.1	1.7	0.0	−0.1	4.4
Rural hospitals	661	0.1	2.5	−0.6	1.4	−0.4	0.0	2.9
Bed Size (Urban):								
0–99 beds	647	0.2	2.5	−1.5	1.7	0.1	−0.1	2.9
100–199 beds	673	0.2	2.5	−0.3	1.5	−0.2	−0.3	3.5
200–299 beds	406	0.3	2.5	0.0	1.8	−0.1	−0.2	4.2
300–499 beds	392	0.3	2.5	0.0	1.6	0.0	−0.3	4.2
500 or more beds	252	0.5	2.4	0.0	1.9	0.2	0.0	5.0
Bed Size (Rural):								
0–49 beds	313	0.1	2.4	−1.3	2.1	−0.5	0.3	3.0
50–99 beds	180	0.1	2.5	−1.6	1.4	−0.5	−0.1	1.7
100–149 beds	95	0.1	2.5	−0.1	1.4	−0.6	0.1	3.4
150–199 beds	42	0.1	2.5	0.0	1.2	−0.3	0.1	3.7
200 or more beds	31	0.2	2.5	0.0	0.9	−0.1	−0.3	3.2
Urban by Region:								
New England	104	0.3	2.5	−0.2	0.8	−0.1	−1.7	1.6
Middle Atlantic	274	0.4	2.5	−0.1	1.3	−0.1	0.7	4.8
East North Central	366	0.3	2.5	−0.3	1.1	0.0	−0.3	3.2
West North Central	156	0.4	2.5	0.0	1.1	0.1	1.4	5.5
South Atlantic	393	0.3	2.4	−0.1	2.4	0.0	0.4	5.5
East South Central	141	0.4	2.4	0.0	2.4	0.0	−0.1	5.2
West South Central	355	0.3	2.3	−0.1	4.4	0.1	0.5	7.7
Mountain	180	0.3	2.5	0.0	1.5	0.1	−0.6	3.8
Pacific	351	0.5	2.5	0.0	0.9	0.0	−1.7	2.3
Rural by Region:								
New England	19	0.3	2.6	−1.6	0.3	−0.2	−0.5	0.8
Middle Atlantic	48	0.1	2.5	−0.2	0.7	−0.4	0.1	2.9
East North Central	106	0.1	2.5	−1.5	1.1	−0.4	−0.3	1.5
West North Central	74	0.1	2.6	−0.4	0.6	−0.4	1.3	3.7
South Atlantic	108	0.1	2.4	−0.8	2.5	−0.5	−0.3	3.5
East South Central	127	0.1	2.5	−0.4	1.9	−0.5	−0.3	3.1
West South Central	116	0.1	2.4	−0.2	2.8	−0.4	0.4	5.2
Mountain	39	0.1	2.6	0.0	0.3	−0.1	0.3	3.1
Pacific	24	0.1	2.6	0.0	0.2	−0.6	−0.7	1.6
Puerto Rico:								
Puerto Rico Hospitals	52	0.1	1.8	0.0	11.2	0.0	−1.7	11.4
By Payment Classification:								
Urban hospitals	1,611	0.3	2.5	0.0	2.0	−0.1	−0.4	4.3
Rural areas	1,422	0.4	2.5	−0.2	1.6	0.0	0.1	4.3
Teaching Status:								
Nonteaching	1,756	0.3	2.5	−0.4	1.6	−0.1	−0.3	3.6
Fewer than 100 residents	986	0.3	2.5	−0.1	1.5	0.0	−0.1	4.1
100 or more residents	291	0.5	2.4	0.0	2.0	0.1	−0.1	4.9
Urban DSH:								
Non-DSH	346	0.3	2.6	−0.1	0.1	0.2	0.3	3.4
100 or more beds	909	0.4	2.5	0.0	2.2	−0.1	−0.5	4.4
Less than 100 beds	356	0.2	2.4	−0.4	2.9	−0.3	−0.1	4.7
Rural DSH:								
Non-DSH	93	0.3	2.6	−1.8	0.0	0.1	−0.3	0.9
SCH	227	0.0	2.5	0.0	0.8	−0.5	0.2	3.1
RRC	863	0.4	2.5	−0.1	1.5	0.1	0.0	4.4
100 or more beds	41	0.3	2.3	−0.5	5.1	0.1	1.0	8.4
Less than 100 beds	198	0.1	2.4	−4.0	3.1	−0.5	0.1	0.9
Urban teaching and DSH:								
Both teaching and DSH	527	0.4	2.4	0.0	2.3	−0.1	−0.5	4.6
Teaching and no DSH	58	0.3	2.6	−0.3	0.1	0.0	0.3	3.0
No teaching and DSH	738	0.3	2.5	0.0	2.1	−0.2	−0.6	4.1
No teaching and no DSH	288	0.3	2.7	0.0	0.0	0.4	0.3	3.6
Special Hospital Types:								
RRC	131	0.2	2.5	−0.6	1.7	−0.2	−0.5	3.1
RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	657	0.4	2.5	−0.1	1.6	0.1	0.0	4.5
SCH	218	0.0	2.5	0.0	1.1	−0.5	0.2	3.4
SCH that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	37	0.0	2.6	0.0	0.1	−0.4	0.1	2.4
SCH and RRC	119	0.1	2.6	0.0	0.7	−0.4	0.0	3.0

TABLE I—IMPACT ANALYSIS OF CHANGES ON PAYMENTS FOR IPPS OPERATING COSTS AND UNCOMPENSATED CARE PAYMENTS FOR FY 2026—Continued

	Number of hospitals [1]	FY 2026 outlier payments (1) [2]	FY 2026 hospital rate update (2) [3]	MDH expiration (3) [4]	FY 2026 uncompensated care payments (4) [5]	FY 2026 weights and DRG changes with application of recalibration budget neutrality (5) [6]	FY 2026 wage index (6) [7 8 9]	All 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	49	0.0	2.6	0.0	0.3	0.0	0.2	3.1
Type of Ownership:								
Voluntary	1,902	0.4	2.5	−0.2	1.3	0.0	−0.1	3.8
Proprietary	724	0.2	2.5	−0.1	1.9	0.0	−0.1	4.4
Government	406	0.5	2.3	−0.1	3.9	0.0	−0.1	6.6
Medicare Utilization as a Percent of Inpatient Days:								
0–25	1,548	0.4	2.4	0.0	2.5	0.0	0.0	5.3
25–50	1,388	0.3	2.6	−0.3	0.8	−0.1	−0.3	3.0
50–65	65	0.2	2.6	−0.4	0.3	0.1	0.4	3.2
Over 65	13	0.6	2.7	−0.6	0.1	2.0	−0.2	4.5
Medicaid Utilization as a Percent of Inpatient Days:								
0–25	1,917	0.3	2.5	−0.2	1.3	0.0	−0.1	3.7
25–50	992	0.4	2.4	0.0	1.9	0.0	−0.1	4.6
50–65	91	0.4	2.1	0.0	8.2	−0.3	−0.4	10.1
Over 65	32	0.3	1.9	0.0	10.9	−0.2	−1.0	12.1
FY 2026 Reclassifications:								
All Reclassified Hospitals	1,093	0.3	2.5	−0.2	1.6	0.0	−0.1	4.2
Non-Reclassified Hospitals	1,940	0.4	2.5	−0.1	1.9	0.0	−0.2	4.4
Urban Hospitals Reclassified	979	0.4	2.5	−0.1	1.6	0.1	0.0	4.4
Urban Non-reclassified Hospitals	1,407	0.3	2.5	0.0	1.9	0.0	−0.4	4.3
Rural Hospitals Reclassified Full Year	268	0.1	2.5	−0.4	1.3	−0.4	0.0	3.1
Rural Non-reclassified Hospitals Full Year	379	0.2	2.5	−0.8	1.5	−0.4	0.1	3.0
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	811	0.4	2.5	−0.2	1.6	0.1	0.1	4.4
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	50	0.1	2.5	−2.5	1.6	−0.5	−0.1	1.1

[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 2.6 percent update to the national standardized amount and the hospital-specific rate (the 3.3 percent IPPS market basket rate-of-increase reduced by the 0.7 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 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 Version 43 GROUPER, the changes to the relative weights and the 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 will decrease by more than ten percent in a given fiscal year. This column displays the application of the recalibration budget neutrality factor and the 10-percent cap budget neutrality factor (which can be found in section II.A.4 of the Addendum of this final rule).

[7] This column displays the effects of the changes to the FY 2026 wage index. This includes (1) the update to wage index data using FY 2022 cost report data, the application of the wage budget neutrality factor and the 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 rural floor. (4) The effects of urban to rural reclassifications under section 1886(d)(8) of the Act on the wage index. (5) The effects of the application of ''LUGAR'' status under section 1886(d)(10) of the Act on the wage index. (6) The 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 final 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 Final Rule Home Page''.)

[9] We note that because the low wage index hospital policy was removed for FY 2025, the discontinuation of the policy effective FY 2026 has no impact on the estimated change in payments from FY 2025 to FY 2026. However, the budget neutral transition for the discontinuation of the low wage index hospital policy will redistribute payments from hospitals that do not benefit from the 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 transition can be found in section II.A.4 of the Addendum of this final rule.

[10] This column shows the estimated change in 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 final 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 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 0.5 percentage points.

Overall, hospitals will experience a 0.3 percent increase in payments primarily due to the estimated 0.5 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 Hospital Update (Column 2)

As discussed in section VI.B. of the preamble of this final rule, this column includes the hospital update, including the 3.3 percent IPPS market basket rate-of-increase reduced by 0.7 percentage point for the productivity adjustment. As a result, we are making a 2.6 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 3.3 percent market basket rate-of-increase reduced by 0.7 percentage point for the productivity adjustment. As a result, we are making a 2.6 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 are expected to experience a 2.5 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the 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 162 MDHs, of which we estimate 82 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 82 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 will 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 Changes in Uncompensated Care Payments (UCP) (Column 4)

Column 4 shows the effects of the changes in uncompensated care payments made to hospitals in FY 2026. As discussed in section IV.E. of the preamble of this final rule, the total UCP and supplemental payments equal approximately $7.8 billion. Overall, hospitals are expected to experience a 1.7 percent increase in total operating IPPS payments due to the change in uncompensated care payments. For a more detailed impact analysis of the changes to uncompensated care payments, we refer readers to section I.G.2 of appendix A to this final rule.

e. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 5)

Column 5 shows the effects of the changes to the MS–DRGs and relative weights with the application of the 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 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 final rule, for FY 2026, we calculated the MS–DRG relative weights using the FY 2024 MedPAR data grouped to the Version 43 (FY 2026) MS–DRGs. The reclassification changes to the GROUPER are described in more detail in section II.C. of the preamble of this final rule.

The ''All Hospitals'' line in Column 5 indicates that changes due to the MS–DRGs and relative weights are expected to 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 final rule) and the recalibration cap budget neutrality factor to the standardized amount (discussed in section II.A.4.b. of the Addendum to this final rule).

f. Effects of the Wage Index Changes (Column 6)

Column 6 shows the impact of the changes to hospitals' FY 2026 wage index as compared to hospitals' FY 2025 wage index. Overall, the FY 2026 wage index changes are expected to lead to a 0.1 percent decrease for all hospitals, as shown in Column 6. This change is a result of the updates to the wage data reported by hospitals, the 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 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 Final Rule Home Page'').

Specifically, this column in Table I shows the combined effects of the application of the following FY 2026 wage index changes relative to FY 2025:

(1) Effects of the Final Changes to the Wage Data

Column 6 reflects the effects of the updated wage data and the labor and non-labor shares, with the application of the 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 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 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 FY 2026 wage index based on FY 2026 reclassifications (as described in further detail in the next section) and the labor-related share of 66.0 percent, while holding other payment parameters, such as use of the Version 43 MS–DRG GROUPER, constant.

In addition, the column incorporates the application of the wage budget neutrality to the national standardized amount. As discussed in section II.A.4.c. of the Addendum to this final rule, for FY 2026 we calculated the wage budget neutrality factor to ensure that payments under the updated wage data and the 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 budget neutrality factor can be found in the summary table of the FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this final 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 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 final rule, we apply a 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 budget neutrality factor can be found in the summary table of the final FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this final rule.

Table 2 listed in section VI. of the Addendum to this final rule and available on the CMS website reflects the reclassifications for FY 2026 at the time of development of this final rule. For further information on MGCRB reclassifications, urban to rural reclassifications and Lugar status redesignations, we refer readers to section III.E of the preamble of this final rule.

(3) The Effects of the Rural Floor, Including Budget Neutrality Adjustment

Column 6 reflects the effects of the application of the rural floor and the application of the rural floor budget neutrality on the wage index for FY 2026 relative to FY 2025. As discussed in section III.F.1. of the preamble of this final rule, section 4410 of Pub. L. 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 final rule. All IPPS hospitals in our model have their wage indexes reduced by the rural floor budget neutrality adjustment. This budget neutrality factor can be found in the summary table of the FY 2026 budget neutrality factors in section II.A.4. of the Addendum to this final rule.

(4) Effects the Application of the Imputed Floor, Frontier State Wage Index and 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 final 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 final rule); and (c) the effects of the out-migration adjustment under section 1886(d)(13) of the Act (as discussed in section III.F.4. of the preamble of this final rule).

g. Effects of All FY 2026 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2025 and FY 2026, resulting from all 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 average increase in payments under the IPPS for all hospitals is approximately 4.3 percent for FY 2026 relative to FY 2025, which is primarily driven by the changes reflected in Column 2 (hospital update) and Column 4 (uncompensated care payments). As described in Column 2, the annual hospital update for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates are expected to result in a 2.5 percent increase in payments in FY 2026 relative to FY 2025 for all hospitals. As described in Column 4, uncompensated care payments are expected to result in a 1.7 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 4.3 percent for FY 2026 (as compared to FY 2025) due to the outlier adjustment, the applicable percentage increase, the MDH program expiration, uncompensated care payments, and changes to the wage index and labor and nonlabor shares. Hospitals in urban areas are expected to experience a 4.4 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 2.9 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 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, are expected to experience a decrease in their payments, while hospitals that generally treat relatively more complex cases, such as larger urban hospitals, are expected to experience an increase in their payments as a result of the changes to the relative weights.

3. Estimated Average Payments per Discharge

Table II displays the results of our analysis of the 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 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 CHANGES ON AVERAGE PAYMENTS PER DISCHARGE FOR OPERATING COSTS AND UNCOMPENSATED CARE

	Number of hospitals (1)	Estimated average FY 2025 payment per discharge (2)	Estimated average FY 2026 payment per discharge (3)	FY 2026 changes (4)
All Hospitals	3,033	17,751	18,515	4.3
By Geographic Location:				
Urban hospitals	2,372	18,187	18,986	4.4
Rural hospitals	661	12,893	13,269	2.9
Bed Size (Urban):				
0–99 beds	647	12,982	13,360	2.9
100–199 beds	673	14,325	14,823	3.5
200–299 beds	406	16,073	16,753	4.2
300–499 beds	392	17,903	18,658	4.2
500 or more beds	252	22,804	23,949	5.0
Bed Size (Rural):				
0–49 beds	313	11,002	11,336	3.0
50–99 beds	180	12,339	12,552	1.7
100–149 beds	95	12,218	12,634	3.4

TABLE II—IMPACT ANALYSIS OF 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 average FY 2026 payment per discharge (3)	FY 2026 changes (4)
150–199 beds	42	14,079	14,597	3.7
200 or more beds	31	15,559	16,063	3.2
Urban by Region:				
New England	104	19,617	19,935	1.6
Middle Atlantic	274	21,119	22,129	4.8
East North Central	366	17,263	17,812	3.2
West North Central	156	16,846	17,769	5.5
South Atlantic	393	16,104	16,992	5.5
East South Central	141	14,936	15,706	5.2
West South Central	355	16,776	18,070	7.7
Mountain	180	17,643	18,317	3.8
Pacific	351	22,188	22,688	2.3
Rural by Region:				
New England	19	17,347	17,492	0.8
Middle Atlantic	48	14,481	14,900	2.9
East North Central	106	12,601	12,786	1.5
West North Central	74	12,828	13,302	3.7
South Atlantic	108	12,218	12,647	3.5
East South Central	127	11,264	11,616	3.1
West South Central	116	11,006	11,578	5.2
Mountain	39	14,739	15,200	3.1
Pacific	24	17,337	17,612	1.6
Puerto Rico:				
Puerto Rico Hospitals	52	13,988	15,587	11.4
By Payment Classification:				
Urban hospitals	1,611	15,990	16,677	4.3
Rural areas	1,422	19,107	19,930	4.3
Teaching Status:				
Nonteaching	1,756	13,357	13,839	3.6
Fewer than 100 residents	986	15,905	16,563	4.1
100 or more residents	291	26,535	27,842	4.9
Urban DSH:				
Non-DSH	346	13,132	13,575	3.4
100 or more beds	909	16,804	17,543	4.4
Less than 100 beds	356	12,361	12,940	4.7
Rural DSH:				
Non-DSH	93	16,180	16,327	0.9
SCH	227	13,778	14,204	3.1
RRC	863	19,792	20,663	4.4
100 or more beds	41	17,825	19,316	8.4
Less than 100 beds	198	10,645	10,743	0.9
Urban teaching and DSH:				
Both teaching and DSH	527	18,326	19,167	4.6
Teaching and no DSH	58	14,607	15,047	3.0
No teaching and DSH	738	13,871	14,440	4.1
No teaching and no DSH	288	12,240	12,685	3.6
Special Hospital Types:				
RRC	131	13,367	13,780	3.1
RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	657	20,458	21,382	4.5
SCH	218	13,194	13,643	3.4
SCH that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	37	15,612	15,992	2.4
SCH and RRC	119	14,306	14,729	3.0
SCH and RRC that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	49	18,018	18,577	3.1
Type of Ownership:				
Voluntary	1,902	17,557	18,231	3.8
Proprietary	724	15,746	16,447	4.4
Government	406	21,551	22,974	6.6
Medicare Utilization as a Percent of Inpatient Days:				
0–25	1,548	19,737	20,791	5.3
25–50	1,388	15,793	16,268	3.0
50–65	65	15,374	15,872	3.2
Over 65	13	12,501	13,061	4.5
Medicaid Utilization as a Percent of Inpatient Days:				
0–25	1,917	15,694	16,282	3.7

TABLE II—IMPACT ANALYSIS OF 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 average FY 2026 payment per discharge (3)	FY 2026 changes (4)
25–50	992	20,848	21,816	4.6
50–65	91	28,395	31,276	10.1
Over 65	32	30,803	34,517	12.1
FY 2026 Reclassifications:				
All Reclassified Hospitals	1,093	18,809	19,606	4.2
Non-Reclassified Hospitals	1,940	16,546	17,272	4.4
Urban Hospitals Reclassified	979	19,685	20,557	4.4
Urban Non-reclassified Hospitals	1,407	15,937	16,621	4.3
Rural Hospitals Reclassified Full Year	268	13,129	13,536	3.1
Rural Non-reclassified Hospitals Full Year	379	12,546	12,920	3.0
All hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) as implemented at 42 CFR 412.103	811	20,066	20,956	4.4
Other Reclassified Hospitals (Section 1886(d)(8)(B), also known as Lugar hospitals)	50	12,108	12,236	1.1

G. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final 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 changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For these 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 changes are discussed in this section.

1. Effects of the Changes Relating to New Medical Service and Technology Add-On Payments

a. FY 2026 Status of Technologies Approved for FY 2025 New Technology Add-On Payments

In section II.E.4. of the preamble of this final rule, we are continuing 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 final rule are based on the applicant's estimate at the time they submitted their original application (or based on updated figures provided during the public comment period) 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 27 new technology add-on payments which we are continuing in FY 2026:

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS TO CONTINUE FOR FY 2026

Technology name	Estimated cases	FY 2026 NTAP amount (65% or 75%)	Estimated total FY 2026 impact
CYTALUX® (pafolacianine) (lung indication)	300	$2,762.50	$828,750.00
EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm) *	157	6,504.07	1,021,138.99
Aveir™ AR Leadless Pacemaker	245	10,725.00	2,627,625.00
Aveir™ Dual-Chamber Leadless Pacemaker	2,250	15,600.00	35,100,000.00
Ceribell Status Epilepticus Monitor	2,477	913.90	2,263,730.30
DETOUR System	600	16,250.00	9,750,000.00
DefenCath™ (taurolidine/heparin)	12,000	3,656.10	43,873,200.00
Phagenyx® System	294	3,250.00	955,500.00
REZZAYO™ (rezafungin for injection)	795	4,387.50	3,488,062.50
SAINT Neuromodulation System	25	12,675.00	316,875.00
TOPS™ System	1,200	11,375.00	13,650,000.00
XACDURO® (sulbactam/durlobactam)	654	13,680.00	8,946,720.00
Annalise Enterprise CTB Triage—OH	271,200	241.39	65,464,968.00
ASTar® System	69,000	97.50	6,727,500.00
Edwards EVOQUE™ Tricuspid Valve Replacement System	800	31,850.00	25,480,000.00
GORE® EXCLUDER® Thoracoabdominal Branch Endoprosthesis (TAMBE Device)	518	47,238.75	24,469,672.50
LimFlow™ System	561	16,250.00	9,116,250.00
Paradise™ Ultrasound Renal Denervation System	200	14,950.00	2,990,000.00

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS TO CONTINUE FOR FY 2026—Continued

Technology name	Estimated cases	FY 2026 NTAP amount (65% or 75%)	Estimated total FY 2026 impact
PulseSelect™ Pulsed Field Ablation (PFA) Loop Catheter	3,402	6,337.50	21,560,175.00
Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter	55	10,400.00	572,000.00
TriClip™ G4	150	26,000.00	3,900,000.00
VADER® Pedicle System	200	28,242.50	5,648,500.00
ZEVTERA™ (ceftobiprole medocaril); ABSSSI and CABP indications	245	5,287.50	1,295,437.50
ZEVTERA™ (ceftobiprole medocaril); SAB indication	571	16,215.00	9,258,765.00
CASGEVY™ (exagamglogene autotemcel); Sickle Cell Disease indication	117	1,650,000.00	193,050,000.00
HEPZATO™ KIT (melphalan for injection/hepatic delivery system)	149	118,625.00	17,675,125.00
LYFGENIA™ (lovotibeglogene autotemcel))	40	$2,325,000.00	$93,000,000.00
Aggregate Estimated Total FY 2026 Impact			603,029,994.79

*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. FY 2026 Applications for New Technology Add-On Payments

In sections II.E.5. and 6. of the preamble to this final rule are 35 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, 18 applicants either withdrew their applications or were not eligible for consideration for new technology add-on payment for FY 2026 (12 alternative and 6 traditional). Of the 35 discussions of technologies in the preamble of this final rule, we are not approving the new technology add-on payment for 8 technologies. This results in a total of 27 new approvals or conditional approvals (5 traditional and 22 alternative) for new technology add-on payments for FY 2026. As explained in the preamble to this final 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 final 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 final rule, and must also still meet the cost criterion.

As fully discussed in section II.E.6. of the preamble of this final rule, we are approving or conditionally approving 22 new technology add-on payments for the alternative pathway applications submitted for FY 2026 new technology add-on payments. The approvals include 20 technologies that received a Breakthrough Device designation from FDA and 2 that were designated as a QIDP by FDA. We did not receive any LPAD applications for add-on payments for new technologies for FY 2026.

Based on information from the applicants at the time of this final rule, we estimate that total payments for the technologies approved under the alternative pathway will be approximately $219 million for FY 2026. Total estimated FY 2026 payments for new technologies that are designated as a QIDP are approximately $7 million, and the total estimated FY 2026 payments for new technologies that are part of the Breakthrough Device program are approximately $212 million.

In the following table, we present detailed estimates for the 22 technologies for which we are approving new technology add-on payments under the alternative pathway in FY 2026:

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE ALTERNATIVE PATHWAY FOR FY 2026

Technology name	Pathway (QIDP, LPAD, or breakthrough device)	Estimated cases	FY 2026 NTAP amount (65% or 75%)	Estimated total FY 2026 impact
EMBLAVEO™ (aztreonam-avibactam)	QIDP	207	$9,000.68	$1,863,140.76
CONTEPO™ (fosfomycin)	QIDP	573	8,775.00	5,028,075.00
4WEB Medical Ankle Truss System	Breakthrough Device	124	15,275.00	1,894,100.00
AeroPace® System	Breakthrough Device	550	23,650.90	13,007,995.00
AGENT™ Paclitaxel-Coated Balloon Catheter	Breakthrough Device	9,010	4,013.75	36,163,887.50
alfapump® system	Breakthrough Device	200	21,450.00	4,290,000.00
aprevo®-C cervical interbody fusion device	Breakthrough Device	400	21,125.00	8,450,000.00
CERAMENT® G	Breakthrough Device	466	5,687.50	2,650,375.00
Emily's Care Nourish Test System (Model 1)*	Breakthrough Device	11	3,347.50	36,822.50
Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	Breakthrough Device	5,300	6,922.50	36,689,250.00
EUROPA™ Posterior Cervical Fusion System	Breakthrough Device	849	80,548.00	68,385,252.00
iFuse TORQ TNT™ Implant System	Breakthrough Device	1,392	4,135.95	5,757,242.40
Merit Wrapsody® Cell Impermeable Endoprosthesis (CIE)	Breakthrough Device	936	3,770.00	3,528,720.00
Minima Stent System**	Breakthrough Device	10	22,685.00	226,850.00
MY01 Continuous Compartmental Pressure Monitor	Breakthrough Device	2,000	2,112.50	4,225,000.00
PBC Separator with Selux AST System	Breakthrough Device	68,149	87.78	5,982,119.22
RECELL® Autologous Cell Harvesting Device	Breakthrough Device	412	4,875.00	2,008,500.00
restor3d TIDAL™ Fusion Cage	Breakthrough Device	96	18,196.75	1,746,888.00
ShortCut™	Breakthrough Device	550	9,750.00	5,362,500.00
The WiSE CRT System	Breakthrough Device	209	41,145.00	8,599,305.00
TriVerity Test	Breakthrough Device	5,755	243.75	1,402,781.25
VITEK® REVEAL™ AST System	Breakthrough Device	19,000	81.25	1,543,750.00
Estimated Total FY 2026 Impact				218,842,533.63

*The applicant did not provide an updated volume during the public comment period. Therefore, based on the volume of claims identified by the applicant in FY 2024 MedPAR data and the expected patient population for this technology (VLBW infants and neonates), we are imputing a volume of 11 for fewer than 11 estimated cases for the purposes of estimating the impact of the technology.

** During the public comment period, the applicant stated that Medicare coverage for this technology is expected to be rare with fewer than 10 anticipated cases (medically complex children) during the new technology add-on payment period. Therefore, for the purposes of estimating the impact of the technology, we are imputing a volume of 10.

As fully discussed in section II.E.5. of the preamble of this final rule, we are approving new technology add-on payments for 5 technologies that applied under the traditional pathway for new technology add-on payments for FY 2026. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the technologies for which we are making new technology add-on payments is approximately $139 million for FY 2026.

In the following table, we present detailed estimates for the 5 technologies for which we are approving new technology add-on payments under the traditional pathway in FY 2026:

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE TRADITIONAL

Technology name	Estimated cases	FY 2026 NTAP amount (65%)	Estimated total FY 2026 impact
AURLUMYN™ (iloprost injection)	300	$28,600.00	$8,580,000.00
BREYANZI® (lisocabtagene maraleucel)	290	316,860.05	91,889,414.50
GRAFAPEX™ (treosulfan)	368	21,411.00	7,879,248.00
IMDELLTRA® (tarlatamab-dlle)	692	7,117.50	4,925,310.00
TECELRA® (afamitresgene autoleucel)	55	472,550.00	25,990,250.00
Estimated Total FY 2026 Impact			139,264,222.50

c. Total Estimated Costs for NTAP in FY 2026

In the following table, we present summary estimates for all new technology add-on payments for FY 2026:

FY 2026 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR FY 2026

Category	Estimated total FY 2026 impact
Technologies Continuing New Technology Add-on Payments in FY 2026	$603,029,994.79
Alternative Pathway Applications	218,842,553.63
Traditional Pathway Applications	139,264,222.50
Aggregate Estimated Total FY 2026 Impact	961,136,770.92

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 final 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 final rule, we are establishing the amount to be distributed as uncompensated care payments (UCP) to DSH-eligible hospitals for FY 2026, which is $7,713,127,500. 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 62.14 percent. For FY 2025, the amount available to be distributed for uncompensated care was $5,705,743,275 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 $107,842,748.53 in supplemental payments in FY 2026, based on the difference between each hospital's FY 2022 UCP (increased by 35.2 percent, which is the projected change between the FY 2026 total UCP amount and the total UCP 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 final rule, the total UCP and supplemental payments equal approximately $7.821 billion. For FY 2026, we are using 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 final rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section V.D. of the preamble of this final rule.

To estimate the impact of the combined effect of the 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 UCP and the supplemental payments estimated in this FY 2026 IPPS/LTCH PPS final 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 Factor 2 of 62.14 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this final 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 UCP) and the hospital's FY 2026 UCP.

Our analysis included 2,364 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 30 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 UCP. 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 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 estimated uncompensated care payments and supplemental payments ($ in millions)	FY 2026 estimated uncompensated care payments and supplemental payments ** ($ in millions)	Dollar difference: FY 2025–FY 2026 ($ in millions)	Percent change ***
	(1)	(2)	(3)	(4)	(5)
Total	2,364	$5,786	$7,821	$2,035	35.2
By Geographic Location:					
Urban Hospitals	1,905	5,456	7,384	1,928	35.3
Other Urban Areas	984	2,433	3,240	807	33.2
Large Urban Areas	921	3,023	4,144	1,121	37.1
Rural Hospitals	459	329	437	107	32.6
Bed Size (Urban):					
0 to 99 Beds	371	244	310	66	27.3
100 to 249 Beds	775	1,198	1,594	396	33.0
250+ Beds	759	4,014	5,480	1,466	36.5
Bed Size (Rural):					
0 to 99 Beds	344	177	233	56	31.6
100 to 249 Beds	105	122	164	42	34.5
250+ Beds	10	30	40	9	30.8
Urban by Region:					
New England	85	145	203	58	40.1
Middle Atlantic	222	618	867	249	40.4
South Atlantic	303	576	738	162	28.0
East North Central	105	289	363	75	25.9
East South Central	319	1,406	1,896	490	34.9
West North Central	124	348	471	123	35.2
West South Central	245	1,248	1,729	481	38.6
Mountain	148	245	348	103	41.8
Pacific	308	508	670	162	31.9
Puerto Rico	46	72	98	25	35.1
Rural by Region:					
New England	8	9	11	2	22.7
Middle Atlantic	34	17	25	7	42.2
South Atlantic	70	42	55	13	31.1
East North Central	31	20	27	7	35.3
East South Central	82	95	124	29	31.0
West North Central	104	61	82	21	34.3
West South Central	103	70	92	22	32.4
Mountain	20	10	13	3	35.1
Pacific	7	6	7	2	27.6
By Payment Classification:					
Urban Hospitals	1,243	2,585	3,469	884	34.2
Large Urban Areas	661	1,546	2,093	548	35.4
Other Urban Areas	582	1,039	1,375	336	32.4
Rural Hospitals	1,121	3,201	4,352	1,151	36.0
Teaching Status:					
Nonteaching	1,246	1,412	1,872	460	32.6
Fewer than 100 residents	828	2,086	2,760	674	32.3
100 or more residents	290	2,288	3,189	901	39.4
Type of Ownership:					
Voluntary	1,509	3,347	4,440	1,093	32.7
Proprietary	497	811	1,089	278	34.3
Government	358	1,628	2,292	664	40.8
Medicare Utilization Percent: ****					
0 to 25	1,389	4,478	6,100	1,623	36.2
25 to 50	948	1,298	1,707	410	31.6
50 to 65	25	10	13	3	31.3
Greater than 65	2	0	0	0	−100.0
Medicaid Utilization Percent: ****					
0 to 25	1,308	2,479	3,289	810	32.7
25 to 50	930	2,646	3,582	936	35.4
50 to 65	93	491	712	221	44.9
Greater than 65	33	169	238	69	41.1

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 $7.821 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 final 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. Factor 1 has increased from the FY 2025 final rule's Factor 1 of $10.509 billion to this final rule's Factor 1 of $11.843 billion. Factor 2 has increased from the FY 2025 final rule's Factor 2 of 54.29 percent to this final rule's Factor 2 of 62.14 percent. In addition, we note that there is a decrease in the number of projected DSH-eligible hospitals to 2,364 at the time of the development of this final rule compared to the 2,398 DSHs at the time of development of 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, FY 2026 UCP and supplemental payments are estimated at approximately $7.821 billion, or an increase of approximately 35.2 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 payments is caused by changes in Factor 3 and the amount of the supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than 35.2 percent indicates that hospitals within the specified category are projected to experience a smaller increase in payments, on average, compared to the universe of projected FY 2026 DSH-eligible hospitals. Conversely, a percentage change greater than 35.2 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 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 supplemental payment.

Urban hospitals, in general, are projected to experience a slightly larger increase in UCP compared to the increase their rural counterparts are projected to experience. Overall, urban hospitals are projected to receive a 35.3 percent increase in payments, while rural hospitals are projected to receive a 32.6 percent increase in payments, which is slightly less than the overall hospital average.

By bed size, rural hospitals with 0 to 99 beds, 100 to 249 beds, and 250+ beds are projected to receive a smaller than average increase of approximately 31.6 percent, 34.5 percent, and 30.8 percent, respectively. Among urban hospitals, the largest urban hospitals, those with 250+ beds, are projected to receive an increase in payments (36.5 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 payments of 27.3 and 33.0 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 North Central, West South Central, Mountain, and Pacific regions are projected to receive smaller than average increases in payments. Rural hospitals in all other regions are projected to receive larger than average increases in payments. Urban hospitals in the South Atlantic, East North Central, East South Central, Pacific regions, and Puerto Rico are projected to receive smaller than average increases in payments, while urban hospitals in all other regions are projected to receive larger than average increases in payments.

By payment classification, hospitals in urban payment areas overall are expected to receive a smaller than average increase in UCP and supplemental payments of 34.2 percent. Hospitals in large urban payment areas are projected to receive a larger than average increase in payments (35.4 percent), while other urban payment areas are projected to receive a smaller than average increase in payments of 32.4 percent. In contrast, hospitals in rural payment areas are projected to receive a larger than average increase in payments of 36.0 percent.

Nonteaching hospitals and teaching hospitals with fewer than 100 residents are projected to receive smaller than average payment increases of 32.6 percent and 32.3 percent, respectively. Teaching hospitals with 100+ residents are projected to receive larger than average payment increases of 39.4 percent. Voluntary hospitals and proprietary hospitals are projected to receive smaller than average increases of 32.7 percent and 34.3 percent, respectively, while government-owned hospitals are expected to receive a larger than average payment increase of 40.8 percent. Hospitals with less than 25 percent Medicare utilization are projected to receive larger than average increases of 36.2 percent, while hospitals with Medicare utilization between 25–50 percent and 50–65 percent are projected to receive smaller than average payment increases of 31.6 percent and 31.3 percent, respectively. There are 2 hospitals with greater than 65 percent Medicare utilization, and the hospitals (250002 and 250017) are projected to have a decrease in payments of 100.0 percent, which reflects the hospitals' projected DSH eligibility. Hospitals with 20–50 percent Medicaid utilization, those with 50–65 percent Medicaid utilization and those with greater than 65 percent Medicaid utilization are projected to receive larger than average increases in payments of 35.4, 44.9 and 41.1 percent, respectively. Hospitals with less than 25 percent Medicaid utilization are projected to receive a smaller than average increase of 32.7 percent.

The impact table reflects the modeled FY 2026 UCP and supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $107.8 million in FY 2026.

3. Effects of Expiration of the Temporary Changes to the Low-Volume Hospital Payment Policy

In section V.D. of the preamble of this final 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 A of this final rule, 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 579 providers that are expected to no longer qualify under the criteria that are effective beginning on October 1, 2025.

Of those 579 hospitals, currently approximately 97 hospitals have a low-volume hospital payment adjustment based on 500 or fewer total discharges, while the remaining approximately 482 hospitals have an adjustment based on having between 500 and 3,800 total discharges. Approximately 55 of the 579 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. of the preamble of this final rule, we discussed 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. *Becerra* (717 F.Supp.3d 33 (D.D.C. 2024). We are not finalizing this proposed change; and therefore, there are no costs.

5. Effects Under the Hospital Readmissions Reduction Program for FY 2026

In section VI.K. of the preamble of the FY 2026 IPPS/LTCH PPS final rule, we are modifying 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. We are also updating the Extraordinary Circumstance Exception Policy. The remaining policies finalized in FY 2025 IPPS/LTCH PPS final rule (89 FR 69400) continue to apply. We refer readers to TABLE VI.K–04 in section VI.K. of this final rule for an estimate of the financial impact reflecting the newly finalized program updates that will begin in FY 2027.

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 for the FY 2026 program year. 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, 2021 and June 30, 2024 (that is, the FY 2026 Hospital Readmissions Reduction Program's applicable period, which is the most recently available data at the time of publication of this final 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 this FY 2026 IPPS/LTCH PPS final rule, we are providing 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.7.–01 include 2,797 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.7.–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.7.–01 indicates the estimated percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 77.76 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.53 percent of eligible hospitals with fewer than 100 residents and 87.76 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in Table I.G.7.–01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.7.–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, 2023, through September 30, 2024 (FY 2024). For example, the penalty as a share of payments for non-teaching hospitals is 0.48 percent. This means that total penalties for all non-teaching hospitals are 0.48 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.

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	2,797	2,304	82.37	0.44
By Geographic Location (n=2,792):				
Urban hospitals	2,147	1,802	83.93	0.44
1–99 beds	497	326	65.59	0.43
100–199 beds	626	553	88.34	0.50
200–299 beds	385	354	91.95	0.53
300–399 beds	269	246	91.45	0.45
400–499 beds	117	106	90.60	0.40
500 or more beds	253	217	85.77	0.38
Rural hospitals	645	499	77.36	0.42
1–49 beds	294	195	66.33	0.38
50–99 beds	184	155	84.24	0.43
100–149 beds	94	85	90.43	0.46
150–199 beds	42	35	83.33	0.43
200 or more beds	31	29	93.55	0.39
By Teaching Status [e] (n=2,792):				
Non-teaching	1,565	1,217	77.76	0.48
Fewer than 100 Residents	933	826	88.53	0.47
100 or more Residents	294	258	87.76	0.37

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] (%)
By Ownership Type (n=2,792):				
Government	388	315	81.19	0.31
Proprietary	608	492	80.92	0.59
Voluntary	1,796	1,494	83.18	0.43
By Safety-Net Status [f] (n=2,792):				
Safety-net hospitals	556	458	82.37	0.41
Non-safety-net hospitals	2,236	1,843	82.42	0.45
By Disproportionate Share Hospital (DSH) Patient Percentage [g] (n=2,792):				
0–24	1,051	838	79.73	0.49
25–49	1,461	1,236	84.60	0.41
50–64	162	133	82.10	0.41
65 and over	118	94	79.66	0.51
By Medicare Cost Report (MCR) Percentage [h] (n=2,792):				
0–24	1,371	1,142	83.30	0.36
25–49	1,354	1,116	82.42	0.52
50–64	59	38	64.41	0.69
65 and over	8	5	62.50	1.81
By Region (n=2,797):				
New England	120	100	83.33	0.68
Middle Atlantic	312	274	87.82	0.55
East North Central	441	376	85.26	0.43
West North Central	222	164	73.87	0.29
South Atlantic	485	424	87.42	0.45
East South Central	247	219	88.66	0.53
West South Central	416	324	77.88	0.41
Mountain	205	144	70.24	0.32
Pacific	349	279	79.94	0.35

Source: The table results are based on the data used to calculate the FY 2026 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2026 payment adjustment factors are based on discharges from July 1, 2021, through June 30, 2024. 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 2025 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 2026 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 geographic location, teaching status, ownership type, safety-net status, DSH percentage, and MCR percentage (n=2,792; missing=5).

[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, 2023, through September 30, 2024 (FY 2024), 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 two 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 final 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 March 2025 update to the FY 2024 MedPAR file.

The estimated impacts of the FY 2026 program year by hospital characteristic, found in Table I.G.6.–01., are based on historical TPSs and sepsis measure results, and reflect removal of the Health Equity Adjustment as discussed in section VI.L.6. 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 March 2025 update to the FY 2024 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this final rule (available via the internet on the CMS website).

The estimated impact analysis shows that, for the FY 2026 program year, the number of hospitals with a positive percent change in base operating DRG (49.25 percent) is lower than the number of hospitals with a negative percent change (50.75 percent). Approximately half of all hospitals experience a percent change in base operating DRG between −1.9 percent and 0.0 percent. On average, 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. 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	0.169
Urban Area	1,984	0.077
Rural Area	547	0.500
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	0.500
0–49 beds	212	0.824
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	0.025
East North Central	311	0.107
East South Central	117	−0.131
West North Central	131	0.302
West South Central	246	−0.002
Mountain	154	0.143
Pacific	320	0.246
Rural By Region	547	0.500
New England	19	0.444
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	1.243
Pacific	24	0.936
By MCR Percent:		
0–25	1,118	0.086
25–50	1,369	0.222
50–65	38	0.533
Over 65	4	0.474
Missing	3	1.683
By DSH Percent:		
0–25	887	0.418
25–50	1,394	0.059
50–65	146	−0.178
Over 65	104	0.000
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 have been used for the updated impact analysis in this final rule.

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 final rule, we did not add or remove any measures from the HAC Reduction Program, nor did we finalize 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, 2022, through June 30, 2024, and version 15.0 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, 2023,

and December 31, 2024. Hospital characteristics are based on the FY 2026 IPPS proposed rule Impact File.

This table includes 2,891 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 final 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, 401 hospitals out of 1,620 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 210 out of 959 hospitals with fewer than 100 residents and 100 out of 295 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, 24.8 percent of the 1,620 hospitals characterized as non-teaching hospitals, 21.9 percent of the 959 teaching hospitals with fewer than 100 residents, and 33.9 percent of the 295 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]	2,891	721	25
By Geographic Location (n=2,874): [d]			
Urban hospitals	2,245	510	22.7
1–99 beds	562	129	23.0
100–199 beds	645	144	22.3
200–299 beds	396	85	21.5
300–399 beds	271	55	20.3
400–499 beds	118	26	22.0
500 or more beds	253	71	28.1
Rural hospitals	629	201	32.0
1–49 beds	276	93	33.7
50–99 beds	186	59	31.7
100–149 beds	94	23	24.5
150–199 beds	42	12	28.6
200 or more beds	31	14	45.2
By Teaching Status [d] (n=2,874): [d]			
Non-teaching	1,620	401	24.8
Fewer than 100 residents	959	210	21.9
100 or more residents	295	100	33.9
By Ownership (n=2,874):			
Government	390	146	37.4
Proprietary	655	94	14.4
Voluntary	1,829	471	25.8
By Safety-Net Status [e] (n=2,874): [d]			
Safety-net	583	162	27.8
Non-safety net	2,291	549	24.0
By Disproportionate Share Hospital (DSH) Patient Percentage [f] (n=2,874):			
0–24	1,103	232	21.0
25–49	1,465	387	26.4
50–64	164	45	27.4
65 and over	142	47	33.1
By Medicare Cost Report (MCR) Percentage (n=2,872):			
0–24	1,455	352	24.2
25–49	1,350	339	25.1
50–64	56	14	25.0
65 and over	11	4	36.4
By Region (n=2,891):			
New England	120	38	31.7
Middle Atlantic	318	86	27.0
East North Central	456	118	25.9
West North Central	227	56	24.7
South Atlantic	491	97	19.8
East South Central	248	83	33.5
West South Central	438	86	19.6
Mountain	219	45	20.5
Pacific	374	112	29.9

Source: FY 2026 HAC Reduction Program estimated final rule results are based on CMS PSI 90 data from July 1, 2022, through June 30, 2024, and CDC's NHSN HAI results from January 1, 2023, through December 31, 2024. Hospital Characteristics are based on the FY 2026 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=2,874; missing=17), and MCR percent (n=2,872; missing=19).

[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=2,891).

[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.

We received no comments on our assumptions regarding these effects.

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 final 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 (89 FR 105049) for up to 10 additional eligible hospitals to participate in the RCHD. Applications were due March 1, 2025. These hospitals have been selected under this solicitation and 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 final rule, the resulting amount applicable to FY 2026 is $47,586,847, which we proposed 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 proposed to continue this general procedure. At this time, for the FY2026 final rule, all of the FY2020 finalized cost reports are available and will be reconciled in FY2026. We received no public comments related to the RCHD regulatory impact analysis in the proposed rule. We are finalizing our policies as proposed.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VIII.B.2. of the preamble of this final 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 section 129 of 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 final 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 did not apply a budget neutrality payment offset to payments to CAHs in FY 2026. This policy will have no impact on any national payment system for FY 2026. We received no comments on this provision and therefore are finalizing this provision without modification.

10. Effects of the Transforming Episode Accountability Model (TEAM)

In section XI.A. of the preamble of this final 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 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 final rule, we are finalizing several policies that we proposed and finalizing some policies where we solicited comments on policy considerations. We believe most of the policies that are being finalized 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, many of the proposals that affect the pricing methodology that we are finalizing in this final rule, 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 we do not anticipate they will result in dramatic shifts to the Medicare savings estimate. We noted in the proposed rule 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 anticipated the direction of the Medicare savings to remain the same. In the proposed rule we stated that 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, in the proposed rule TEAM's financial impact to the Medicare program remained unchanged from the FY 2025 IPPS/LTCH PPS final rule.

[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.

While the Medicare savings estimate remained unchanged for TEAM in the proposed rule, we noted in section I.O. of this Appendix, that we assessed the potential financial impact of a low volume policy on the model. Further, we indicated in the proposed rule that we would update the Medicare savings estimate for the final rule to reflect actual TEAM participants participating in the model, inclusive of those hospitals that voluntarily opted into the model, and updated baseline spending assumptions. Additionally, we noted that should a policy that we considered become finalized, such as the low volume hospital policy, we would update the Medicare savings estimate to reflect that policy as well.

Given the policies we are finalizing in this final rule, and our desire to account for all TEAM participants, inclusive of the hospitals that have voluntarily joined the model, we have updated the Medicare savings estimate as a result of implementing TEAM. Table J.G.12–01 shows the projected financial impacts of TEAM over the course of the five-year model test. The first performance year (2026) of TEAM is expected to cost the Medicare program $28 million because we assume most TEAM participants will elect participation in Track 1, which is not subject to downside risk. In performance year 2 (2027), TEAM participants in Track 1 will have no downside risk while TEAM participants in Track 2 and Track 3 will be subject to both upside and downside risk, and we estimate TEAM participants on net (that is, repayment amounts less reconciliation payments) will pay $16 million to CMS, and that TEAM will save the Medicare program $71 million. In performance year 3 (2028), we estimate TEAM participants on net will pay $33 million to CMS, and that TEAM will save the Medicare program $89 million. We estimate that TEAM participants on net will pay CMS $60 million in performance year 4 (2029) and $61 million in performance year 5 (2030), and that TEAM will save the Medicare program $117 million and $119 million for these performance years, respectively. We estimate that CMS will pay TEAM participants $381 million and TEAM participants will pay CMS $469 million, and that TEAM will save the Medicare program approximately $368 million over the 5 performance years (2026 through 2030).

TABLE J.G.12.—01: PROJECTED FINANCIAL IMPACTS OF TEAM

[In Millions]

	2026	2027	2028	2029	2030
TEAM episode spending	$5,398	$5,478	$5,567	$5,661	$5,751
(+) Reconciliation payment amounts (positive)	$82	$81	$75	$71	$72
(+) Reconciliation repayment amounts (negative)	0	−$97	−$108	−$131	−$133
− Baseline episode spending	$5,452	$5,533	$5,623	$5,718	$5,809
Impact	$28	−$71	−$89	−$117	−$119
Impact as % of Baseline	0.5%	−1.3%	−1.6%	−2.0%	−2.0%

* These estimates are before financial interactions with Part B premium or the Medicare Advantage program.

(1) Assumptions

We assumed TEAM episode volume is estimated to grow at the same rate as projected Medicare FFS enrollment as indicated in the 2025 Medicare Trustees Report.[510] We also assumed that TEAM participants are estimated to reduce episode spending by 1 percent as a result of participating in TEAM. We note in the sixth annual evaluation report of the Comprehensive Care for Joint Replacement (CJR) model indicated that CJR resulted in roughly a 3.5 percent reduction in lower extremity joint replacement (LEJR) spending (not including reconciliation payments) for participants in performance year 6.[511] Since participation in CJR is mandatory in 34 metropolitan statistical areas, and LEJR episodes make up a significant portion of the episodes included in TEAM, the CJR evaluation results appear to be a reasonable proxy for what to expect in TEAM. However, the episode length in CJR is 90 days, whereas in TEAM the finalized length is 30 days. Internal analysis indicated that the 30-day episode is approximately 75 percent as costly as a 90-day episode for LEJR procedures. In addition, post-acute care spending has been declining in recent years for episodes that we are testing in TEAM, which could limit the potential for TEAM participants to achieve significant improvements in efficiency. Thus, we believe that the intervention effect of TEAM on episode spending will be a reduction of 0 to 3 percent (see Table J.G.12–02 for a sensitivity analysis for how the financial impact is affected by changes in this assumption).

We also note that starting from actual episode spending that occurred in the first half of 2023, average baseline spending per episode is estimated to increase by 1.5 percent every year. The national average per episode spending growth for all TEAM episode types in years 2018, 2019, 2022, and 2023 was approximately 1.3 percent. Annual growth rates for each episode type were weighted by spending, and historical experience during 2020 and 2021 were excluded due to possible impacts from the peak of the COVID–19 pandemic. Since some of the historical experience in these years includes Medicare policy changes for LEJR episodes that resulted in surgeries occurring in more efficient care settings, translating to spending decreases that may not be duplicated in future years, the assumed annual trend is slightly greater than the observed average trend from the historical experience.

Additionally, our estimates do not include the impact of TEAM beneficiary overlap with total cost of care models, such as when a TEAM beneficiary is also assigned to a Medicare Shared Savings Program ACO. However, given the precision in the Shared Savings Program projections, we do not anticipate a practical difference in the ACO's shared savings estimates. Nor do we anticipate TEAM beneficiary overlap with total cost of care models having a meaningful effect to TEAM's projected financial impacts, described in Table J.G.12–01.

Because the financial impact is based on projections of spending, the estimates implicitly assume that there will be no meaningful difference between the projected episode spending used to calculate the prospective target prices and actual episode spending, as observed in an internal analysis of simulated reconciliation results using the first three quarters of 2024. This assumption has a large degree of uncertainty, and the actual TEAM financial impacts will be sensitive to this difference. However, some of the financial risk of the projection error is mitigated by the retrospective trend factor. Target prices will still be susceptible to some error risk if the projection error exceeds the retrospective trend factor cap. The direction, magnitude and timing of projection inaccuracies would all affect the overall financial impact estimate.

(2) Sensitivity Analysis

We also performed a sensitivity analysis to assess various intervention effects on TEAM. Overall financial impacts are sensitive to the intervention effect TEAM would have on TEAM participants' episode spending. Table J.G.12–02 includes financial impacts at various intervention effect assumptions (note that negative values indicate savings):

[510] *https://www.cms.gov/oact/tr/2025.*

[511] *https://www.cms.gov/priorities/innovation/data-and-reports/2024/cjr-py6-annual-report.*

TABLE J.G.12—02: TEAM SENSITIVITY ANALYSIS AT VARIOUS INTERVENTION EFFECTS

Intervention effect (%)	2026 (%)	2027 (%)	2028 (%)	2029 (%)	2030 (%)
−3.0	−0.7	−1.8	−2.7	−3.1	−3.1
−1.0	0.5	−1.3	−1.6	−2.0	−2.0
0.0	1.2	−1.0	−1.0	−1.5	−1.5

The sensitivity is due to the lack of the requirement that TEAM participants participate in downside risk during performance year 1 and the effect that reductions in episode spending during performance years would have on target prices for future performance years.

b. Effects on Medicare Beneficiaries

We believe the refinements to TEAM finalized in this final rule will 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 will 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 finalized that may have a direct effect on TEAM beneficiaries are positive. In section XI.A.2.b.(3) of the preamble of this final rule, we finalized the policy to include the Information Transfer PRO–PM, specific to episodes initiated in the hospital outpatient department setting, in the quality measure set that will be tied to payment with the belief that doing so will 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 final rule that we finalized the policy 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 finalized policy will help improve beneficiary freedom of choice and access to care, such that beneficiaries in rural or underserved areas could receive PAC services closer to their home.

We welcomed public comments on our impact of TEAM on Medicare beneficiaries. We received no comments and therefore are finalizing this provision without modification.

12. Effects of the Health Data, Technology, and Interoperability: Electronic Prescribing, Real-Time Prescription Benefit, and Electronic Prior Authorization

a. Regulatory Planning and Review Analysis

This final rule implements relevant policy priorities outlined in Executive Orders (E.O.) 12866, 13563, 14221, and 14192. In 1993 E.O. 12866 was issued to ensure that regulations are cost-effective, necessary, and minimally burdensome. To build upon this, E.O. 13563, called for grounding in the best available science to ensure objectivity and transparency in rulemaking. In addition, this final rule reinforces the administration's policy goals set forth in E.O. 14221 to support pricing transparency, automation, patient empowerment through accessible and actionable information. Finally, this rule aligns with E.O. 14192, Unleashing Prosperity Through Deregulation, which seeks to reduce the private expenditures required to comply with federal regulations.

(1) Costs and Benefits

ASTP/ONC has estimated the potential monetary costs and benefits of this final rule for health IT developers, health care providers, patients, and the Federal Government (that is, ASTP/ONC), and have broken those costs and benefits out by section. The impact analysis primarily assesses the costs and benefits of finalized changes to the Certification Program as applicable for certified health IT developers and the health care providers purchasing health IT. We expect the undiscounted costs to developers of certified health IT and health IT purchasers equal to $228 million.

The Certification Program, as described elsewhere in this rule, is voluntary. Developers who present technology for certification do so for varied reasons such as supporting health IT users engaged in quality improvement programs and demonstrating conformance with federally adopted standards. However, we recognize there are real costs associated with any changes to certified health IT and requirements for developers of certified health IT to maintain certification. We estimate these costs to the best of our ability, examining the development tasks and burden associated with each proposal. We also estimate and articulate the expected cost savings and benefits of these proposals. Whereas we estimate the costs and cost savings associated with development tasks for developers of certified health IT, benefits and less-direct costs can be more far reaching—affecting developers directly through standards harmonization and well-delineated processes for technology development while also affecting health care providers, patients, and payers by providing for electronic health information exchange, access to electronic health information, and automation of clinical and administrative processes.

Although participation in the Certification Program is voluntary, we believe that requirements to use certified health IT by Federal programs, to adopt health IT standards, and to make data available to health care providers, patients, and payers provide reasons for developers to present health IT for certification. Certification Program requirements are meant to harmonize health IT development and promote interoperability through common health IT standards and rules of information exchange and access. The benefits described more thoroughly, later in this section, such as those for interoperability that we have described in prior rulemaking (for example, ONC Cures Act Final Rule (85 FR 25642)), are derived from more universal adoption of these standards and from rules that enable data to be electronically recorded, stored, exchanged, and accessed more harmoniously. These actions may remove artificial barriers to information exchange that often result in the duplication of diagnostic and laboratory testing, fragmented care, missing medical record information, and less consumer choice in the healthcare market.[512] [513]

The benefits, both quantifiable and not quantifiable, articulated in this impact analysis have the potential to remove barriers to interoperability and EHI exchange, improve the efficiency of and reduce the administrative overhead involved in health care delivery. These policies first require effort by developers of certified health IT to reflect the policies in their software. Software must then be implemented by end-users to achieve the stated benefits—improving healthcare delivery and improving the overall ability of technology to document, transmit, and integrate EHI across multiple data systems.

Our cost calculations quantify health IT developers' time and effort necessary to implement these policies through new development and administrative activities. Our cost estimates use publicly available data and information to estimate time and effort. We also, where applicable, carry forward cost estimates from prior rulemakings to be consistent in time and effort estimates. Novel cost estimates also use a mix of subject matter expertise and appropriate proxies to quantify costs and cost savings. We note these methods and sources in the tables. We recognize that the costs developers incur as a result of these policies may be passed on to certified health IT end-users. These end-users include but are not limited to the nearly 5,000 non-federal hospitals who provide acute, inpatient care and the over 1 million clinicians who provide outpatient care to all Americans. Official statistics show that nearly all U.S. non-federal acute care hospitals and the vast majority of outpatient

[512] Jones S.S., Rudin R.S., Perry T., Shekelle P.G. Health information technology: an updated systematic review with a focus on meaningful use. Ann Intern Med. 2014 Jan 7;160(1):48–54. doi: 10.7326/M13–1531. PMID: 24573664. *https://pubmed.ncbi.nlm.nih.gov/24573664/*.

[513] Everson J., Adler-Milstein J. Sharing information electronically with other hospitals is associated with increased sharing of patients. Health Serv Res. 2020 Feb;55(1):128–135. doi: 10.1111/1475–6773.13240. Epub 2019 Nov 12. PMID: 31721183; PMCID: PMC6980958. *https://pubmed.ncbi.nlm.nih.gov/31721183/*.

physicians use certified health IT.[514] [515] These policies affect the technology that all of these health care providers use.

In our analysis and estimates of costs in the proposed rule, we did not assess the costs that health care providers incur in using certified health IT. Such costs may include changes in how the provider electronically documents information in the medical record, changes to workflow, or the costs incurred by a particular implementation of the technology at a care delivery site. The costs estimated the expected burden on health IT developers in developing and providing the revised technology to their users, not the expected burden on users incurred in implementing and using the revised technology. We noted that the costs and benefits of requirements imposed by Federal agencies on health care providers are often estimated and explained in those rules' regulatory impact analysis. However, in this final rule we have determined it appropriate to consider the costs and benefits for certified health IT purchasers. We believe it is appropriate to include these costs because, while there are HHS programs incentivizing electronic transactions, this final rule is directly applicable for the specific requirements for certified health IT developed by health IT developers to meet the adopted standards and purchased by health care providers.

We have limited data on the fees and costs charged by health IT developers and how those fees and costs are distributed across various health IT purchasers. The estimated costs described for health IT developers are not solely borne by developers of certified health IT and could be passed on to health IT purchasers through health IT developers' licensing, maintenance, and other operating fees and costs, not including additional training to learn the new software and process or workflow changes to integrate the new software into daily practice. Given the ongoing nature of updates made by ASTP/ONC to the Certification Program, health IT developers may have already included the costs associated with making these updates in their existing contracts. Where they have not already been incorporated, these costs may be passed on to health IT purchasers in different ways by developers of certified health IT and across different health care provider organization types. In the section, ''Number of End Users that Will Be Impacted by ASTP/ONC's Required Regulations,'' we estimate the number of health IT purchasers impacted by these new requirements and the estimated share of total costs quantified in this impact analysis that could be passed on from developers of certified health IT to them. Large integrated healthcare systems may face different fees and other pricing structures than smaller health care provider organizations. The diversity of the healthcare system also limits our ability to accurately model how these costs could be passed on, even if there were data available (much of this data is considered proprietary or trade secrets). Finally, we recognize there may be non-purchase related costs for health care provider use of the certified technology such as staff training. However, the use of the adopted standards within the health IT dramatically limits any necessary manual interaction with the technical processes.

What we can describe with more certainty is the overall impact of these policies on the healthcare system as a whole. These policies affect the certified technology used by health care providers that care for the vast majority of Americans. Nearly all emergency room visits, hospital stays, and regular check-ups are documented and managed using certified health IT. These policies affect the interoperability of EHI for these care events and patients' electronic access to their health information. Certified health IT is a nearly ubiquitous part of U.S. healthcare, and the costs and benefits estimated here encompass the widespread use of these technologies and their impact on all facets of care.

Overall, it is highly speculative to quantify benefits or cost savings associated with the new technical requirements and standards for certification criteria we have proposed in this final rule. Emerging technologies may be used in ways not originally predicted. For example, ASTP/ONC supported the development of SMART on FHIR®, which defines a process for an application to securely request, receive and use data. ASTP/ONC could not have predicted the scale this technical advancement achieved. Today, it is used to support major health IT products and utilized by numerous digital health and technology companies to connect and integrate with health IT products to provide healthcare and other services to health app users.[516] It is speculative to quantify benefits for specific stakeholders because benefits owing to advancements in interoperability do not necessarily accrue to stakeholders developing and implementing the technologies. Benefits related to interoperability are spread across the healthcare ecosystem and can be considered a societal benefit. We have sought to describe benefits for each of the specific policies, using the best available data and studies to support our analysis.

All estimates are rounded to the nearest dollar and all estimates are expressed in 2024 dollars. The wages used to derive cost estimates are from the May 2024 National Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics.[517] Estimates presented in sections titled ''Employee Assumptions and Hourly Wage,'' ''Quantifying the Estimated Number of Health IT Developers and Products,'' ''Number of End Users that Will Be Impacted by ASTP/ONC's Required Regulations'', and ''Comparative Analysis Between Standardized and Non-standardized Application Programming Interfaces'' are used throughout.

In this final rule, we estimate direct benefits wherever research supports such direct estimates of impact. For policies where no such research was identified to be available, we developed estimates based on a reasonable proxy. We note that interoperability can positively impact patient safety, efficacy, care coordination, and improve healthcare processes and other health-related outcomes.[518] However, interoperability is a function of several factors including the capabilities of the technology used by health care providers. Therefore, to assess the benefits of our policies, we must first consider how to assess their respective effects on interoperability, holding other factors constant.

Comment: We requested comment on the increase in software licensing costs and other fees resulting from these finalized policies, and if ongoing licensing costs and fees already encompass the costs of meeting new regulations and certification requirements (*that is,* some or none of the estimated costs of the proposed rule would be passed on to technology end-users). We received no comments regarding the impact on software licensing costs and other fees resulting from these policies.

Response: The final impact analysis updates costs based on new information on the number of products that are likely to require new functionality and the impact of these finalized policies. Cost estimates were updated to reflect wages of software developers as of 2024. Quantified cost savings were updated in this final impact analysis, given new information and availability of data.

(a) Employee Assumptions and Hourly Wage

Unless otherwise noted, we have consistently used the May 2024 National Occupational Employment and Wage Estimates reported by the U.S. Bureau of Labor Statistics (BLS) to calculate private sector employee wage estimates.[519] These wage estimates are a national average and do not represent any possible regional variation in wages. We also do not account for possible variation in the average wages for software developers in health care IT positions versus IT positions, more generally, which the BLS wage estimate is based upon. We updated average wages used in the proposed rule, which were based upon May 2022 BLS statistics. We most commonly use the mean hourly wage for a Software Developer (Standard Occupational Code: 15–1252), which is $69.50, to measure costs associated with our finalized policies. We have concluded that a 100 percent expenditure on

[514] *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records*

[515] *https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption*

[516] Wesley Barker, Natalya Maisel, Catherine E Strawley, Grace K Israelit, Julia Adler-Milstein, Benjamin Rosner, A national survey of digital health company experiences with electronic health record application programming interfaces, Journal of the American Medical Informatics Association, Volume 31, Issue 4, April 2024, Pages 866–874, *https://doi.org/10.1093/jamia/ocae006*.

[517] BLS. Occupational Employment and Wage Statistics: *https://data.bls.gov/oes/#/industry/000000*.

[518] Nir Menachemi, Saurabh Rahurkar, Christopher A Harle, Joshua R Vest, The benefits of health information exchange: an updated systematic review, Journal of the American Medical Informatics Association, Volume 25, Issue 9, September 2018, Pages 1259–1265, *https://doi.org/10.1093/jamia/ocy035*.

[519] BLS. Occupational Employment and Wage Statistics: *https://data.bls.gov/oes/#/industry/000000*.

benefits and overhead is an appropriate estimate based on research conducted by HHS.[520]

(b) Quantifying the Estimated Number of Health IT Developers and Products

As we described in the HTI–2 proposed rule (89 FR 63498), we do not assume that all developers of certified health IT and their products would be affected by this final rule.[521] We estimate that, in total, 395 health IT developers will certify 520 health IT products impacted by this final rule. These totals reflect revisions from the original proposals, using up to date data. The analysis and models used to estimate the totals remain the same, as proposed.

We received no comments on our quantification of developers and products affected by this final rule.

(c) Number of End Users That Will Be Impacted by ASTP/ONC's Required Regulations

As previously noted in ASTP/ONC rulemaking (89 FR 63667 and 89 FR 63498), for the purpose of this impact analysis, the population of end users impacted are the number of health care providers that possess certified health IT. Due to data limitations, our analysis is based on the number of hospitals and clinicians who participate in Medicare and who may be required to use certified health IT to participate in various CMS programs, inclusive of those providers who received incentive payments to adopt certified health IT as part of the Medicare EHR Incentive Program (now known as the Medicare Promoting Interoperability Program and the Promoting Interoperability performance category under MIPS).

One limitation of this approach is that we are unable to account for the impact of our provisions on users of certified health IT that were ineligible or did not participate in the CMS EHR Incentive Programs or current Medicare programs (*for example,* the Medicare Promoting Interoperability Program). For example, in 2017, 78 percent of home health agencies and 66 percent of skilled nursing facilities reported adopting an EHR.[522] Nearly half of these facilities reported engaging in aspects of health information exchange. However, we are unable to quantify, specifically, the use of certified health IT products among these provider types.

Despite these limitations, these Medicare program participants represent an adequate sample on which to base our estimates. An analysis of the CMS Provider of Services file for Hospitals and CMS National Downloadable File of Doctors and Clinicians provides a current accounting of Medicare-participating hospitals and practice locations.[523] [524] In total, we estimated about 4,800 non-Federal acute care hospitals from the Provider of Services file and 1.25 million clinicians (including doctors and advanced nurse practitioners) across over 350,000 practice locations. If we assume that 96 percent of these hospitals and 80 percent of these practice locations use certified health IT, as survey data estimate, approximately 4,600 hospitals and 283,000 practice locations may face some passed-on costs from these requirements.[525] [526]

As detailed in the Accounting Statement, we estimate the total undiscounted costs to developers of certified health IT over a 10-year period to be $228 million or about $577K per developer of certified health IT (n=395) and $438K per certified health IT product (n=580). Replicating prior modeling work (85 FR 25642 and 89 FR 63667), the average hospital user (n=4,600) of certified health IT is expected to face up to $16,519.00 on average additional costs associated with implementing technology that adopt these policies.[527] The average clinician practice site (n=283,000) will face up to $537.00 on average additional costs associated with implementing technology that adopt these policies.[528] Described in later sections are the quantifiable cost savings to health IT purchasers of these finalized policies and the average pass-through costs from developers of certified health IT to purchasers.

These costs are not expected to be borne at once. Requirements from this finalized rulemaking may be implemented over several years, so in some cases an individual hospital or health IT purchaser's share of pass-through costs from their health IT developer may be distributed over one or more years. We reiterate that some of these costs may have already been incorporated within existing contracts and thus it is possible that the actual additional costs experienced by hospitals and clinicians may be lower than what is estimated. We do not have insights into proprietary contracts between EHR developers and their clients, and thus cannot speculate on the extent to which the estimated additional costs will be passed on to clients.

It is unknown if the estimated cost savings will have the same distribution. A single clinician may not benefit the same as a single hospital, nor will one hospital benefit the same as another. However, given the same constraints to model costs across different provider types, we choose to assume a similar distribution for benefits as we propose for costs.

(d) Comparative Analysis Between Standardized and Non-Standardized Application Programming Interfaces

Standardization, by its nature, enables predictable, programmable methods of communication between IT systems. When a receiving IT system can ingest, parse, and translate a payload from a transmitting IT system, it can do so automatically with little to no manual intervention. Furthermore, when this process is built on common, industry standards the receiving and transmitting IT systems can be built with this interoperability in mind. The receiving system does not have to predict or intuit the payload's form, structure, and purpose, it knows what it is automatically because the receiving and transmitting systems speak the same computer language and share an information payload that conforms to each system's specifications. For example, one health IT product, built with standards-based application programming interface (API) specifications (developed once and deployed enterprise wide) can be connected to another IT system (for example, an app or information database) that supports these same specifications. Each additional connection has a marginal cost, but each is built on the same foundational infrastructure, enabling more connections at lower marginal costs than if configured using non-standards-based APIs.

In the 2015 Edition Final Rule (80 FR 62602), three API criteria were finalized: 45 CFR 170.315(g)(7), (g)(8), and (g)(9). These were the first API criteria adopted by the Certification Program, and we note that they were finalized as ''functional'' criteria that did not require conformance to a specific standard or method, beyond implementing a RESTful API, to respond to a query for a patient record. In that rulemaking, we estimated that building each of these APIs would require on average per product approximately 300 to 400 hours in development time. In the ONC Cures Act Final Rule (85 FR 25642), we finalized the ''standardized API for patient and population services'' criterion in 45 CFR 170.315(g)(10), which replaced the criterion in 45 CFR 170.315(g)(8) and required support for an API using industry standards in place of proprietary methods. We estimated in Table 16 of the ONC Cures Act Final Rule that the effort to replace the functional requirements of the API specified in 45 CFR 170.315(g)(8) and adopt the HL7 Fast Healthcare Interoperability Resources (FHIR) standard specified in the criterion in 45 CFR 170.315(g)(10) would require 1600 to 6000 hours, depending on whether the product already adopted the FHIR standard for its 45 CFR 170.315(g)(8) API (lower bound) or needed to do a complete re-build (upper bound).[529] We also estimated in Table 16 that it would cost 800 to 1500 hours to adopt the Substitutable Medical Applications, Reusable Technologies (SMART) on FHIR App Launch Framework implementation guide, which standardizes the way in which a requesting application that connects to the standardized API securely accesses data from the FHIR

[520] See U.S. Department of Health and Human Services, Office of the Assistant Secretary for Planning and Evaluation (ASPE), Guidelines for Regulatory Impact Analysis, at 28–30 (2016), available at *https://aspe.hhs.gov/reports/guidelines-regulatory-impact-analysis.*

[521] *https://www.federalregister.gov/d/2024-14975/p-2051.*

[522] *https://www.healthit.gov/data/data-briefs/electronic-health-record-adoption-and-interoperability-among-us-skilled-nursing.*

[523] *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/provider-of-services-file-hospital-non-hospital-facilities.*

[524] *https://data.cms.gov/provider-data/dataset/mj5m-pzi6.*

[525] *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

[526] *https://www.healthit.gov/data/quickstats/office-based-physician-electronic-health-record-adoption.*

[527] Formula: [$228m * (⅓)]/4,600.

[528] Formula: [$228m * (⅔)]/283,000.

[529] *https://www.federalregister.gov/d/2020-07419/p-3033.*

server.[530] Together these two standardized approaches to enable patient-level data queries and securely and uniformly respond to those requests amounted to 2400 to 7500 hours of effort or a median of approximately 5,000 hours to replace the functional API with a standards-based API. This is about 15 times the effort of building the functional, non-standardized API, specified in the criterion in 45 CFR 170.315(g)(8) that was finalized in the 2015 Edition Final Rule (80 FR 62602).

This is a meaningful difference in development effort. Why require this larger additional effort to replace an API with no required standards with one that conforms to one or more standards? Standardization promotes more uniform and predictable access and exchange across many different possible exchange partners (or in computer terms, IT system nodes). If a developer is building an API for a specific, non-scalable purpose to achieve a specific proprietary or internal need, customizing it to align with an industry standard may not be feasible or reasonable. Standards, however, permit multiple uses of the API or many possible users of the API. In the case of the 45 CFR 170.315(g)(10) API, standards were adopted to enable broad implementation across hundreds of certified health IT products to enable use and access by hundreds, if not thousands of application (''app'') developers, health care organization innovators, and entrepreneurial health care providers, seeking to use their standardized data access to create novel applications to treat and care for their patients. Prior to the finalization of the ONC Cures Act Final Rule (85 FR 25642), the potential number of applications that could connect to a health IT product were numerous; standardizing the API would lead to more competition and innovation in the market.[531] And, within the context of FHIR APIs, competition and innovation have resulted. Studies as early as 2020 show hundreds of distinct apps connecting to health IT products via standards-based and proprietary APIs, and other later studies show nearly all application developers or digital health companies building their applications and services using the FHIR standard by default given the broad availability of FHIR APIs in the market.[532] [533] Nearly all surveyed companies in the Barker, et al. study reported they were connecting with 2 or more companies and more so if they were FHIR adopters.[534] These findings show that standardization can enable more connections and broaden the reach of technological innovation across the ecosystem of health care apps and technology.

If an app developer can predictably build their app to connect to one health IT product via a FHIR API, the infrastructure they built once can be used to connect to 2, 3, or more health IT products. And for health IT product developers, enabling easier integrations with their EHR or other health IT system can provide more choice to their customers, and can broaden the product and service offerings available through their platform. Services and tools that the health IT product developer could not provide alone can be provisioned through any number of app developers who can connect and integrate with the health IT product, permitting use of the app directly in the health IT product instance. Furthermore, if a health IT product adopts a standardized API, an innovative company working with the health IT product's competitor can connect to the competitor's health IT products as well, without having to build a custom interface to a proprietary, non-standards-based API.

We find that there are large potential savings for a developer of certified health IT if they adopt this standards-based approach. In our model, we assume certain tasks are necessary for an app to connect to and integrate with a health IT product. We also estimate the effort required by a health IT product to support one or many integrations. In Table I.G.12.-01, we list some common tasks necessary to successfully connect an app to a health IT product via an API. We also provide the expected number of hours required to complete each task via a standards-based and non-standards-based API. For a standards-based API, we assume that the app and health IT product both adopt the same standards-based methods to connect via an API, in this case the FHIR and USCDI standards, as adopted in the 45 CFR 170.315(g)(10) certification criterion. We also assume that, even when utilizing a standards-based API, there is still some effort to integrate. However, when both the app and health IT product support the same standards, many of the tasks can be done at less or no additional effort. This is because the app connecting to the health IT product adopts similar API specifications and a similar data model to fetch data elements from the health IT product. Comparing this effort to a scenario where an app must connect via a non-standards-based API, the effort to connect to the non-standards-based API is greater. This is because the health IT product developer must provide greater support (and the app must expend more effort) to review the novel API's documentation; to map how the app records data elements; and to understand how the corresponding health IT product API makes those or similar data elements available. This effort could be considerable (nearly 60 percent of the entire effort) as mapping data elements is an essential task to programmatically query, fetch, and ingest data via an API. Standardizing APIs and standardizing any data exchange process are essential to reduce the effort to do this mapping.

TABLE I.G.12.–01—TIME ON TASK FOR API INTEGRATIONS, NON-STANDARDS-BASED VS. STANDARDS-BASED API

Task	Task details	Via non-standards-based API (hours)	Via standards-based API (hours)
Review API Documentation	Get details on specific workflows to use the API and how to fetch data (data resources and endpoints needed to get specific data elements). Syntax for the API (to be used to incorporate into application code). Process to discover and connect to API endpoints.	40	8
Mapping Data Elements	Map data received (to be ingested) via an API query to the same or similar data elements in the developer's application.	150	0
Authorization	What credentials and how to present them when requesting data via a secure API end-point.	20	0
Registration	Get authorized access to API host's non-public facing tools and API information permitted only after user is verified and trusted.	2	2
Testing	Conduct testing via sandbox or synthetic data to verify successful API connection and data ingestion from host server to developer application.	40	40
Total		252	50

Table I.G.12.–01 shows that it takes about 5 times the effort to connect via a non-standards-based API. However, we also calculated that the base cost to build the infrastructure for the standardized API is nearly 15 times the effort to build a non-

[530] *https://build.fhir.org/ig/HL7/smart-app-launch/*.

[531] Dullabh P, Hovey L, Heaney-Huls K, Rajendran N, Wright A, Sittig DF. Application programming interfaces in health care: findings from a current-state sociotechnical assessment. Appl Clin Inform2020; 11 (1): 59–69.

[532] Barker W, Johnson C. The ecosystem of apps and software integrated with certified health information technology. J Am Med Inform Assoc. 2021 Oct 12;28(11):2379–2384. doi: 10.1093/jamia/ocab171. PMID: 34486675; PMCID: PMC8510286.

[533] Wesley Barker, Natalya Maisel, Catherine E Strawley, Grace K Israelit, Julia Adler-Milstein, Benjamin Rosner, A national survey of digital health company experiences with electronic health record application programming interfaces, *Journal of the American Medical Informatics Association,* Volume 31, Issue 4, April 2024, Pages 866–874, *https://doi.org/10.1093/jamia/ocae006*.

[534] Ibid.

standardized API. How can the standardized API, therefore, be preferred over a non-standardized API if it costs less to do the initial build? The savings are earned as more and more connections between a health IT product and apps are completed. In Table -I.G.12.–02, we compare the costs of building the base API infrastructure for a standards and non-standards-based API, as well as the marginal costs of connecting one or more apps to that health IT product. We find that on average the cost to build the standards-based API infrastructure and complete 24 app integrations would cost about the same as doing so via a non-standards-based API. However, the integration of more apps beyond 24 integrations yields savings, as the incremental costs to connect more apps become more costly via a non-standards-based API than a standards-based API. As the referenced studies and the updated analysis show, there are hundreds of apps (that we know of from public data sources) that currently connect to health IT products with consistent growth year after year.[535]

TABLE I.G.12.–02—COMPARISON OF COSTS TO INTEGRATE APPS WITH A HEALTH IT PRODUCT VIA STANDARDS AND NON-STANDARDS-BASED APIS

	Standards-based		Not standards-based		Differential costs		
	Average hours [1]	Cumulative hours	Average hours	Cumulative hours	Cumulative hour difference	Cumulative hours for all certified API products [2]	Cost difference ($) [3]
Base build	5,000	5,000	350	350	4,650	1,088,100	$151,245,900
1 App	50	5,050	250	600	4,450	1,041,300	144,740,700
10 Apps	500	5,500	2,500	2,850	2,650	620,100	86,193,900
24 Apps [4]	1,200	6,200	6,000	6,350	−150	−35,100	−4,878,900
25 Apps	1,250	6,250	6,250	6,600	−350	−81,900	−11,384,100
50 Apps	2,500	7,500	12,500	12,850	−5,350	−1,251,900	−174,014,100
100 Apps	5,000	10,000	25,000	25,350	−15,350	−3,591,900	−499,274,100

Notes: (1) Average hours are the median of the lower (2,400) and upper (7,500) bound hours calculated for the combined 45 CFR 170.315(g)(10) criterion.
(2) Total = (Cumulative Hour Difference) × (All Certified API Products, n=234).
(3) Total $ = (Cumulative Hours for All Certified API Products) × (Wage Rate Used in this Impact Analysis, $139).
(4) On average, the breakeven point for a certified API product to adopt a standards-based API (versus a non-standards-based API) is 24 apps. Formula: 50x + 5000 = 250x + 350; x = 4650/200; x = 23.25.

The growth in new apps and digital health companies coming on the market and number of integrations between these apps and health IT products demonstrates the effectiveness of adopting industry standards to establish software interoperability and promote competition and innovation in the health care market. Standards-based APIs permit less costly and burdensome connections between certified health IT products and third-party apps and services and enable greater predictability in how a single app or digital service can connect to one or many certified health IT products. This model provides evidence for the likely savings that can accrue to certified health IT and third-party developers alike from the adoption and use of standards-based APIs. We replicate this model in our impact analysis, of adopting standards-based electronic prior authorization APIs to show the value of adopting industry standards versus proprietary, non-standards-based methods of exchange.

b. Revised Electronic Prescribing Certification Criterion

ASTP/ONC finalized updates to the ''electronic prescribing'' certification criterion in 45 CFR 170.315(b)(3) including the incorporation of NCPDP SCRIPT standard version 2023011. These updates include revising the list of required transactions, removing optional transactions, and adoption of several new transactions in light of changes to the NCPDP SCRIPT standard and other relevant considerations, including updated vocabulary standards.

(1) Costs

The required updates to the ''electronic prescribing'' certification criterion include five tasks: (1) incorporate NCPDP SCRIPT Standard Version 2023011 for all required transactions; (2) require the eight Electronic Prior Authorization transactions and the PANotification transaction in alignment with NCPDP SCRIPT standard version 2023011; (3) adopt FDA National Drug Code (NDC) terminology for coded drugs; (4) adopt RxNorm, December 4, 2023, and (5) enable a user to capture race and ethnicity information for a patient when performing the following prescription-related electronic transactions: RxFill; RxChangeRequest, RxChangeResponse; CancelRx; and RxRenewalRequest, RxRenewalResponse. These tasks have their own levels of effort, and these estimates are detailed in Tables I.G.12.–03 and 04 are based on the following assumptions:

- Health IT developers are assumed to use the same labor rates and data modeling approach. Table I.G.12.–03 presents the estimated labor costs per product to support updates. While actual costs may vary across developers, for these purposes, all certified health IT developers are assumed to incur all costs outlined in Table I.G.12.–04.
- 199 products certified by 150 developers will be required to adopt the revised criterion. We estimate that, in total, 395 health IT developers will certify 520 health IT products impacted by this rulemaking. However, not all these developers and products certify to the ''electronic prescribing'' certification criterion and need to meet the proposed requirements. As of the end of 2024, 38 percent of developers and 38 percent of products certified to the ''electronic prescribing'' certification criterion. We applied this modifier to our total developer and product estimate as an overall estimate of the number of developers and products impacted by the proposed modifications to the certification criterion.
- According to the May 2024 Bureau of Labor Statistics (BLS) occupational employment statistics, the mean hourly wage for a Software Developer (Standard Occupational Code: 15–1252) is $69.50.[536] Assumptions include that overhead costs and benefits are equal to 100 percent of pre-tax wages, so the hourly wage including overhead costs is $139.00.
- Although electronic prior authorizations transactions were previously finalized as optional for the ''electronic prescribing'' criterion under the Certification Program, many products support them in practice to comply with Medicare Part D requirements. Certification to the revised criterion still requires effort; however, for products already supporting these transactions, the cost is expected to be lower than initially estimated, as the functionality is not net new and development work is likely already completed. Analysis of public Medicare Quality Payment Program data[537] show that 81 percent of active products certified for electronic prescribing (161 of 199 products impacted by this final rule) are used to report for Promoting Interoperability (PI) performance, while 19 percent (38 of 199 products) are not. The 161 products actively used for PI reporting are also assumed to support electronic prescribing for Medicare Part D, which has required the use of the NCPDP SCRIPT standard version 2017071

[535] *https://www.healthit.gov/sites/default/files/2023-05/Insights%20into%20Data%20Sharing%20between%20EHRs%20and%20Apps%20508.pdf.*

[536] BLS. Occupational Employment and Wage Statistics: *https://data.bls.gov/oes/#/industry/000000.*

[537] *https://data.cms.gov/quality-of-care/quality-payment-program-experience/data.*

and associated PA transactions since 2022 and finalized requirements for the use of the NCPDP SCRIPT standard version 2023011 in the ''Medicare Program; Medicare Prescription Drug Benefit Program; Health Information Technology Standards and Implementation Specifications'' final rule (Part D and Health IT Standards Final Rule) which appeared in the **Federal Register** on June 17, 2024 (89 FR 51238).[538]

The estimated cost burden for the finalized 45 CFR 170.315(b)(3) ''electronic prescribing'' certification criterion has been reduced due to market readiness, policy alignment, and technical efficiencies. Health IT developers are already supporting many of these required functionalities, due to CMS requirements, industry standards, or existing implementations.

Table I.G.12.–03 presents the estimated labor hours per product, by task, based on the assumptions noted previously.

TABLE I.G.12.–03—ESTIMATED LABOR HOURS TO MODIFY 45 CFR 170.315(b)(3) ELECTRONIC PRESCRIBING CERTIFICATION CRITERION

Task	Details	Lower bound hours	Upper bound hours	Remarks
Task 1: NCPDP SCRIPT Standard Version 2023011 for all required transactions.	Update required electronic prescribing transactions from NCPDP SCRIPT Standard Version 2017071 to NCPDP SCRIPT Standard Version 2023011.	200	600	There are no changes related to these transactions between the 2017071 and 2023011 versions of the NCPDP SCRIPT Standard. We expect low implementation effort, similar to prior transitions, where it was estimated in the final rule impact analysis that 50–150 labor hours were required for the 2014 Edition. There, ASTP/ONC finalized requirements to adopt NCPDP SCRIPT Standard Version 10.6 for NewRx (the only required transaction at the time). For this update, the same approach is applied by reducing the level of effort per transaction by half, given the lack of changes, and multiplying across the eight required transactions: New prescription (NewRx); Request and respond to change prescriptions (RxChangeRequest, RxChangeResponse); Request and respond to cancel prescriptions (CancelRx, CancelRxResponse); Request and respond to renew prescriptions (RxRenewalRequest, RxRenewalResponse); Receive fill status notifications (RxFill); Relay acceptance of a transaction back to the sender (Status); Respond that there was a problem with the transaction (Error); and Respond that a transaction requesting a return receipt has been received (Verify). Signatura (Sig) functionality, which was optional in prior rulemaking (including the Cures Update), is embedded within the required NCPDP SCRIPT standard. Developers who previously implemented Sig as part of a certified Health IT Module under prior rulemaking are assumed to face lower development costs related to minor internal configurations and testing to comply with the new requirements.
Task 2a: (i) Electronic Prior Authorization transactions and (ii) new PANotification transaction. *Actively used products already supporting Part D Requirements through PI reporting.*	Electronic Prior Authorization transactions are now required. These were optional under Cures Update regulations. Also, it is now required to implement the transaction, PANotification.	250	500	Products for electronic prescribing being actively used to report for Medicare PI performance are required to conduct electronic prescribing through Part D, which as of 2022, requires the use of the SCRIPT standard and its associated PA transactions. For those products which already support this functionality for Part D prescribers and are affected by this final rule, we estimate the cost for certification for this revised criterion and testing.
Task 2b: (i) Electronic Prior Authorization transactions and (ii) new PANotification transaction. *Products not represented in PI Reporting and may not yet support these transactions.*	Electronic Prior Authorization transactions are now required. These were optional under Cures Update regulations. Also, it is now required to adopt and require transaction, PANotification.	250	3600	In the 2015 Certification Edition, new transactions were required for this criterion. It was estimated that it would require 250–400 labor hours to implement each new transaction. We take a similar approach here with remaining products not represented in PI reporting. Additionally, those who voluntarily adopted the transactions as part of a certified Health IT Module under prior rulemaking will face less development costs to adopt under new requirements.
Task 3: FDA National Drug Code (NDC) terminology for coded drugs.	NDC is required in NCPDP SCRIPT Standard Version 2023011 for coded drugs.	40	80	NDC is already widely adopted and seen as critical for coding drugs. NDC is now a required part of adopting 2023011 but high current adoption should reduce overall effort to implement in certified Health IT Modules.
Task 4: Update to RxNorm December 4, 2023, Full Update Release terminology.	Aligns with more current version of vocabulary standard.	40	80	Vocabulary standard is likely to already be incorporated into fielded technology. Some effort expected to align with updated certification requirements.
Task 5. Race and Ethnicity data for four transactions.	NCPDP standard supports the capability to capture these data for transactions.	40	80	Developers must map to patient's race and ethnicity data and support exchange of these data for four transactions. This requirement does not require capture or transmission by clinicians.

TABLE I.G.12.–04—TOTAL COST TO MODIFY ELECTRONIC PRESCRIBING

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (199 products)	$5,532,200.00	$16,596,600.00
Task 2a (161 products)	5,594,750.00	11,189,500.00
Task 2b (38 products)	1,320,500.00	19,015,200.00

[538] *https://www.federalregister.gov/documents/2024/06/17/2024-12842/medicare-program-medicare-prescription-drug-benefit-program-health-information-technology-standards.*

TABLE I.G.12.–04—TOTAL COST TO MODIFY ELECTRONIC PRESCRIBING—Continued

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 3 (199 products)	1,106,440.00	2,212,880.00
Task 4 (199 products)	1,106,440.00	2,212,880.00
Task 5 (199 products)	1,106,440.00	2,212,880.00
Total (199 products and 150 developers)	15,766,770.00	53,439,940.00

The cost to a health IT developer to make the required modifications to the ''electronic prescribing'' certification criterion for its Health IT Module would range from $79,230 to $268,542.00 per product, on average. Therefore, assuming 199 products overall and a labor rate of $69.50 per hour, we estimate that the total cost to all health IT developers would, on average, range from $15.7 million to $53.4 million.

(2) Cost Savings

As stated previously, the final revised criterion's incorporation of NCPDP SCRIPT standard version 2023011 aligns with Medicare Part D requirements for sponsors and prescribers. Standards alignment is crucial to ensure interoperability between IT systems. Alignment with regulatory requirements is also crucial to ensure that technology used to support electronic prescribing for Part D prescribers adopts and uses standards in similar ways to avoid additional costs to developers and their end users to support multiple methods to electronically prescribe. Regulatory alignment ensures that the products used by Medicare clinicians to participate in Promoting Interoperability and to prescribe medications via Part D use the same standards and function in the same way. This eliminates redundancies and reduces inefficiencies in how certified technology is updated to meet multiple, overlapping federal regulations.

(3) Benefits

The updates to the ''electronic prescribing'' certification criterion at 45 CFR 170.315(b)(3) align the criterion with the NCPDP SCRIPT Standard Version 2023011, enhancing interoperability, clarity, and efficiency across electronic prescribing transactions. These changes support federal policy goals to empower patients with information, improve patient safety, improve transparency, and reduce regulatory burden through automation and standardization. Adoption of updated code sets and structured data fields, including Sig, ePA transactions, RxNorm, and NDC terminology for coding drugs, and the capability of health IT developers to capture patient information will support consistent, high-value clinical workflows and more effective communication with pharmacy systems.

For Task 1, this alignment is in step with a reciprocal Medicare Part D requirement for Part D sponsors, prescribers, and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, to use a standard in 45 CFR 170.205(b), which includes the NCPDP SCRIPT standard version 2023011, for all required and optional electronic prescribing transactions. NCPDP SCRIPT standard version 2023011 includes important updates to terminology standards, transactions, and other data elements. Moreover, the adoption through rulemaking of a new NCPDP SCRIPT standard version and corresponding updates to the certification criterion for ''electronic prescribing'' align with public feedback and consensus on how to ensure these transactions and the ''electronic prescribing'' certification criterion are advancing interoperability.

In addition, communicating how a prescriber intends for a patient to take a medication is critical for safe and effective care. Standardizing prescription directions via the codified and structured Sig format has the potential to reduce medication errors and improve patient care. These instructions are essential for accurate prescription labeling, appropriate patient counseling and education from a pharmacist, and optimal medication use. The industry has been slow to adopt structured and codified Sig functionality, with unstructured free text Sig directions still the most commonly used format. The wide variation in unstructured Sig limits the clarity, utility, and reusability of the data, therefore diminishing the potential impact on patient safety and clinical outcomes. Sig is also an important factor in a provider's capacity to follow the CDC Guideline for Prescribing Opioids for Chronic Pain, especially in cases where the provider lacks information about days' supply, but still seeks to calculate quality improvement opioid measures as part of a larger strategy to support careful and selective use of long-term opioid therapy in the context of managing chronic pain.[539] Implementation of the structured and codified Sig format in electronic prescribing has shown measurable benefits, including more complete details.[540] The Sig requirement provides greater clarity, utility, and reusability of the data, moving from an unstructured free text Sig to a structured and codified functionality.[541]

For Task 2, comments submitted in response to ASTP/ONC's ''Request for Information: Electronic Prior Authorization Standards, Implementation Specifications, and Certification Criteria,'' published on January 24, 2022 (87 FR 3475), emphasized that requiring prior authorization transactions would advance interoperability and reduce administrative burden related to medication prior authorization processes. These transactions also help to streamline prescription workflows, improve patient safety, and support capabilities to address transparency and affordability gaps. Making these transactions mandatory will help ensure that pharmacy data systems can communicate consistently across all Health IT Modules certified to this criterion, eliminating the need to build different workflows for different systems. This requirement aligns with Medicare Part D, aligning certification requirements with broader federal healthcare policy (89 FR 51238).

For Task 3, National Drug Codes (NDC) is critical for specific product identification in research, dispensing, and administrative workflows. NDC is the key, unique product identifier and is the standard of practice used throughout the pharmacy industry to identify the specific product. The pharmacy industry heavily relies on NDC in all aspects of its business, including, but not limited to, drug ordering, medication dispensing, reporting, billing, rebates, adverse event reporting, and patient safety. In NCPDP SCRIPT standard version 2023011, NDC is required for coded drugs in the standard. NDC is also adopted as a medical data code set for reporting drugs and biologics on retail pharmacy claims under the HIPAA Transaction and Code Set rule.[542] The requirement of NDC is expected to ensure greater interoperability with pharmacy data systems and facilitate correct identification of prescribed products.

For Task 4, updating Health IT Modules to use up-to-date versions of the RxNorm code set version is important for interoperability. Currently, modules certified to this certification criterion align with a prior RxNorm version; this new requirement transitions to a new baseline version, which will ensure Health IT Modules certified to this certification criterion are required to comply with a consistent baseline for these codes and can communicate with pharmacy data systems more effectively. This requirement promotes standardized

[539] Overdose Prevention. Overdose Prevention | Overdose Prevention | CDC.

[540] Implementation outcomes of the Structured and Codified SIG format in electronic prescription directions. Implementation outcomes of the Structured and Codified SIG format in electronic prescription directions | Journal of the American Medical Informatics Association | Oxford Academic.

[541] A Prescription for Enhancing Prescribing Safety. A Prescription For Enhancing Electronic Prescribing Safety.

[542] HIPAA Transaction and Code Set *https://www.ecfr.gov/current/title-45/section-162.1002#p-162.1002(a)(3)*

terminology across systems, reduces ambiguity in medication-related data exchange, and supports more accurate prescribing and dispensing.

For Task 5, Health IT Modules certified to the ''electronic prescribing'' criterion now must enable users to exchange a patient's race and ethnicity data when conducting the following four transactions: RxFill; RxChangeRequest/Response; CancelRx; and RxRenewalRequest/Response. While the NCPDP SCRIPT standard version 2023011 currently supports exchange of these data as an optional feature, this requirement would ensure consistent support across certified health IT. This requirement for developers will help support improved interoperability and data consistency.

The resulting improvements to interoperable exchange of health information will significantly benefit prescribers, pharmacists, payers, and patients and improve the quality of health care provided. These requirements align with a reciprocal Medicare Part D requirement in the Part D and Health IT Standards Final Rule for Part D sponsors, prescribers, and dispensers, when electronically transmitting prescriptions and prescription-related information for covered Part D drugs for Part D eligible individuals, to use a standard in 45 CFR 170.205(b), which includes the NCPDP SCRIPT standard version 2023011. Prescribers, pharmacists, and payers will benefit from the updates to the standards and to the certification criterion through increased standardization and interoperability of electronic prescribing.

c. New Real-Time Prescription Benefit Certification Criterion

(1) Background

We finalized a ''real-time prescription benefit'' certification criterion in 45 CFR 170.315(b)(4) based on the NCPDP Real-Time Prescription Benefit (RTPB) standard version 13. We also finalized inclusion of this certification criterion in the Base EHR definition in 45 CFR 170.102. We believe the ''real-time prescription benefit'' certification criterion will increase the use of real-time prescription benefit tools; reduce the costs and complexity of using these tools; and increase competition between vendors, promoting widespread adoption of more effective real-time prescription benefit tools, and helping to lower drug costs for Medicare beneficiaries. Use of real-time prescription benefit tools enables Medicare providers and enrollees to make cost-informed decisions about prescriptions, and a standardized approach will ensure that critical drug and drug price data is available to providers when they need it.

The final certification criterion includes the following standards and functional requirements:

- Incorporate the NCPDP RTPB standard version 13 and vocabulary standards, RxNorm (45 CFR 170.207(d)(1)) and National Drug Codes (45 CFR 170.207(d)(2)), to enable a user to send and receive patient-specific benefit information, estimated cost information, and product alternatives within the workflow at the point of care, specifically standard transactions:
- Transaction segments and associated data elements for RTPBRequests and RTPBResponse transactions;
- Error transaction or RTPBResponse reject code; and
- Exclusive use of XML format for all transactions.

NCPDP RTPB standard version 13 permits the use of the EDI or XML format for payloads. We have finalized that a Health IT module certified to the certification criterion must enable a user to perform the specified NCPDP RTPB standard version 13 transactions using the XML format. ASTP/ONC similarly requires that a Health IT Module certified to the ''electronic prescribing'' certification criterion, which uses the NCPDP SCRIPT standard, use the XML format for payloads. In public comments on ASTP/ONC's RFI on Pharmacy Interoperability in the HTI–1 Proposed Rule (88 FR 23848) and on ASTP/ONC's HTI–2 proposed rule (89 FR 63498), there was broad support for use of XML. We do not estimate additional costs to developers to exclusively use XML to implement this certification criterion, as it is broadly supported and required as part of the functionally similar ''electronic prescribing'' certification criterion. The ''real-time prescription benefit'' certification criterion also requires use of NCPDP RTPB standard version 13 to send and receive patient-specific benefit, estimated cost information, and product alternatives. We do not estimate additional costs to developers to implement the standard and certification criterion in this manner.

(2) Costs

We estimate costs to certified health IT developers to incorporate the NCPDP RTPB standard version 13 and vocabulary standards, RxNorm (45 CFR 170.207(d)(1)) and National Drug Codes (45 CFR 170.207(d)(2)) to send and receive transaction segments and associated data elements for RTPBRequest and RTPBResponse transactions and the Error transaction.

We have updated estimated effort for these tasks from the proposed rule. While the effort per developer and product remains constant, we have updated assumptions about the number of products that will be impacted by this criterion. Levels of effort are detailed in Tables I.G.12.–05 and 06 and are based on the following assumptions:

- Health IT developers will use the same labor costs and data models. Table I.G.12.–05 shows the estimated labor costs per product to develop the certification criterion. We recognize that health IT developer costs will vary; however, our estimates in this section assume all health IT developers will incur the costs noted in Table I.G.12.–06.
- We estimate that 199 products certified by 150 developers will certify to the ''real-time prescription benefit'' criterion. This estimate represents a subset of the total number of estimated health IT developers and certified products we estimated previously.

The estimate of 199 products certified by 150 developers is derived as follows. We estimate that, in total, 395 health IT developers will certify 520 health IT products impacted by this final rule. The final rule requires Health IT Modules certified to the ''electronic prescribing'' certification criterion to certify to the finalized ''real-time prescription benefit'' certification criterion. We therefore use the estimated number of developers and products that certify to the ''electronic prescribing'' certification criterion as a proxy for the expected number of developers and products that will certify the proposed ''real-time prescription benefit'' certification criterion. As of the end of 2024, 38 percent of developers and 38 percent of products were certified to the ''electronic prescribing'' certification criterion. We applied this modifier to our total developer and product estimate as an overall estimate of the number of developers and products impacted by the proposed certification criterion.

- In this final rule, we estimate that 50 percent of the products that will certify to the ''real-time prescription benefit'' criterion in 45 CFR 170.315(b)(4) have already implemented functionality supporting the NCPDP RTPB standard version 13 or will incur de minimis costs that would meet the certification criteria. This assumption differs from the proposed rule and is based on several factors.

First, industry has had substantial time and incentive to implement the NCPDP RTPB standard. The standard was published in 2021, allowing several years for industry uptake by January 1, 2028, when the certification criterion will be added to the Base EHR definition. Similarly, CMS requirements for Part D plan sponsors to support the standard were finalized at 42 CFR 423.160(b)(5) with requirements beginning January 1, 2027, so that developers of certified health IT will have additional incentive to begin supporting the standard regardless of the inclusion of the ''real-time prescription benefit'' criterion in the Certification Program. Given the timing of the finalization of those requirements for Part D plan sponsors and the publication of the HTI–2 Proposed Rule, we were not able to account for its impact on developer behaviors.

Second, published reports indicate wide adoption of real-time prescription benefit capabilities. ASTP/ONC analysis of the 2023 American Hospital Association Health Information Technology Supplement indicated that more than half (56.2 percent) of non-federal, acute care hospitals have implemented EHR functionality that integrates health insurer real-time prescription benefit information for all or nearly all payers; another 15.8 percent have implemented such a functionality for a limited set of payers; 17.7 percent have not implemented the functionality; and 10.3 percent of respondents did not know if they had implemented such a system.[543] Additional data from 2020 indicated that approximately 20 percent of physicians had access to real-time prescription benefit information. Similarly, according to one source, as of the end of 2022, 98 percent of U.S. prescribers were served by EHRs with

[543] *https://www.healthit.gov/data/quickstats/hospital-adoption-real-time-benefit-tools.*

access to an available real-time prescription benefit tool, and over half of prescribers used real-time prescription benefit to access medication pricing.[544] We believe a substantial portion of those EHRs supported the NCPDP RTPB standard.

Third, our market research found multiple tools available in the marketplace from health IT software vendors; health plans; and pharmacy benefit managers (PBMs) indicating that there is choice in the market for these tools.[545] [546] [547] [548] [549] Conversations with EHR market leaders, indicated that there is variation in adoption and implementation: some have deployed their own tools; some depend on third-party developers to provide these services; and others do not currently deploy a tool to their customers. There is also mixed adoption and perspectives on standard approaches to develop and deploy these tools, with some developers currently supporting the NCPDP RTPB standard, some being supportive of tools using the NCPDP RTPB standard, and others agnostic.

Finally, in requiring that Part D plan sponsors implement RTBTs compliant with the NCPDP RTPB standard version 13, CMS stated in the Part D and Health IT Standards Final Rule that ''because Part D sponsors have invested in the hardware, software, and connectivity necessary to utilize RTBTs, we believe that adopting the NCPDP RTPB standard version 13 will impose de minimis cost on the industry and that costs will be largely offset by the advantages and efficiencies associated with interoperability that a standard brings. CMS does not require prescribers to utilize RTBTs, but for prescribers who do utilize RTBTs, we believe that the burden associated with using an RTBT that does not use a standard will be the same as using an RTBT that uses NCPDP RTPB standard version 13'' (89 FR 51262). Similarly, it is likely that many certified health IT products offer RTBT capabilities to support physician and hospital access to real-time prescription benefit information and leverage the NCPDP RTPB standard. We believe this implies de minimis costs to these developers to complete the certification criterion for those products. In this final rule, we therefore assume that, of the 199 products using electronic prescribing, only 100 will incur costs.

- According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $69.50.[550] As noted previously, we have assumed that overhead costs (including benefits) are equal to 100 percent of pre-tax wages, so the hourly wage including overhead costs is $139.00.

TABLE I.G.12.–05—ESTIMATED LABOR HOURS TO DEVELOP REAL-TIME PRESCRIPTION BENEFIT CERTIFICATION CRITERION IN 45 CFR 170.315(B)(4)

Task	Details	Lower bound hours	Upper bound hours	Remarks
Task 1: NCPDP Real-Time Prescription Benefit (RTPB) standard version 13 and all associated transactions.	Transactions include RTPBRequests, RTPBResponse. Requests include 6 transaction segments and Response includes 5 segments..	500	1,000	For the 2015 Edition of health IT certification criteria, new transactions were added to the ''electronic prescribing'' criterion. It was estimated that it would require 250–400 labor hours to implement each new transaction. We take a similar approach here.
Task 2: RxNorm vocabulary standard for relevant transaction segments and associated data elements.	.....	40	80	RxNorm is widely implemented and is a required vocabulary standard for ''electronic rescribing''. Mapping using these codes should create little extra effort to implement in certified Health IT Modules.
Task 3: National Drug Codes vocabulary standard for transaction segments and associated data elements.	.....	40	80	NDC is widely implemented and seen as critical for coding drugs. NDC is now a required part of implementing the NCPDP SCRIPT standard as well as the RTPB standard. Mapping using these codes should create little extra effort to implement in certified Health IT Modules.

TABLE I.G.12.–06—TOTAL COST TO DEVELOP REAL-TIME PRESCRIPTION BENEFIT CERTIFICATION CRITERION

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (100 products)	$6,950,000	$13,900,000
Task 2 (100 products)	556,000	1,112,000
Task 3 (100 products)	556,000	1,112,000
Total (100 products)	8,062,000	16,124000

The cost to a health IT developer to develop a Health IT Module certified to the ''real-time prescription benefit'' criterion ranges from $80,620 to $161,240 per product, on average. Therefore, assuming 100 products, we estimate that the total cost to all health IT developers would, on average, range from $8.1 million to $16.1 million. This would be a one-time cost to developers per product that is certified to the specified certification criterion. We acknowledge that these costs may be passed from health IT developers to their customers (*that is,* health care providers) during the licensing of their health IT modules. We cannot calculate the per entity costs for health care providers, because we do not know the exact number of health care providers who will be affect or the extent to which costs will be passed on from developers to providers rather than borne by developers. We expect that health care providers who currently do *not* have access to an EHR with an RTBT that meets the NCPDP standard version 13 will be disproportionately affected, as these EHRs will bear the brunt of the development costs.

[544] *https://surescripts.widen.net/s/mvtqvvf5sd/2022-national-progress-report#page=1.*

[545] *https://surescripts.com/who-we-serve/ehr-vendors.*

[546] *https://arrivehealth.com/wp-content/uploads/2022/11/Arrive-Health-Physician-Insights-Whats-Needed-to-Improve-Prescribing-Workflows.pdf.*

[547] *https://www.optum.com/content/dam/optum4/resources/pdf/wf2167397_pcs_improving_prescribing_process.pdf.*

[548] *https://www.humana.com/provider/pharmacy-resources/tools/real-time-benefit-tool#:~:text=Real%2DTime%20Benefit%20Check%20(RTBC,your%20electronic%20medical%20record%20representative.*

[549] *https://www.express-scripts.com/corporate/articles/scriptvision-gives-physicians-real-time-access-patient-specific-information.*

[550] *https://data.bls.gov/oes/#/industry/000000.*

(2) Cost Savings

As stated previously, the final revised criterion incorporates the adopted NCPDP RTPB standard version 13 specified in Medicare Part D requirements. Standards alignment is crucial to ensure interoperability between IT systems. Alignment across regulatory requirements is also crucial to ensure that technology used to support electronic prescribing for Part D prescribers implements and uses standards for real-time prescription benefit in similar ways to avoid additional costs to developers and their end users. This eliminates redundancies and reduces inefficiencies in how certified technology is updated to meet multiple related federal regulations.

In 2019, CMS finalized in the ''Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses'' final rule (84 FR 23832) that Part D plan sponsors must make a real-time benefit tool (RTBT) available to prescribers. Then in 2024, CMS and ASTP/ONC released the Part D and Health IT Standards Final Rule (89 FR 51238) which adopted the NCPDP RTPB standard version 13 and finalized that RTBTs established by Part D plan sponsors must conform to that standard by January 1, 2027. The certification criterion finalized at 45 CFR 170.315(b)(4) will incorporate published, adopted standards and functional requirements by January 2028, thus promoting interoperability between certified health IT, plans, and PBMs, and helping to deliver on the promising benefits of the real-time ability of providers and their patients to make informed choices about medication costs.

Benefits for providers, patients, PBMs, and technology developers from this criterion are likely to manifest via multiple pathways. The finalized criterion is likely to result in greater implementation and uptake of RTBTs, and tool implementation can reduce time and effort and improve the accuracy of information, lead to reduced prescription costs for patients and payers, improve medication adherence, and generate other downstream benefits. However, data are not available to estimate the increase in use of RTBTs resulting from finalization of this policy or the resulting benefit to patients. Therefore, we have updated our qualitative description of the benefits from this criterion based on available evidence, some of which was published between the publication of the HTI–2 Proposed Rule and this final rule.

We anticipate that provider organizations and healthcare professionals will benefit from the finalization of real-time prescription benefit provisions in the final rule in several ways:

- Among the 34.1 percent of hospitals responding to the American Hospital Association Health Information Technology Supplement survey that had not implemented EHR functionality integrating real-time prescription benefit information, many were smaller hospitals located in rural areas.[551] Additionally, many provider groups that are not affiliated with hospitals likely have not yet implemented any real-time prescription benefit functionality in their EHRs. Finalization of this criterion and inclusion in the Base EHR definition will ensure that real-time prescription benefit information is available for more practices and hospitals that use certified health IT.
- Interviews with providers as well as comments on the HTI–2 Proposed Rule from provider organizations reveal that while providers appreciate the current access to RTBTs, they experience inaccurate cost estimates and inappropriate product alternatives. Providers may avoid using RTBTs due to concerns that inaccuracies will increase their administrative burden and time burden. We expect that regulations requiring that Part D sponsors, PBMs, and certified health IT developers meet RTPB standards will improve the accuracy of the information, thereby increasing trust in and utilization of RTBTs by providers.
- Greater provider use of tools leveraging the NCPDP RTPB standard version 13 due to the final rule may result in prescribers providing more informed choices to their patients and increased efficiencies in prescribing and approving products. Several commenters to on the proposed rule noted that addressing cost and coverage in real-time during the clinical encounter may reduce the frequency of post-visit telephone calls and administrative burden related to utilization management. In a survey of providers commissioned by an RTBT, a majority of respondents stated they need to change or manage a prescription order more than 25 percent of the time after it has been sent to the pharmacy.[552] When one research hospital's health system implemented their RTBT, researchers were able to guide prescribers to choose alternatives without prior authorization requirements, convert from drugs covered with restrictions, and/or to convert from drugs not covered to one covered with restrictions.[553] Upfront coverage information may also steer providers toward medications that do not require prior authorization when clinically appropriate, thus further reducing paperwork, phone calls, and overall administrative burden. One industry-led study estimates that when clinicians switched to medications that did not require prior authorization, they saved up to 50 minutes on prior authorization requests and denials.[554]
- ASTP/ONC has heard reports that healthcare organizations currently need to contract with multiple PBMs or RTBT vendors that each uses its own proprietary data exchange/API to obtain cost, coverage, and product alternative information for their patient population. This creates financial and administrative burden for healthcare organizations related to contracting with each party and maintaining each system. By requiring that certified health IT certified to 45 CFR 170.315(b)(4) support the same standard as PBMs, this final rule will reduce barriers to universal access to price information, resulting in lower burden on healthcare organizations. With information more readily available, RTBT developers may pivot to competing on features and functionality rather than access to specific Part D plan sponsors.

We anticipate that patients will benefit from the finalization of real-time prescription benefit provisions in several ways:

We expect that finalization of the new certification criterion and its inclusion in the Base EHR definition will increase the availability of RTBTs that support the NCPDP RTPB standard. As a result, more prescribers will have broader access to more accurate price information. Research shows that patients benefit from RTBTs in several ways, and broader access to real-time prescription benefit information will multiply these benefits. Benefits to patients include:

- Increased treatment adherence: Studies have shown that patients who pay less for their medications overall have higher rates of medication adherence. A review of interventions to improve medication adherence found that reducing out-of-pocket costs to patients can be an effective mechanism.[555] Consistent with this, ASTP/ONC-affiliated researchers conducted a survey of respondents 65 and older, finding that 20.2 percent reported cost-related medication non-adherence—most often delaying prescription fills, not filling prescriptions, or skipping doses.[556] Reducing prescription copays and formulary decision support have previously been shown to improve medication adherence,[557] [558] suggesting that RTBTs may also be a useful mechanism. One retrospective study appears to support this, finding that prescriptions placed using RTBTs were associated with a higher fill rate (79.8 percent vs. 71.7 percent) and lower cancellation rate (9.3 percent vs. 14.9 percent).[559]
- Lower out-of-pocket costs: In a cluster-randomized trial comparing clinics with versus without access to an RTBT, patients saved $28 per month on medications that had an available lower-cost alternative. Savings were even higher (up to $100 per month) for medications with the highest out-of-pocket costs.[560] So far, no studies have evaluated the impact of RTBT use on cost of or access to medical supplies, but there is a strong potential for savings. One study estimated that patients with diabetes may spend up to $2,700 per year on glucose monitoring supplies alone, including glucometers,

[551] *https://jamanetwork.com/journals/jama-health-forum/fullarticle/2824904.*

[552] *https://arrivehealth.com/wp-content/uploads/2022/11/Arrive-Health-Physician-Insights-Whats-Needed-to-Improve-Prescribing-Workflows.pdf.*

[553] *https://ncpdpfoundation.org/pdf/NCPDPFoundationRTPBGrant_FinalReport.pdf.*

[554] *https://www.optum.com/content/dam/optum4/resources/pdf/wf2167397_pcs_improving_prescribing_process.pdf.*

[555] *https://www.acpjournals.org/doi/10.7326/0003-4819-157-11-201212040-00538.*

[556] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012.*

[557] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/409766.*

[558] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/773454.*

[559] *https://www.sciencedirect.com/science/article/abs/pii/S0002934322005289?via%3Dihub* via *https://link.springer.com/article/10.1007/s11606-022-07945-z.*

[560] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2796059.*

lancets, test strips, and insulin syringes or pen needles.[561]

• Increased consideration of financial tradeoffs in medical decision-making: An ASTP/ONC-affiliated research review notes that 86 percent of providers believe that cost should influence treatment decisions, but barriers to cost conversations include physicians' knowledge of patients' cost burdens and lack of information about insurance coverage and prices. In one study of 889 primary care providers and 137,860 medication orders, prescribers changed their medication order 12 percent of the time after viewing an RTBT cost estimate and lower-cost alternative.[562] Prescribers were more likely to change their medication order if the potential cost savings were higher. Another retrospective study found that prescribers adjusted the days' supply of their prescriptions in 44 percent of cases and adjusted quantity (for example, of pills or tablets) in 69 percent of cases, in response to an RTBT's suggestion.[563] Another study, however, did not find changes in the frequency of 90-day supply prescriptions after RTBT use.[564] These early findings suggest that once providers see an RTBT cost estimate, they consider cost in their medical decision-making.

Similarly, work by ASTP/ONC-affiliated researchers has highlighted the desire of patients to have conversations about costs with their prescribers. In one survey, the majority of respondents (79.3 percent) expressed a desire to speak to their physician about the cost of all or some of their medications, with respondents who reported cost-related non-adherence more likely to want to speak with their physician.[565] 89.5 percent of respondents indicated a desire for physicians to use real-time benefit tools and 89.8 percent indicated a desire to discuss the estimated prices, with greater interest among those with any cost-related nonadherence.[566] Similarly, in focus groups with patients, most indicated a desire for physicians to use real-time benefit tools and discuss the estimated prices, with greater interest among those with cost-related nonadherence.[567] While other tools such as formulary guides exist that can help facilitate cost conversations and lead to savings, that information is not real-time and may not be up to date,[568] and patients may lose confidence in estimates or their providers if the provided information proves to be wrong.[569] Interviews with providers reveal that access to RTBTs has made them more aware of the cost-related barriers to care that patients face and has made them more willing to discuss costs and consider costs in medical decisions.

We anticipate that Medicare Part D plan sponsors and PBMs will benefit from the finalization of the ''real-time prescription benefit'' criterion and related standards. Medicare Part D plan sponsors are required to implement the NCPDP RTPB standard version 13 by January 1, 2027. By including the ''real-time prescription benefit'' certification criterion in the Base EHR definition, certified health IT used by almost all hospitals and most office-based physicians will support the standard. As a result, PBMs will be able to provide cost and coverage information in a format that EHRs certified to the criterion will be able to consume reducing the need for proprietary or specific APIs. We expect that this will reduce the overall development work required to support sharing of real-time prescription benefit information.

We anticipate that developers of certified health IT will benefit from the finalization of the ''real-time prescription benefit'' criterion and related standards in several ways. Rather than develop proprietary interfaces to integrate with multiple RTPB vendors or PBMs, developers of certified health IT will be able to focus on implementing the standardized approach. Given requirements for Medicare Part D plans to support the NCPDP RTPB standard, health IT products certified to 45 CFR 170.315(b)(4) will be able to access prescription benefit information from all Part D plans. We expect that this will reduce the overall development work required to support broad exchange of prescription benefit information across plans.

The cost savings of these modifications are not quantifiable at this time, but we expect the resulting improvements to interoperable exchange of health information to provide significant benefits. Data show that RTBTs are available to nearly all US prescribers through prescribers' EHRs, though only half use the tool itself.[570] The proposed ''real-time prescription benefit'' certification criterion would standardize tools across all EHRs certified to the criterion and establish a baseline of functionality. This may increase use, but the data show the certification criterion may have a negligible effect on the availability of the tools.

Comment: We received no comments regarding the impact analysis of the real-time prescription benefit provisions.

Response: The final impact analysis is consistent with the proposed rule and updates costs based on information on the number of products that are likely to require new functionality. Cost estimates were updated to reflect wages of software developers as of 2024.

d. New Electronic Prior Authorization Certification Criteria

We have finalized a set of certification criteria to enable API-based electronic prior authorization for providers in 45 CFR 170.315(g)(31) through (33) that aim to complement and advance the policies that CMS has developed to increase patient, provider, and payer access to information. If health IT developers (including those that support payers or are part of a payer) were to seek testing and certification to these finalized certification criteria, we believe that they would be better positioned to support more effective exchange of prior authorization information. Further, this would help ensure that technology used to satisfy the reciprocal CMS requirements has been tested for conformance with widely available industry standards designed to support interoperability for each use case. These finalized certification criteria reference a set of API implementation specifications based upon the HL7® FHIR® standard. The new certification criteria also incorporate FHIR capabilities finalized in 45 CFR 170.315(j).

The finalized certification criteria would enable users of certified health IT to utilize APIs established under CMS API requirements for the Prior Authorization API (87 FR 76285). These criteria could further enable providers to successfully complete the Electronic Prior Authorization measures finalized by CMS for the Medicare Promoting Interoperability Program and the MIPS Promoting Interoperability performance category. We finalize to adopt and reference CMS-recommended implementation specifications for electronic prior authorization within the certification criteria.

(1) Costs

The new certification criteria are as follows:

• 45 CFR 170.315(g)(31) Provider prior authorization API—coverage requirements discovery.

• 45 CFR 170.315(g)(32) Provider prior authorization API—documentation templates and rules.

• 45 CFR 170.315(g)(33) Provider prior authorization API—prior authorization support.

Certification criteria (g)(31), (g)(32), and (g)(33) adopt and reference the same recommended implementation specifications that CMS identified in the Interoperability and Prior Authorization Final Rule (FR 8945). The certification criteria provide a predictable and transparent method for health IT developers to test and certify health IT modules that meet the implementation specifications identified by CMS, providing developers seeking to support customers that seek to utilize API meeting CMS requirements a way to demonstrate conformance to their users. Certification criteria (g)(31), (g)(32), and (g)(33) enable bi-directional exchange and transfer of data between payer systems (who must meet CMS API requirements) and provider systems who receive information from payer systems to inform patient care and facilitate prior

[561] *https://www.goodrx.com/conditions/diabetes/true-cost-of-diabetes?srsltid=AfmBOopd8-vmB-6TlpDZ1f34I1HxaavmKy-yyhauZ6PxHbFD1qyxmfdY.*

[562] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2809102.*

[563] *https://www.ajmc.com/view/implementation-and-cost-validation-of-a-real-time-benefit-tool.*

[564] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2796059.*

[565] Dusetzina, Stacie B., et al. ''Cost-related medication nonadherence and desire for medication cost information among adults aged 65 years and older in the US in 2022.'' *JAMA Network Open* 6.5 (2023): e2314211–e2314211. *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012.*

[566] Ibid.

[567] Mattingly, T. Joseph, et al. '' ''Worth it if you could afford it'': Patient perspectives on integrating real-time benefit tools into drug cost conversations.'' *Journal of the American Geriatrics Society* 71.5 (2023): 1627–1637. *https://agsjournals.onlinelibrary.wiley.com/doi/abs/10.1111/jgs.18226.*

[568] *https://councilreports.ama-assn.org/councilreports/downloadreport?uri=/councilreports/n21_cms_report_2.pdf.*

[569] *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2805012.*

[570] *https://surescripts.widen.net/s/mvtqvvf5sd/2022-national-progress-report#page=1.*

authorization. These certification criteria do not implement CMS finalized API requirements (which only affect payer systems), but the criteria can further enable interoperability between payer and provider systems if adopted by health IT developers.

The finalized certification criteria: ''provider prior authorization API—coverage requirements discovery,'' ''provider prior authorization API—documentation templates and rules'', and ''provider prior authorization API—prior authorization support'' have their own level of effort and these estimates are detailed in Tables I.G.12.- 07A, 08A, and 09A and are based on the following assumptions:

- Health IT developers will use the same labor costs and data models. Tables I.G.12.- 05A, 05B, and 05C show the estimated labor costs per product to develop ''provider prior authorization API—coverage requirements discovery,'' ''provider prior authorization API—documentation templates and rules'', and ''provider prior authorization API—prior authorization support'' criteria. We recognize that health IT developer costs will vary; however, our estimates in this section assume all health IT developers will incur the costs noted in Tables I.G.12.- 07B, I.G.12.- 08B, and I.G.12.- 09B.
- We estimate that 234 products certified by 189 developers will be affected by our proposal. These estimates are a subset of the total estimated health IT developers and certified products we estimated previously. The estimate of 234 products certified by 189 developers is derived as follows. We estimate that, in total, 395 health IT developers will certify 520 health IT products impacted by this final rule. However, not all of these developers and products will certify these new criteria. As of the end of 2024, 48 percent of developers and 45 percent of products certified to the ''standardized API criterion for patient and population services'' certification criterion. We applied this modifier to our total developer and product estimate as an overall estimate of the number of developers and products impacted by these finalized certification criteria.
- According to the May 2024 BLS occupational employment statistics, the mean hourly wage for a ''Software Developer'' is $69.50. As noted previously, we have assumed that overhead costs (including benefits) are equal to 100 percent of pre-tax wages, so the hourly wage including overhead costs is $139.

TABLE I.G.12.–07A—ESTIMATED LABOR HOURS TO DEVELOP 45 CFR 170.315(G)(31) PRIOR AUTHORIZATION API—COVERAGE REQUIREMENTS DISCOVERY

Task	Details	Lower bound hours	Upper bound hours
Task 1: HL7 FHIR Da Vinci—Coverage Requirements Discovery (CRD) Implementation Guide: Version STU 2.0.1—STU 2.	Support the request and exchange of information that supports the identification of coverage requirements.	500	1,000
Task 2: HL7 CDS Hooks FHIR Implementation Guide version 2.0.		0	1,000
Task 3: Support for ''order-sign'' hook		75	150

Notes: The lower and upper bound hours estimated to complete each task are estimates of labor hours required for each product.

TABLE I.G.12.—07B—TOTAL COST TO DEVELOP 45 CFR 170.315(G)(31)

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (234 products)	$16,263,000	32,526,000
Task 2 (234 products)	0	32,526,000
Task 3 (234 products)	2,439,450	4,878,900
Total (234 products and 189 developers)	18,702,450	69,930,900
Total (1 product and 1 developer)	79,925	298,850

TABLE I.G.12.–08A—ESTIMATED LABOR HOURS TO DEVELOP 45 CFR 170.315(G)(32) PRIOR AUTHORIZATION API—DOCUMENTATION TEMPLATES AND RULES

Task	Details	Lower bound hours	Upper bound hours
Task 1: HL7 FHIR Da Vinci—Documentation Templates and Rules (DTR) Implementation Guide: Version STU 2.0.1—STU 2	Support ''Full DTR EHR'' ability to exchange and execute rules to ensure that prior authorization documentation requirements are met	500	1,000
Task 2: Support for the SMART App Launch Framework ''confidential app'' profile		0	80

Notes: The lower and upper bound hours estimated to complete each task are estimates of labor hours required for each product.

TABLE I.G.12.–08B—TOTAL COST TO DEVELOP 45 CFR 170.315(G)(32)

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (234 products)	$16,263,000	$32,526,000
Task 2 (234 products)	0	2,602,080
Total (234 products and 189 developers)	16,263,000	35,128,080
Total (1 product and 1 developer)	69,500	150,120

TABLE I.G.12.–09A—ESTIMATED LABOR HOURS TO DEVELOP 45 CFR 170.315(G)(33) PRIOR AUTHORIZATION API—PRIOR AUTHORIZATION SUPPORT

Task	Details	Lower bound hours	Upper bound hours
Task 1: HL7 FHIR Da Vinci—Prior Authorization Support (PAS) Implementation Guide: Version STU 2.0.1—STU 2.	Ability of the API to create and send prior authorization requests and to receive prior authorization responses.	500	1,000
Task 2: Subscriptions R5 Backport Implementation Guide version 1.1.0 (Backport IG).	Requirements to include: (1) topic-based Subscription support for FHIR R4 and (2) support of the REST-hook Subscription channel.	500	1500
Task 3: Support R4/B Topic-Based Subscription Profile	Conformance to profile, support for ''must support'' elements, and use of canonical URL of Subscription Topic.	250	500
Task 4: Support for R4 Topic-Based Subscription Server Capability Statement.	Support the creation, update, and deletion of Subscription resources in the Capability Statement.	50	100

Notes: The lower and upper bound hours estimated to complete each task are estimates of labor hours required for each product.

TABLE I.G.12.–09B—TOTAL COST TO DEVELOP 45 CFR 170.315(G)(33)

[2024 Dollars]

Activity	Estimated cost	
	Lower bound	Upper bound
Task 1 (234 products)	$16,263,000	$32,526,000
Task 2 (234 products)	16,263,000	48,789,000
Task 3 (234 products)	8,131,500	16,263,000
Task 4 (234 products)	1,626,300	3,252,600
Total (234 products and 189 developer)	42,283,800	100,830,600
Total (1 product and 1 developer)	180,700	430,900

The cost to a health IT developer to develop all three criteria ''provider prior authorization API—coverage requirements discovery'', ''provider prior authorization API—documentation templates and rules'', and ''provider prior authorization API—prior authorization support'' for their Health IT Modules would range from $330,000 to $880,000 per product, on average. Individually, the cost to develop ''Provider prior authorization API—coverage requirements discovery'' would be $80,000 to $310,000 per product; ''provider prior authorization API—documentation templates and rules'' $69,000 to $139,000 per product; and ''provider prior authorization API—prior authorization support'' $181,000 to $431,000 per product. In total, we estimate that for all applicable products (n = 234), the total cost to adopt these criteria for developers of certified health IT would be $77m to $206m.

Studies show that prior authorization accounts for $35 billion in annual administrative health care costs.[571] This cost is estimated to be proportional among payers, physician groups, and hospitals. These studies also show that prior authorization is one of the least ''electronic'' administrative workflows in health care, wherein about 20 percent of transactions are fully electronic compared to claim submission (96 percent) and eligibility and benefit verification (84 percent), respectively.[572] Payers and providers have both adopted electronic prior authorization and it has increased from 12 percent to 31 percent from 2018 to 2023, according to other studies.[573] [574] However, phone and fax are largely used by payers to manage prior authorizations and the peer-to-peer review process for denial appeals.[575] Prior authorization poses a large financial and administrative burden on clinicians with large potential savings from improvements to the prior authorization, including movement to a more streamlined, electronic process.[576] A 2023 survey found that physicians spent 1 hour per week on average, nursing and other clinical support staff spent about 2.5 hours per week on average, and clerical staff spent about 9 hours per week on average completing prior authorization activities.[577] This aligns with the findings of Casalino, et al. whose 2009 study first measured prior authorization costs on physician practices.[578] However, although the total hours (~13) per week spent on prior authorization remained the same across these personnel categories, the burden of effort has shifted from frontline clinical staff to support and administrative personnel. The Sahni, et al. (2023) study also shows the range of different personnel who may complete prior authorization in any given practice setting, showing the complexity and range and type of staff needed to process these authorizations.[579] This complexity is but one facet of the burden and effort involved in prior authorization that could be ameliorated by standardized, electronic solutions.

The American Medical Association (AMA) regularly surveys physicians to understand their prior authorization experience. In 2021, their survey of 1,000 physicians found that the average practice completed 41 prior authorizations per week.[580] This effort involved over 13 hours of the average physician and their support staff's time each week. Furthermore, 2 in 5 physicians report needing to dedicate staff resources, for example registered nurses or other support staff, exclusively toward prior authorizations—findings supported by studies referenced previously. The AMA published results of their analysis of the latest survey 2024) in early 2025, showing very little has changed in the past 4 years, despite progress in the digitization and automation of other healthcare services and tasks.[581] Even as an increasing volume of prior authorization (69 percent in 2023) transactions are fully electronic (via the HIPAA Transaction Standard: ASC X12N 278) or partially electronic (web portals), effort and burden remain high.[582] Unpublished results from an ASTP/ONC analysis of American Board for Family

[571] *https://jamanetwork.com/journals/jama/fullarticle/2785480.*

[572] Ibid.

[573] *https://www.caqh.org/sites/default/files/2022-caqh-index-report%20FINAL%20SPREAD%20VERSION.pdf.*

[574] *https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.*

[575] *https://ascopubs.org/doi/full/10.1200/EDBK_100036.*

[576] *https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.*

[577] *https://academic.oup.com/healthaffairscholar/article/2/9/qxae096/7727862.*

[578] *https://www.healthaffairs.org/doi/10.1377/hlthaff.28.4.w533.*

[579] *https://academic.oup.com/healthaffairscholar/article/2/9/qxae096/7727862.*

[580] *https://apps.legislature.ky.gov/CommitteeDocuments/7/20788/10%2026%202022%20Tailor%20-%202021%20AMA%20Physician%20Prior%20Auth%20Survey.pdf.*

[581] *https://www.ama-assn.org/practice-management/prior-authorization/prior-authorization-research-reports.*

[582] *https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.*

Medicine (ABFM) survey data shows that although most family medicine physicians report using their EHR to conduct prior authorization (that is via a transaction standard or portal), the effort and burden are no different than for those physicians who perform these tasks manually, which supports prior findings reported by Salzbrenner, et al. published only a few years ago.[583] [584] The current methods, either electronic or manual, to complete a prior authorization are not reducing burden and take precious time away from vital provider-patient interactions.

In 2023, the CAQH estimated that the cost to providers of a manual prior authorization approval was $10.97 per claim, while the cost to payers was $3.52 per claim.[585] In addition, a policy paper for The Hamilton Project calculated that staff time is approximately 25 hours per week in resolving 37 prior authorization adjudications at $20 per hour, which equals $14 per claim as a cost to medical staff.[586] Administrative costs per claim vary slightly, and studies show that current electronic methods can reduce the per claim cost of prior authorization, showing that on average a fully electronic prior authorization transaction costs $5.79 for the average provider—nearly half what it costs to do this work manually.[587]

Based on a survey of 1,147 responses from 100,000 providers, University of Nebraska Medical Center physicians and researchers found it took health plans less time to submit decisions electronically, though providers had similar challenges with electronic prior authorizations as they did with manual prior authorizations.[588] Although electronic prior authorization processes exist, they're not uniformly implemented across plans, creating a hodge podge of options for the average practice, who treat patients across numerous plans. Plans may benefit from implementing an electronic prior authorization process that enables providers to transmit authorizations through a portal or other electronic method, but without more uniformity in electronic prior authorization across health plans, providers are left holding the bag on managing a complex web of prior authorization management.

The prior authorization API criteria finalized in this final rule will standardize electronic prior authorizations, providing complementary APIs to the APIs plans will be required to establish as part of the CMS final rule (89 FR 8758), enabling interoperable exchange of prior authorization requests (from providers) and decisions (from plans). Several pilots are underway or have been completed to test the prior authorization API. One pilot, led by Regence, used the HL7 FHIR standard to automate prior authorization.[589] Using the SmartAuth app integrated with the Epic EHR, they were able to automatically populate policy criteria and automatically extract clinicals from the EHR. They were able to make immediate determinations on over 90 percent of the requests with nearly all determined that prior authorization was not required. Furthermore, staff realized nearly 68 percent in time savings using this standardized API-based process—time savings that can be directed toward other activities. Whereas, without the use of the app and automated process, providers might wait hours or days just to find out prior authorization is not required. In some cases, prior authorization was automatically processed, enabling an immediate decision to prescribe or suggest a treatment. This was all enabled using an API built using the FHIR standard—the exact method and standard finalized in these prior authorization criteria.

Setting a standard, electronic method to facilitate payer and provider exchange and the prior authorization of certain treatments and medications can reduce overall time and effort for payers and providers alike. A standard, uniform process can also be replicated across many IT systems, ensuring reliable interoperability between systems and more certainty to providers that they can electronically submit a prior authorization to a payer and receive a response congruent with their technology and workflow. When two partners in exchange have technology that adopt the same methods of communication (in this case automated, machine-based), they can connect and share information with lower effort and more consistency. In the same manner that a recipient must have an email server in order to receive email, a sender cannot transmit a FHIR-based payload via a DaVinci API to a recipient who does not have a similarly compliant FHIR server. A fragmented system where providers may need to follow different procedures and processes for different payers increases burden on providers and administrators and reduces their time to treat and manage patients. These finalized prior authorization APIs for providers, therefore, shall enable cost savings to developers of certified health IT and their provider users and benefits in the form of time savings to provider users of this technology.

(2) Comparative Analysis Between Standardized and Non-standardized Application Programming Interfaces for Electronic Prior Authorization

There are important trends towards the wide uptake of electronic prior authorization in the absence of this rule, including requirements on certain CMS-regulated health plans to support standards-based prior authorization APIs and for providers to report on Electronic Prior Authorization measures that require them attest to using prior authorization APIs within the Promoting Interoperability program and MIPS Promoting Interoperability performance category. In addition, a recent pledge by insurers to support electronic prior authorization indicates clear momentum towards building electronic prior authorization that developers of certified health IT will likely be pushed to meet by their customers.[590] Due to this market momentum, we believe that in a baseline state absent this rule, these trends would lead developers of certified health IT to develop further support for prior authorization APIs to ensure their customers can attest to the Promoting Interoperability measures. However, absent this rule, health plans may not have incentive to closely follow open implementation guides to implement prior authorization APIs. As a result, developers of certified health IT working to support their customers connections to these APIs may be required to largely overhaul connectivity they build to connect customers to each plan, leading to high marginal costs, some of which will be passed through to their customers. We believe this would result in development of a limited amount of connectivity between providers and payers at high marginal costs so that: (1) developers of certified health IT would implement connectivity with only a small fraction of health plans; and (2) low overall reduction in provider time and effort because of limited connectivity between providers through their certified health IT and health plans.

In this context, we believe the gains from economies of scale of standardizing point-to-point connections between plan and provider IT systems and the demand for a standardized prior authorization method that can reduce, if not wholly automate this process, will create savings to developers of certified health IT and health IT purchases. First, developers of certified health IT who must build and deploy this technology will realize savings as they will only need to support one method to electronically connect their systems to plan systems to process a prior authorization transaction. Health plans would in turn have incentives to ensure they are able to engage in prior authorization transactions according to this standard and related implementation guides. This method can also support automation of prior authorization and enable innovation from the broader digital health ecosystem to partner with developers of certified health IT and deliver solutions powered by artificial intelligence and other modern technologies that can further reduce effort to develop and deploy this technology.[591] Finally, health IT purchasers who must learn multiple prior authorization methods and the contact information for a multitude of health plans will realize savings as their EHR can be configured to process prior authorizations more seamlessly and with reduced manual intervention.[592] These APIs can reduce the time and expense to train staff on prior authorization and focus their efforts on a single, standardized method adopted by

[583] [Unpublished manuscript] MH Gabriel, et al. Navigating the Primary Care Physician's Triple Burden—Health Info Hunting, Prior Authorization, and 'Pajama Time'.

[584] *https://www.jmcp.org/doi/10.18553/jmcp.2022.28.10.1121.*

[585] *https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.*

[586] *https://www.hamiltonproject.org/wp-content/uploads/2023/01/Cutler_PP_LO.pdf.*

[587] *https://www.caqh.org/hubfs/43908627/drupal/2024-01/2023_CAQH_Index_Report.pdf.*

[588] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10332446/.*

[589] *https://www.cms.gov/files/document/hiig-august-2023-isc-speaker-slides.pdf.*

[590] *https://www.hhs.gov/press-room/kennedy-oz-cms-secure-healthcare-industry-pledge-to-fix-prior-authorization-system.html.*

[591] *https://showroom.epic.com/stage?id=35&t=23&c=259.*

[592] *https://www.cms.gov/files/document/hiig-august-2023-isc-speaker-slides.pdf.*

most, if not all health plans that cover their patients.

As described previously, prior authorization today is completed through a mix of fully and partially electronic, as well as manual methods (for example, fax, phone calls). This is due in part to the range of ways health plans process prior authorizations, as well as the technological capabilities of medical practices and hospitals. Some plans may provide portals to process prior authorizations, others do not. Some providers may have a health IT product that enables electronic messaging of prior authorization requests, but plans' ability to process these electronic prior authorizations varies. Some medical practices may default to manual methods, because they perceive no real difference in electronic or manual methods, as some data also show. Health IT products enable electronic processing to deliver a helpful service to their customers, but they face much effort enabling prior authorization between their myriad customers and the hundreds of health plans that provide health care coverage nationwide. Without a standardized, and potentially automatable prior authorization process, health IT product developers are left configuring 1-to-1 connections (if available) between their customers and the health plans that cover their patient population, and providers are left deciding between two sub-optimal methods for prior authorization. So, if the 300+ CMS-covered plans all configure their IT systems to share prior authorization decisions via a standards-based API, as finalized by the CMS Interoperability and Prior Authorization Final Rule (89 FR 8758) and the providers that serve patients covered by these plans (nearly all providers and patients nationwide) have certified health IT configured to these same standards-based APIs, the IT developers can all build infrastructure in the same fashion, ensuring electronic prior authorization interoperability. At present, one health IT product would need to support multiple methods of prior authorization and, if using electronic methods, would have to support diverging methods of transactional prior authorization or via an online portal, all of which require some manual provider intervention to complete.

In the section ''Comparative Analysis Between Standardized and Non-standardized Application Programming Interfaces'' of this impact analysis, we analyzed the alternatives with using a standards-based API and a non-standards-based API to enable interoperable connections between an average health IT product and one or many third-party apps that can connect to that health IT product to provide additional digital services beyond the capabilities of the health IT product to the health IT product users. This model has been applied to the standards-based electronic prior authorization APIs we adopt in this final rulemaking. The CMS Interoperability and Prior Authorization Final Rule (89 FR 8758) affects 300+ plans nationwide. All those plans will need to connect to the dozens of health IT products that serve the hundreds of hospitals and thousands of practice groups that serve Medicare and Medicaid patients nationwide. When a health IT product that serves many types of clients across multiple states needs to get prior authorization from the dozens (if not hundreds) of plans that serve their patients, implementing a standards-based process to exchange that information generates savings—both for health IT products who have to establish those connections for their clients and plans who need to send and relay prior authorization decisions to their enrollees' providers.

In Table I.G.12.–10 we replicate the API comparison model and replace the ''app'' connections with ''plan'' connections, as the prior authorization APIs connect health IT product and plan IT systems, rather than health IT product and app IT systems. Table I.G.12.–10 compares the costs to perform prior authorization using standards-based and non-standards-based APIs. As shown in the API comparison model, the base build for the standards-based prior authorization APIs is more expensive than a non-standards-based or functional API. However, as more and more connections are done between the health IT product and one or more health plans, the smaller marginal costs of connecting via a standards-based API outweigh the costs of connecting to the same number of health plan IT systems via a non-standards-based API. If the average health IT product were to connect to 20 health plan IT systems (fewer than 10 percent of CMS-sponsored plans nationwide), the combined costs of the base infrastructure of the standards-based APIs and the effort to connect to all 20 IT systems would incur lower costs, compared to the cost of the same effort and base infrastructure for non-standards-based APIs. When we extrapolate connections to 300 or more plans, the savings could be immense across all certified API developers. If all certified API products were to connect to 300 CMS-sponsored health plans, the savings in 2024 dollars would exceed $1.8 billion. For all products to connect to 50 plans, the total cost savings would be nearly $200 million.

TABLE I.G.12.–10—COMPARISON OF COSTS TO INTEGRATE HEALTH PLAN PRIOR AUTHORIZATION APIS VIA AN HEALTH IT PRODUCT

	Standards-based		Not standards-based		Differential costs		
	Average hours [1]	Cumulative hours	Average hours	Cumulative hours	Cumulative hour difference	Cumulative hours for all certified API Products [2]	Cost difference ($) [3]
Base build	4,300	4,300	350	350	3,950	924,300	$128,477,700
1 Plan	50	4,350	250	600	3,750	877,500	121,972,500
10 Plans	500	4,800	2,500	2,850	1,950	456,300	63,425,700
20 Plans [4]	1,000	5,300	5,000	5,350	−50	−11,700	−1,626,300
25 Plans	1,250	5,550	6,250	6,600	−1,050	−245,700	−34,152,300
50 Plans	2,500	6,800	12,500	12,850	−6,050	−1,415,700	−196,782,300
300 Plans	15,000	19,300	75,000	75,350	−56,050	−13,115,700	−1,823,082,300

Notes: (1) Average hours are the midpoint of the lower (2,375) and upper (6,330) bound hours calculated for the combined 45 CFR 170.315(g)(31), (g)(32), and (g)(33) criteria.
(2) Total = (Cumulative Hour Difference) X (All Certified API Products, n=234).
(3) Total $ = (Cumulative Hours for All Certified API Products) X (Wage Rate Used in this Impact Analysis, $139).
(4) On average, the breakeven point for a certified API product to adopt a standards-based API (versus a non-standards-based API) is 20 plans. Formula: 50 × +4,300 = 250 × +350; × = 3,950/200; × = 19.75.

Standardization enables certified health IT to support an API to connect many if not all plans, increasing the number of prior authorization transactions that can be done via the API and reducing manual effort to issue a prior authorization and receive a determination. We estimated that that for all applicable products (n = 234), the total cost to adopt these criteria for developers of certified health IT would be $77 million to $206 million or a median cost of $142 million. As the APIs are designed to connect to health plan systems to conduct prior authorization, the effort to complete these individual health plan connections is important to consider when weighing the option of a standards-based or non-standards-based API. Considering the potential cost differences estimated in Table I.G.12.- 10 of all applicable products connecting to 20 or more health plans to conduct prior authorization using the adopted standards-based APIs, we estimate that the initial effort to adopt the standards-based APIs outweigh

the cost of adopting non-standards APIs, given the larger marginal cost of connecting to one or more plans via a non-standards-based API. This initial investment in standards-based APIs is an overall cost saver to developers of certified APIs. The requirements will also have a measurable quantifiable benefit on the time it takes to process a prior authorization and the use of these time savings toward more productive and health-focused activities for patients and providers alike.

(3) Benefits

The finalized prior authorization API criteria for providers, which adopt and reference the same standards recommended in CMS's Interoperability and Prior Authorization Final Rule (89 FR 8758) and incorporate these standards to enable interoperability with the CMS-finalized APIs health plans are required to adopt, will ensure bi-directional exchange between plans and providers and, importantly, enable automation of these tasks—capabilities not enabled by current electronic prior authorization tools.[593]

In the final rule (89 FR 8758), CMS assessed the overall benefit and level of effort to standardize prior authorization and payer exchange.[594] CMS estimates, over a ten-year period, that physician groups and hospitals could face reduced costs of $15.3 billion if they adopted this technology to standardize prior authorization. As stated, these finalized certification criteria adopt standards and functionality identified by CMS and we believe that these certification criteria, if adopted by developers of certified health IT, would help ensure that the technology are developed and deployed in a standard, uniform way, culminating in the expected benefits to physician groups and hospitals estimated by CMS in their final rule.

CMS assessed the impact of the Interoperability and Prior Authorization Final Rule on the Medicare-covered clinician population, inclusive of physician groups and hospitals. CMS estimated 199,543 physician groups (based on data in the CY 2023 Physician Fee Schedule proposed rule (87 FR 46410)) and 7,911 hospitals, which includes general acute care hospitals (3,150), critical access hospitals (1,350), and outpatient hospitals (3,411), which are generally ambulatory surgical centers and urgent care/emergency care facilities. The number of physician groups (199,543) was based off a rough estimation using the total count of clinicians CMS estimated to be affected by the CY23 PFS (87 FR 46410) (1,596,340) divided by the median number of clinicians per practice (8) as estimated in Muhlestein and Smith.[595] This is a novel method of calculating physician groups, as other sources, including CMS's own National Downloadable File of doctors and clinicians and the AHRQ Compendium of Health Systems both put physician groups more at an average of 225,000.[596] [597] Despite the differences, we agree that a truly accurate estimate of the total physician groups affected by the CMS and ASTP/ONC final rules is difficult to calculate. Nevertheless, we believe the CMS estimate of 199,543 is reasonable and based on reliable data. CMS' calculation of hospitals is accurate and is much easier to calculate, as it is based on reliable data from multiple sources that mutually validate these counts. However, for our analysis, we focus on the count of general acute care (3,150) and critical access (1,350) hospitals (4,500 in total), and exclude the count of outpatient hospitals (3,411) used in the CMS analysis.

The CMS model assumed an immediate impact on MIPS-eligible clinicians and groups in 2027, based on the implementation date established in the prior authorization final rule. It also assumed an incremental impact on other covered clinicians, up to 50 percent of these groups by 2036. CMS described the reasoning to limit the total benefit estimate to 50 percent of groups, but also noted that according to the National Center for Health Statistics' National EHR Survey (NEHRS) (which is fielded in partnership with ASTP/ONC), 78 percent of physicians report using a certified EHR. As CMS notes, this statistic could indicate an underestimation of the benefits, that is estimating the impact to only 50 percent of practice groups may underestimate the full benefits of the adoption of electronic prior authorization under the final rule. We agree with CMS' assessment and believe that the combined impact of both the CMS final rule and this final rule would be greater. We believe additional benefits would be gained as prior authorization APIs are widely adopted by developers of certified health IT supporting a wide range of sites of service. We believe the combined impact would realize time savings for a broader scope of providers from a standardized and automatable prior authorization process. We further describe these likely additional benefits in this regulatory impact analysis.

In addition, CMS treated the hospital prior authorization experience the same as the average physician group experience in the CMS final rule for the purposes of calculating cost and benefits. At the time, this approach was supported by a need to develop a more general single estimate for average savings. However, we believe that the actual average hospital and physician group experience are not equal in part due to the nature of care provided in different facility types and also due to economies of scale. Hospitals deliver more services covered by prior authorization (for example, surgeries, diagnostics, medications—particularly pain medication, and durable medical equipment), and the average hospital treats and discharges more patients per annum than the average practice. The volume of patients encounters, treatments, and diagnostics among hospitals should merit greater weighting in the impact of these technology policies on the operations of U.S. hospitals. Given that nearly all hospitals use a certified EHR and report for PI annually, we estimate that from 2027 to 2031 all 95 percent hospitals will have this API technology, with all hospitals adopting the technology by 2036.[598] [599]

Table I.G.12.–11 shows the counts of patient visits across US hospitals. As of 2020, a portion of all hospitals, general and acute care hospitals comprise the vast majority of all hospital-based care (86 percent), with over 700 million outpatient visits occurring each year. These outpatient visits occurred at 4,500 hospitals nationwide. That is just under 160,000 visits per hospital per year. As hospitals are often open continuously throughout the year, that is about 436 patients per day or 18 per hour on average. Very large hospitals are likely to see many more patients on average, compared to smaller hospitals. In contrast, as shown in Table I.G.12.–12, as of 2019, nationally all physician offices had over 1 billion patient office visits. Although we cannot be truly precise, we consider the total outpatient visits from the NCHS/NAMCS data to be representative of the number of practice groups included in the CMS analysis and used here in this analysis as well (199,543). Using these counts, we estimate that each practice has over 5,000 patient visits per year (considering 250 working days a year, that is about 20 patient visits per group per year.) It should be recognized that the NAMCS does exclude some physician types from its scope, so its accounting may underestimate the true count of all outpatient visits inclusive of the physician groups within scope of this analysis. If we were to adjust this count by 25 percent, total outpatient visits would increase to 6,500 per annum per practice.

TABLE I.G.12.–11—HOSPITAL ENCOUNTER TYPES BY ALL AND GENERAL AND CRITICAL ACCESS HOSPITALS

Encounter type	All hospitals	General and critical access hospitals	% of All	Per general hospital (n=4,500)
Outpatient visits	834,034,000	717,159,000	86	159,368

[593] *https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.*

[594] *https://www.federalregister.gov/documents/2024/02/08/2024-00895/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-advancing-interoperability.*

[595] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0130.*

[596] *https://data.cms.gov/provider-data/dataset/mj5m-pzi6.*

[597] *https://www.ahrq.gov/chsp/data-resources/compendium-2023.html.*

[598] *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

[599] *https://data.cms.gov/provider-data/dataset/f4ga-b9gx.*

TABLE I.G.12.–11—HOSPITAL ENCOUNTER TYPES BY ALL AND GENERAL AND CRITICAL ACCESS HOSPITALS—Continued

Encounter type	All hospitals	General and critical access hospitals	% of All	Per general hospital (n=4,500)
Hospital admissions	33,357,000	31,393,000	94	6,976
Length of stay	6.3	5.6		
Total days	210,149,100	175,800,800	84	39,066

Source: NCHS/Division of Analysis and Epidemiology, Hospital admission, average length of stay, outpatient visits, and outpatient surgery by type of ownership and size of hospital, 2020, *https://data.cdc.gov/National-Center-for-Health-Statistics/DQS-Hospital-admission-average-length-of-stay-outp/rear-2epk/about_data.* **Note:** General and critical access hospitals are tabulated using the nonfederal, community hospital category. 4,500 total hospitals of this type.

TABLE I.G.12.–12—PHYSICIAN GROUP OUTPATIENT VISITS, 2019

Encounter type	All physicians	Primary care	Percentage of all	Per practice (n=199,543)
Outpatient visits	1,036,484,000	521,466,000	50	5,194

Source: NCHS, National Ambulatory Medical Care Survey, 2019 National Summary Tables, *https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2019-namcs-web-tables-508.pdf.* **Note:** 199,543 practices.

Taken together, these results show that hospitals and physician groups are not equal in the volume of patients seen: 160,000 per hospital vs 5,000 (to 6,500) per practice group, which is a difference of over 20 times more per year. We know less about what portion of patient visits involve prior authorization. However, based on what we know about the range of services a hospital provides versus the average practice group, it is likely the same burden per 100 patients if not more. Comparing this to studies that show that the overall costs for prior authorization are equal for all hospital and physician groups, we believe this final rule in combination with the requirements in the CMS Interoperability and Prior Authorization Final Rule should create broad estimated time savings to both physician groups and hospitals at fairly similar levels.[600] If EHR technology that supports these prior authorization APIs are adopted at similar rates across physician groups and hospitals, the time savings in total to practices and hospitals should be fairly equal, rather than the average cost savings to practices and hospitals being fairly equal, as has been previously finalized.estimated. This final rule shows the broader impact that adoption across both physician groups and general hospitals of these provider prior authorization APIs might have. As an estimated 78 percent of physicians use a certified EHR (and about an equal number of physician office visits occur at a practice that uses a certified EHR) and over 96 percent of general hospitals use a certified EHR, we believe the adoption of these certified APIs that can connect in an interoperable manner with over 300 health plans nationwide will generate significant cost savings to the health care providers who deliver the vast majority of daily, outpatient care nationwide.[601] [602]

TABLE I.G.12.–13—TOTAL HOURS (IN MILLIONS) AND DOLLARS (IN MILLIONS) SAVED OVER 10 YEARS AS A RESULT OF HOSPITALS ADOPTING CERTIFIED PRIOR AUTHORIZATION APIS

Year	Savings per hospital (hour), average	Savings per hospital ($), average	Percentage of hospitals adopting the APIs	Total number of hospitals	Reduced hours per years (millions), average	Reduced cost per years ($ millions), average
2027	4,410	315,390	75	4,500	14.9	1,064
2028	4,410	315,390	80	4,500	15.9	1,135
2029	4,410	315,390	85	4,500	16.9	1,206
2030	4,410	315,390	90	4,500	17.9	1,277
2031	4,410	315,390	96	4,500	19.1	1,362
2032	4,410	315,390	97	4,500	19.2	1,377
2033	4,410	315,390	98	4,500	19.4	1,391
2034	4,410	315,390	99	4,500	19.6	1,405
2035	4,410	315,390	99	4,500	19.6	1,405
2036	4,410	315,390	100	4,500	19.8	1,419
Total					182	13,043

Notes: The savings per hospital and overall reflect an average of the lower bound and upper bound estimates of the amount of prior authorization per hospital as compared to per physician group. The lower bound assumes the average hospital experiences 10x the prior authorization burden of the average physician group. The upper bound assume the average hospital experiences 20x the prior authorization burden of the average physician group. The average is 15x the amount of burden.

[600] *https://jamanetwork.com/journals/jama/fullarticle/2785480.*

[601] *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

[602] *https://www.cdc.gov/nchs/data/ahcd/namcs_summary/2019-namcs-web-tables-508.pdf.*

TABLE I.G.12.–14—DIFFERENCE IN TOTAL HOURS (IN MILLIONS) AND DOLLARS (IN MILLIONS) SAVED OVER 10 YEARS AS A RESULT OF HOSPITALS ADOPTING CERTIFIED PRIOR AUTHORIZATION APIS

Year	Provider API, API effect, hours per year (in millions)	Provider API, API effect, dollars per year (in millions)
2027–2036	177.7	12,686

Notes: The difference subtracts the number of hours and dollars saved accounted for in CMS Rule (89 FR 8758) from the total hours and dollars saved as totaled in Table C6.

TABLE I.G.12.–15—TOTAL HOURS (MILLIONS) AND DOLLAR (MILLIONS) SAVED OVER 10 YEARS AS A RESULT OF PHYSICIAN GROUPS ADOPTING CERTIFIED PRIOR AUTHORIZATION APIS

Year	Savings per practice (hour)	Savings per practice ($)	Percentage of practices adopting the APIs	Total number of practices	Reduced hours per year (in millions)	Reduced cost per year ($ in millions)
2027	294	21,026	27.5	199,543	16.1	1,151.7
2028	294	21,026	33.2	199,543	19.5	1,392.9
2029	294	21,026	39.0	199,543	22.9	1,634.2
2030	294	21,026	44.7	199,543	26.2	1,875.4
2031	294	21,026	50.5	199,543	29.6	2,116.7
2032	294	21,026	56.2	199,543	33.0	2,357.9
2033	294	21,026	62.0	199,543	36.3	2,599.2
2034	294	21,026	67.7	199,543	39.7	2,840.4
2035	294	21,026	73.5	199,543	43.1	3,081.7
2036	294	21,026	79.2	199,543	46.5	3,322.9
Total					313	22,373

Notes: The savings reflect adjustment in the percentage of practices adopting the finalized prior authorization APIs, as adjusted from the percentage accounted for in CMS Rule (89 FR 8758). The average savings per practice remain the same.

TABLE I.G.12.–16—DIFFERENCE IN TOTAL HOURS (MILLIONS) AND DOLLARS (MILLIONS) SAVED OVER 10 YEARS AS A RESULT OF PHYSICIAN GROUPS ADOPTING CERTIFIED PRIOR AUTHORIZATION APIS

Year	Provider API API effect, hours per year (millions)	Provider API API effect, $ per year (millions)
2027	0.0	0.0
2028	2.3	161.9
2029	4.5	318.4
2030	6.6	468.9
2031	8.6	613.3
2032	10.6	750.9
2033	12.3	881.5
2034	14.1	1,004.3
2035	15.7	1,119.1
2036	17.2	1,225.1
Total	91.8	6,543.4

Notes: The difference subtracts the number of hours and dollars saved accounted for in CMS Rule (89 FR 8758) from the total hours and dollars saved as totaled in Table C8.

As shown in tables I.G.12.–13–16, we find that there are significant time savings that can be realized from the adoption of both the CMS-finalized prior authorization APIs (for plans) and the ASTP/ONC-finalized prior authorization API health IT criteria (for providers). Importantly we find the difference in savings estimated in CMS final rule (89 FR 8758) from the updated calculations we estimate previously. In total we find $12.7 billion in cumulative cost savings from 2027 to 2036 for hospitals (Table I.G.12.–14) and $6.5 billion in additional cumulative savings from 2027 to 2036 for practice groups (Table I.G.12.–16), totaling $19.2 billion in total savings from the additional impact of finalizing these standardized prior authorization APIs for providers.

(4) Benefits

Implementing these capabilities will deliver a more automated and seamless experience for clinicians and medical professionals across physician practice groups and general hospitals, who provide critical frontline, primary, and emergency care to tens of millions of Americans every year. As studies show that existing prior authorization processes (including current electronic methods) create undue burden and take precious time away from patient care and personal conversations between patients, their caregivers, and providers, these standardized APIs will reduce these burdens and free time to providers and patients to focus on health and well-being, not paperwork and overhead.

Comment: We received no comments regarding the impact analysis of the API requirements.

Response: The final impact analysis updates costs based on new information on the number of products that are likely to require new functionality and the impact of these finalized policies. Cost estimates were updated to reflect wages of software developers as of 2024. Quantified savingsbenefits were updated in this final impact analysis, given new information and availability of data.

e. New Certification Criteria for Modular API Capabilities

We finalized two new criteria: 45 CFR 170.315(j)(20): ''Workflow triggers for decision support interventions—clients'' and 45 CFR 170.315(j)(21): ''Subscriptions—client'', which would be available for certification based on certain contexts or other programs requiring the use of the specified certified capabilities. The new certification criteria create flexibility to test and certify Health IT Modules and introduce new technical functionalities with synergy with other certification criteria finalized in this final rule.

Finalized certification criteria in 45 CFR 170.315(j)(20) and 45 CFR 170.315(j)(21) reflect new technical functionalities. However, this final rule does not require adoption of these new certification criteria by health IT developers. These two certification criteria are referenced as conditional or as required functionality for other finalized certification criteria. The impact analyses for these two finalized certification criteria assess the expected level of effort and development tasks required to adopt the new certification criteria, but do not assume required adoption for these certification criteria for any current developers of certified health IT. We separately estimate the cost and benefits for the specific certification criteria that reference these modular functionalities in order to create a clear correlation of cost and benefits to requirements, as well as to avoid duplication within our estimates.

(1) Workflow Triggers for Decision Support Interventions

We finalized adoption of the HL7 Clinical Decision Support (CDS) Hooks Release 2.0.1 in 45 CFR 170.215(f) as a mandatory compliance prerequisite to facilitate API-driven workflow triggers for decision support interventions in 45 CFR 170.315(j)(20). This requirement would establish adoption of a ''hook''-based pattern for initiating clinical decision support, either allowing decision support results to be integrated seamlessly into a provider's EHR workflow or launching an interactive CDS application from within the workflow.

(a) Costs

TABLE I.G.12.—17. ESTIMATED LABOR HOURS TO DEVELOP WORKFLOW TRIGGERS FOR DECISION SUPPORT INTERVENTIONS 45 CFR 170.315(J)(20)

Task	Details	Lower round hours	Upper round hours	Remarks
Task 1: HL7 CDS Hooks Release 2.0.1	CDS Hooks FHIR Release 2.0.1 in 45 CFR 170.215(f) as a prerequisite to facilitate API-driven CDS workflow triggers in 45 CFR 170.3315(j)(20).	0	1.000	First balloted over 5 years ago, CDS Hooks in mature but still in trial use. We finalize a minimal implementation of the standard and believe this implementation is likely supported and deployed by some developers, but not all in some fashion.

Notes: The lower and upper bound hours estimated to complete each task are estimates of labor hours required for each product.

This proposal may also impose some costs and challenges that are not easily quantifiable. While some scholars posit that CDS Hooks are in a state of relative immaturity compared to other HL7 standards, their growing popularity suggests further standards development for CDS Hooks is likely on the horizon. Part of the developing maturity level comes from exploration of new hook definitions for workflow trigger points, security best practices, response analytics, and suggestions for improved interoperability for items like recommended prescriptions.[603] Based on public feedback on ASTP/ONC's request for information in the HTI–1 Proposed Rule, some commenters expressed concerns for slow real-world adoption of CDS Hooks. Although CDS Hooks is reasonably mature, many developers and other organizations are not using this technology. One review of ''original studies describing development of specific CDS tools or infrastructures'' using FHIR, SMART, CQL, and CDS Hooks published in 2021 found that only 18 percent used CDS Hooks. These authors note that it is too early to determine a mature-state uptake rate of CDS Hooks based on the current early stage and the limited number of studies.[604]

Many commenters were partial to certification requirements for specific use cases, such as prior authorization, immunization decision support, evidenced-based treatment decisions and alternatives, etc. Notably, prior authorization was indicated to be a high priority use case. Furthermore, one market leading EHR developer indicated in RFI comments that it does not believe certification of CDS Hooks is necessary to materially advance interoperability and supports allowing market forces to drive adoption. The developer noted they make CDS Hooks available but is utilized by only about 10 percent of end users, potentially due to its effect of slowing clinician workflows.

There are examples of successful implementations of CDS Hooks, but these implementations are not without challenges. In one study by Dolin et al., the researchers developed a pharmacogenomics CDS service prototype based on the FHIR and CDS Hooks standards.[605] The researchers noted that they were able to meet the goals of deploying a functional prototype but identified some challenges with CDS Hooks. They found that the process for executing an authenticated query request in a system outside of the EHR from a trigger within the EHR was very complex and noted constraints on the variety of actionable CDS recommendation types that could be returned from the decision support tool.

One randomized control trial assessed the cost of using CDS Hooks to clinician end-users. CDS Hooks was shown to be more burdensome to end-users, requiring many clicks and a greater level of effort than other EHR prompts. Based on a cluster RCT in an emergency department using Epic, single-click prompts, such as ordering HIV screening laboratory tests, take less effort and clicks than CDS Hooks. Single-click app launching occurs with some CDS Hooks; for example, the Epic EHR uses CDS Hooks for pop-up alerts. However, single-click launching does not happen for all Epic prompts, including Storyboard prompts (patient summaries that are always displayed in the EHR for an individual patient). Instead of a single click, the user must click on the Storyboard prompt and then eventually access the hyperlink to the hook. Accessing the hyperlink is nonintuitive to most users, which is why the researchers in this study requested Epic to have a single-click for CDS Hooks in the Storyboard prompt.[606] These challenges faced by end-users suggest that there may be room for growth in CDS Hooks implementations.

(b) Benefits

The benefits of these modifications are not quantifiable at this time, but we expect the resulting improvements to interoperable exchange of health information to significantly benefit clinician end users and improve the quality of health care provided. Clinicians will benefit from the updates to the standard and to the certified criterion through increased standardization and

[603] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8324242/.*

[604] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8416232/.*

[605] *https://pubmed.ncbi.nlm.nih.gov/30605914/.*

[606] Ibid.

interoperability of CDS Hooks technology. Certified use of CDS Hooks is expected to facilitate more patient-specific results from clinical decision support tools, assisting providers in a more patient-centric approach to care.

Based on public feedback on ASTP/ONC's request for information in the HTI–1 Proposed Rule, commenters were generally more supportive of certification criteria for adoption of the v2.0 specification of FHIR CDS Hooks, as opposed to v1.0. Many also preferred ASTP/ONC supporting narrow certification criteria related to a particular user guide, as we have specified in this proposal.

Although many argue that adoption is growing slowly for CDS Hooks, based on comments received as part of the HTI–1 Proposed Rule RFI, a commenter expressed support for modular certification of this technology, noting the belief that it is significantly developed and mature, as well as citing the fact that the CMS Interoperability and Prior Authorization Proposed Rule is dependent on this technology (a large-scale implementation example).

Based on public feedback on ASTP/ONC's request for information in the HTI–1 Proposed Rule, commenters were generally supportive of the utility of CDS Hooks and believed the specification to be mature. Based on the literature, use of CDS Hooks appears to offer utility to patients and providers. In a randomized control trial of CDS Hooks' feasibility to increase use of SMART on FHIR apps, researchers found that CDS Hooks may lead to reduction in usability issues with SMART on FHIR apps.[607] This would likely create better access to clinical care recommendations on its own, in addition to more complex decision logic due to the use of an external CDS engine through CDS Hooks services that could then be implemented using native EHR CDS approaches. These improvements in CDS could subsequently improve care decisions and patient outcomes. Another likely benefit of CDS Hooks is time savings from interoperability because (similar to SMART on FHIR apps), CDS Hooks can be shared across EHR platforms and health systems.

Beyond the opportunity for clinical decision support tools to facilitate reduced cognitive load and timesaving for providers, another anticipated benefit of CDS Hooks is that it gives clinicians using CDS tools the option to utilize these tools only when needed.[608] Relatedly, use of CDS Hooks allows decision support results to be accessed at any time during a patient's care, and not only when the results of an ordered lab are received. This is expected to benefit patients by reducing the risk of adverse health events and preventing duplication of lab tests. Due to resulting increases in care efficiency, this is also expected to lead to notable cost-savings for health systems utilizing the CDS Hooks tool.

In one RCT trial, researchers aimed to assess the feasibility of using CDS Hooks to increase SMART on FHIR app utilization. The researchers found that developer burden can be reduced because CDS Hooks use FHIR as both the data model and exchange standard and the same logic is used for SMART on FHIR apps. Morgan et al, advise that to justify the significant time and resources EHR developers must invest in building the hook, development should focus on single-click prompts where the end-user burden is most likely to benefit (however, developer effort is not quantified in this RCT).[609] CDS Hooks largely addresses this concern, as it uses a hyperlink to SMART on FHIR app that allows users to launch the app in a single click.[610]

(2) Subscriptions

We finalized that Health IT Modules certified to 45 CFR 170.315(j)(21) demonstrate support for FHIR-based API subscriptions according to the HL7 FHIR Subscriptions Framework. FHIR Subscriptions allow a server to notify a user when information has been added or altered within a record, as well as offers the ability to submit a payload with a notification. We finalized the adoption of the Subscriptions R5 Backport Implementation Guide version 1.1.0 (Backport IG) in 45 CFR 170.215(h)(1) as a baseline standard conformance requirement in 45 CFR 170.315(j)(21), and, specifically, that Health IT Modules support the requirements specified in section ''1.6 Topic-Based Subscriptions—FHIR R4'' of the implementation specification in 45 CFR 170.215(h)(1).

We further finalized the following requirements for certification of a Health IT Module in 45 CFR 170.315(j)(21):

- Conformance to the ''R4/B Topic-Based Subscription'' profile detailed in the as specified in the Backport IG.
- Conformance to the ''R4 Topic-Based Subscription Server Capability Statement'' of the implementation specification in 45 CFR 170.215(h)(1), including. Server support of create, update and delete interactions for Subscription resources (create and delete are currently optional).
- At a minimum, support of the REST-hook Subscription channel as a means of notifying subscribers of the availability of new results.

(a) Costs

Each of the defined tasks has a corresponding level of effort, and these estimates are detailed in Table I.G.12.–18:

TABLE I.G.12.—18. ESTIMATED LABOR HOURS TO DEVELOP SUBSCRIPTIONS 45 CFR 170.315(J)(21)

Task	Details	Lower bound hours	Upper bound hours
Task 1: Implementation of Subscriptions R5 Backport Implementation Guide version 1.1.0 (Backport IG).	Requirements to include: (1) topic-based Subscription support for FHIR R4 and (2) support of the REST-hook Subscription channel.	500	1,500
Task 2: Support R4/B Topic-Based Subscription Profile	Conformance to profile, support for ''must support'' elements, and use of canonical URL of Subscription Topic.	250	500
Task 3: Support for R4 Topic-Based Subscription Server Capability Statement.	Support the creation, update, and deletion of Subscription resources in the Capability Statement.	50	100

Notes: The lower and upper bound hours estimated to complete each task are estimates of labor hours required for each product.

We acknowledge that these costs may be difficult to estimate given the current state of FHIR Subscription implementations. ASTP/ONC requested public comment in a ''FHIR Subscriptions Request for Information'' in the HTI–1 Rule proposal, and some commenters expressed concern for cost. A commenter specifically indicated a concern for costs to implement and a need for more information on relevant use cases, given a current lack of real-world implementations of FHIR Subscriptions according to the specifications in the R5 Backport IG. Further, we do not know the extent to which costs and benefits may balance one another. Subscriptions are intended to provide active event notifications to users immediately when data in a record is updated or changed.[611] However, academic literature on this topic does not currently reflect concrete benefits of this notification service. We request comment on these cost estimates, in particular the burden hours and necessary tasks to develop this functionality.

(b) Benefits

The benefits of these modifications are not quantifiable at this time, but we expect the resulting improvements to interoperable exchange of health information to significantly benefit patients, providers, and health care workers and improve the quality of health care provided. Currently, patient access and decision support applications need to periodically poll 45 CFR 170.315(g)(10)-certified APIs to check for

[607] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9382378/.*

[608] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7233102/.*

[609] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9382378/.*

[610] Ibid.

[611] *https://build.fhir.org/ig/HL7/fhir-subscription-backport-ig/.*

updates to patient records. Using the HL7 FHIR Subscriptions Framework, these apps can receive notifications when relevant updates are available. This means that patient apps and decision support apps can have more timely, real-time access to the latest records, ensuring that they always have the most up-to-date information. The current API polling model requires applications to make requests to the server, even when there are no updates available. This can result in unnecessary network traffic and resource utilization. Using HL7 FHIR Subscriptions, applications receive notifications when updates are available, and can use these notifications to make server queries to receive patient record updates, reducing the overall network traffic and resource usage. Provider applications can similarly benefit by receiving real-time notifications to update decision support modules and other supporting services.

The FHIR Subscriptions IG has a maturity level of 3 (on a 5-point Likert scale) and is currently in Trial Use. Although it has been deemed ready for use in production systems, it has not seen widespread use in production.[612] According to the HL7 website, this would mean that the ''FMM2 + the artifact has been verified by the work group as meeting the Conformance Resource Quality Guidelines; has been subject to a round of formal balloting; and has at least 10 distinct implementer comments recorded in the tracker drawn from at least 3 organizations resulting in at least one substantive change.'' [613] The HL7 website further states that subscribers (in this case, developers) typically would not need to implement many channel types, so it is unlikely that these developers would spend a significant portion of time with trial and error.[614] We specifically require support only for the REST-hook channel for modular certification in 45 CFR 170.315(j)(21). We note in the proposal that this channel uses the RESTful model, is used extensively in the FHIR standard, and is considered the lowest bar for implementation. Given these points, we believe the burden to developers who wish to achieve modular certification in 45 CFR 170.315(j)(21) to be minimized. As a note, no academic literature has been found that assesses end-user burden of event notifications/Subscriptions R5 Backport IG.

Although the literature does not highlight clear, quantifiable benefits of FHIR Subscription services, we anticipate FHIR Subscriptions to ease interorganizational transactions through the functionality to transmit a payload along with a notification, as well as to reduce the burden of reporting across several public health use cases. Subscriptions are expected to be relevant in clinical, public health, administrative, and research use cases.

The public was asked to provide comments on ASTP/ONC's FHIR subscriptions request for information in the HTI–1 rule proposal, and responses were considered in the development of proposals pertaining to FHIR subscriptions in HTI–2. Commenters generally noted that the FHIR version R5 Backport IG as a better option for implementation guidance than the R4B IG. Feedback received also included recommendations to start with small defined use cases and a subset of topics thought to be most beneficial.

Comment: We received no comments regarding the impact analysis of the modular API requirements.

Response: The final impact analysis is consistent with the proposed rule and updates costs based on information on the number of products that are likely to require new functionality. Cost estimates were updated to reflect wages of software developers as of 2024.

f. Revisions to Real World Testing Requirements

We finalized updates to the Real World Testing Condition of Certification at 45 CFR 170.405(a) to include the criteria in 45 CFR 170.315(g)(31), (g)(32), and (g)(33), and criteria in 45 CFR 170.315(j)(20), and (j)(21). This rule also finalizes a new certification criterion, 45 CFR 170.315(b)(4), which as a 45 CFR 170.315(b) criterion is considered part of real world testing. We estimate costs for developers of certified health IT to plan, conduct, and report on this new testing.

(1) Costs

We assume, as 45 CFR 170.315(j)(20) is required to be certified as part of 45 CFR 170.315(g)(31) and 45 CFR 170.315(j)(21) is required to be certified as part of 45 CFR 170.315(g)(33), that the full cost of conducting real world testing for 45 CFR 170.315(g)(31) and 45 CFR 170.315(g)(33) would include testing for 45 CFR 170.315(j)(20) and 45 CFR 170.315(j)(21), as these are dependent criteria. Therefore, we do not estimate separate costs to conduct real world testing for 45 CFR 170.315(j)(20) and 45 CFR 170.315(j)(21).

In the Cures Final Rule (85 FR 25642), we finalized the Real World Testing Condition of Certification at 45 CFR 170.405(a). The condition applied to 23 certification criteria at the time of finalization. In the Cures Rule, we estimated that it would cost per developer on average $109,557 annually to comply with the condition and conduct real world testing for the applicable criteria.[615] The original impact estimates for real world testing included costs per developers to (i) design a testing approach and submit plan; (ii) prepare staff and environments to collect data; (iii) perform testing; and (iv) collect results and prepare/submit report. We estimated these costs would be annual to align with annual reporting requirements. Averaging this overall, we estimate the cost per criterion per developer to plan, conduct, and report for real world testing to be $4,763.[616]

For the new criteria added to real world testing finalized in this rule, we estimate a lower incremental cost to complete real world testing for these new criteria, considering that some real world testing costs ((i) through (iv) noted previously) would be less or de minimis given existing investments into the infrastructure and capacity to conduct real world testing for other criteria. Specifically, we assume that the additional effort to design a testing approach and submit a plan will be limited to the effort to design a testing approach for new criteria (90 percent of task cost) and assume the effort to submit the plan (10 percent of task cost or 3 percent of the total real world testing cost) will be de minimis, as this is work already conducted by the average developer for existing reporting requirements. We also assume that the additional effort to collect results and prepare and submit the report will be de minimis (20 percent of overall RWT cost per developer). We estimate that work to prepare staff and environments and perform testing will be net new for these criteria, as we assume they require net new infrastructure and capacity-building to conduct real world testing.

Therefore, we consider that 23 percent of the original cost to conduct real world testing per developer to not apply toward the addition of new criteria to real world testing, and that the incremental cost of new real world testing requirement would be roughly 75 percent of the original estimated cost. Per criterion and per developer that equals $3,667.[617] We must also consider wage inflation associated with the increase in labor rates for staff in 2025 and beyond, compared to labor rates used to estimate real world testing in the Cures Rule. We estimate an average 21 percent wage inflation across all labor categories included in the Cures Rule (Table I.G.12.–19).

TABLE I.G.12.–19—WAGE INFLATION FOR ALL REAL WORLD TESTING LABOR CATEGORIES, 2017–2024

Labor category	2017 wage	2024 wage	Wage inflation
Computer Systems Analysts	89	108	21.0%
Information Security Analysts	96	103	7.1
Software Developers	107	139	29.9
Database Administrators	86	103	20.1
Network and Computer Systems Administrators	83	97	17.2
Computer Network Architects	104	131	25.6

[612] *https://build.fhir.org/subscriptions.html.*

[613] *https://build.fhir.org/versions.html#maturity.*

[614] *https://build.fhir.org/subscriptions.html.*

[615] *https://www.federalregister.gov/d/2020-07419/p-3125.*

[616] Formula: $109,557/23 = $4,763.

[617] Formula: $4,763 × (1–0.23) = $3,667

TABLE I.G.12.–19—WAGE INFLATION FOR ALL REAL WORLD TESTING LABOR CATEGORIES, 2017–2024—Continued

Labor category	2017 wage	2024 wage	Wage inflation
Computer Occupations, All Other	88	112	27.5
Computer Network Support Specialists	65	77	17.8
All	90	109	21.1

Note: Rates from Bureau of Labor Statistics occupational employment statistics. 2017 rates copied from *85 FR 25642.* 2024 from: *https://data.bls.gov/oes/#/industry/000000.*

Using this cost inflation, we estimate, using all the figures described previously and presented in Table I.G.12.–20 that new annual costs for real world testing will total $3.3 million. However, these costs, would not be incurred at the same time. Developers of certified health IT would be required to meet new 45 CFR 170.315(b)(4) requirements by January 1, 2028. Therefore, related reports and results would not be required until the following year after certification. We assume, beginning in 2027, developers would incur costs to plan, prepare, and report real world testing for this criterion. 45 CFR 170.315(g)(31), (g)(32), and (g)(33), however, do not have a specific certification timeline, but we assume that most developers will certify by January 1, 2027 to comply with current CMS timelines for eligible clinicians, eligible hospitals, and critical access hospitals to report on Electronic Prior Authorization measures during 2027 Promoting Interoperability program year reporting periods. We assume, beginning in 2027, developers would incur costs to plan, prepare, and report real world testing for these criteria.

TABLE I.G.12.–20—ANNUAL REAL WORLD TESTING COST FOR 45 CFR 170.315(g)(31), (g)(32), AND (g)(33) AND 45 CFR 170.315(b)(4)

Criterion	Per criterion cost	New criterion cost (%)	Number of developers	Cost inflation (labor rate)	Total cost (per annum)
45 CFR 170.315(b)(4)	4,763	77%	150	21%	$696,414
45 CFR 170.315(g)(31)	4,763	77	189	21	877,481
45 CFR 170.315(g)(32)	4,763	77	189	21	877,481
45 CFR 170.315(g)(33)	4,763	77	189	21	877,481
All					3,328,857

Notes: Number of developers based on estimates included in respective impact analyses for 45 CFR 170.315(b)(4), (g)(31), (g)(32), and (g)(33). Formula: $[(\$4{,}763 \times (1 - 0.23)) \times N^{developer}]/(1–0.21)$ = Total cost per annum per criterion.

(2) Benefits

We estimated benefits for the original finalization of real world testing as part of the Cures Rule (85 FR 25642) and believe the addition of these new criteria to real world testing will provide additional transparency and awareness of the benefit of these criteria toward improvements in interoperability and how they are deployed in real world settings.

g. Corrections for HTI–2 Final Rule

Corrections for the HTI–2 Final Rule correct erroneous updates and omissions to the CFR and do not create additional burden and effort.

13. Finalization of the Provisions of the FY 2025 IFC

In section XI.C. of the preamble of this final rule, we are finalizing the provisions of the FY 2025 IFC that implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those revisions, and made conforming changes to the hospital IPPS and LTCH PPS payment rates for FY 2025 to reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp.* v. *Becerra.* As discussed in greater detail in that section, after consideration of public comments we are finalizing the provisions of that IFC without modification.

In the FY 2025 IFC (89 FR 80414 through 804020), we presented an impact analysis to illustrate the effects of the provisions of that IFC on hospitals' FY 2025 payments by comparing the total estimated change in payments under the FY 2025 IFC and the total estimated change in payments from the FY 2025 IPPS/LTCH PPS final rule, as corrected. This analysis shows the effects of the removal of the low wage index hospital policy and the application of the transition policy, along with the also include the conforming changes to the rates and factors established in that IFC (for example, the outlier threshold).

We estimate that acute care hospitals will experience an increase of approximately $41 million in FY 2025 due to the provisions of the FY 2025 IFC. This change is primarily due to the application of the non-budget neutral transitional payment exception policy. The estimated change in operating payments is approximately $37 million (discussed in section VI.A. of the FY 2025 IFC). The estimated change in capital payments is approximately $3 million (discussed in section VI.B. of the FY 2025 IFC). The total differs from the sum of the components due to rounding. Table I of section VI.A. of the FY 2025 IFC and Table II of section VI.B. of the FY 2025 IFC demonstrate the estimated redistributional impacts of the provisions of the FY 2025 IFC. As noted previously and as discussed in greater detail in that section, after consideration of public comments as discussed in greater detail in section XI.C. of the preamble of this final rule, we are finalizing the provisions of that IFC without modification. For additional details, refer to the Regulatory Impact Analysis in section VI. of the FY 2025 IFC (89 FR 80414 through 804020).

13. Finalization of the Provisions of the FY 2025 IFC

In section XI.C. of the preamble of this final rule, we are finalizing the provisions of the FY 2025 IFC that implemented revised Medicare wage index values for FY 2025, established a transitional payment exception for low wage hospitals significantly impacted by those revisions, and made conforming changes to the hospital IPPS and LTCH PPS payment rates for FY 2025 to reflect the removal of the low wage index hospital policy following the appellate court decision in *Bridgeport Hosp.* v. *Becerra.* As discussed in greater detail in that section, after consideration of public comments we are finalizing the provisions of that IFC without modification.

In the FY 2025 IFC (89 FR 80414 through 804020), we presented an impact analysis to illustrate the effects of the provisions of that IFC on hospitals' FY 2025 payments by comparing the total estimated change in payments under the FY 2025 IFC and the total estimated change in payments from the FY 2025 IPPS/LTCH PPS final rule, as corrected. This analysis shows the effects of the removal of the low wage index hospital policy and the application of the transition policy, along with the also include the

conforming changes to the rates and factors established in that IFC (for example, the outlier threshold).

We estimate that acute care hospitals will experience an increase of approximately $41 million in FY 2025 due to the provisions of the FY 2025 IFC. This change is primarily due to the application of the non-budget neutral transitional payment exception policy. The estimated change in operating payments is approximately $37 million (discussed in section VI.A. of the FY 2025 IFC). The estimated change in capital payments is approximately $3 million (discussed in section VI.B. of the FY 2025 IFC). The total differs from the sum of the components due to rounding. Table I of section VI.A. of the FY 2025 IFC and Table II of section VI.B. of the FY 2025 IFC demonstrate the estimated redistributional impacts of the provisions of the FY 2025 IFC. As noted previously and as discussed in greater detail in that section, after consideration of public comments as discussed in greater detail in section XI.C. of the preamble of this final rule, we are finalizing the provisions of that IFC without modification. For additional details, refer to the Regulatory Impact Analysis in section VI. of the FY 2025 IFC (89 FR 80414 through 804020).

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2025, there were 94 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 11 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 final rule. The impacts of the changes on LTCHs are discussed in section I.J. of the appendix of this final rule.

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 FY 2026 percentage increase in the 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 second quarter 2025 forecast of the 2023-based IPPS market basket increase, we are estimating the FY 2026 update to be 3.3 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section VI.B. of the preamble of this final rule. Section 1886(b)(3)(B)(xi)(I) of the Act requires a productivity adjustment (0.7 percentage point reduction for FY 2026), resulting in a 2.6 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section VI.B. of the preamble of this final 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 2023-based IPPS operating market basket for FY 2026, currently estimated at 3.3 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 final rule, we used data from the March 2025 update of the FY 2024 MedPAR file and the March 2025 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2025 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 final rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each 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 March 2025 update of the FY 2024 MedPAR file, we simulated payments under the capital IPPS for FY 2025 and the 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 final rule, the update to the capital Federal rate is 2.8 percent for FY 2026.
- In addition to the FY 2026 update factor, the FY 2026 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9918, a budget neutrality factor for the 5-percent cap on wage index decreases policy and the transition for the discontinuation of the low wage index hospital policy of 0.9989, and a outlier adjustment factor of 0.9616.

2. Results

We used the payment simulation model previously described in section I.I. of the Appendix of this final rule to estimate the potential impact of the changes for FY 2026 on total capital payments per case, using a universe of 3,033 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2025 update of the FY 2024 MedPAR file, the March 2025 update to the PSF, and the most recent available cost report data from the March 2025 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2025 and estimated total payments per case for FY 2026 based on the FY 2026 payment policies. Column 2 shows estimates of payments per case under our model for FY 2025. Column 3 shows estimates of payments per case under our model for FY 2026. Column 4 shows the total percentage change in payments from FY 2025

to FY 2026. The change represented in Column 4 includes the 2.8 percent update to the capital Federal rate and other 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 3.2 percent compared to capital payments per case in FY 2025. This expected increase is primarily due to the 2.8 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 changes in GAFs, and are generally consistent with the projected changes in payments due to the changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.F. of the appendix of this final rule.

The net impact of these changes is an estimated 3.2 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 will increase by an estimated 3.2 percent for hospitals in both urban and rural areas from FY 2025 to FY 2026.

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 1.6 percent increase for the New England urban region to a 5.5 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 1.8 percent increase for the Pacific rural region to a 6.6 percent increase for the West North Central rural region. Capital IPPS payments per case for hospitals located in Puerto Rico are projected to decrease by 0.7 percent. These regional differences are primarily due to the changes in the GAFs.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that voluntary hospitals are expected to experience an increase in capital payments per case from FY 2025 to FY 2026 of 3.2 percent. Proprietary hospitals are expected to experience an increase in capital payments per case from FY 2025 to FY 2026 of 3.5 percent. Government hospitals are expected to experience an increase in capital payments per case from FY 2025 to FY 2026 of 3.3 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 final rule for FY 2026, we show the 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 3.5 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 3.0 percent. Rural reclassified hospitals are expected to experience an increase in capital payments per case of 3.2 percent; rural nonreclassified hospitals are expected to experience an increase in capital payments per case of 3.3 percent.

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE

FY 2025 Payments compared to FY 2026 payments	Number of hospitals	Average FY 2025 payments/case	Average FY 2026 payments/case	Change
All Hospitals	3,033	1,182	1,220	3.2
By Geographic Location:				
Urban hospitals	2,372	1,215	1,254	3.2
Rural hospitals	661	814	840	3.2
Bed Size (Urban):				
0–99 beds	647	903	935	3.5
100–199 beds	673	1,017	1,046	2.9
200–299 beds	406	1,111	1,146	3.2
300–499 beds	392	1,213	1,251	3.1
500 or more beds	252	1,442	1,493	3.5
Bed Size (Rural):				
0–49 beds	313	675	699	3.6
50–99 beds	180	781	805	3.1
100–149 beds	95	787	815	3.6
150–199 beds	42	889	918	3.3
200 or more beds	31	981	1,007	2.7
Urban by Region:				
New England	104	1,314	1,335	1.6
Middle Atlantic	274	1,365	1,419	4.0
East North Central	366	1,138	1,170	2.8
West North Central	156	1,137	1,199	5.5
South Atlantic	393	1,072	1,113	3.8
East South Central	141	1,000	1,032	3.2
West South Central	355	1,097	1,142	4.1
Mountain	180	1,219	1,254	2.9
Pacific	351	1,552	1,581	1.9
Rural by Region:				
New England	19	1,052	1,081	2.8
Middle Atlantic	48	938	969	3.3
East North Central	106	815	834	2.3
West North Central	74	799	852	6.6
South Atlantic	108	747	768	2.8
East South Central	127	732	747	2.0
West South Central	116	722	748	3.6
Mountain	39	865	904	4.5
Pacific	24	1,055	1,074	1.8
Puerto Rico:				
Puerto Rico Hospitals	52	609	605	-0.7
By Payment Classification:				
Urban hospitals	1,611	1,116	1,149	3.0
Rural areas	1,422	1,232	1,275	3.5

TABLE III.—COMPARISON OF TOTAL PAYMENTS PER CASE—Continued

FY 2025 Payments compared to FY 2026 payments	Number of hospitals	Average FY 2025 payments/case	Average FY 2026 payments/case	Change
Teaching Status:				
Nonteaching	1,756	965	995	3.1
Fewer than 100 residents	986	1,103	1,140	3.4
100 or more residents	291	1,594	1,647	3.3
Urban DSH:				
Non-DSH	346	1,011	1,052	4.1
100 or more beds	909	1,159	1,191	2.8
Less than 100 beds	356	831	856	3.0
Rural DSH:				
Non-DSH	93	1,115	1,152	3.3
SCH	227	837	868	3.7
RRC	863	1,277	1,321	3.4
100 or more beds	41	1,108	1,159	4.6
Less than 100 beds	198	685	705	2.9
Urban teaching and DSH:				
Both teaching and DSH	527	1,215	1,249	2.8
Teaching and no DSH	58	1,084	1,125	3.8
No teaching and DSH	738	1,022	1,050	2.7
No teaching and no DSH	288	967	1,007	4.1
Special Hospital Types:				
RRC	131	916	938	2.4
RRC with Section 401 Rural Reclassification	657	1,328	1,374	3.5
SCH	218	788	814	3.3
SCH with Section 401 Rural Reclassification	37	969	1,004	3.6
SCH and RRC	119	882	912	3.4
SCH and RRC with Section 401 Rural Reclassification	49	1,128	1,175	4.2
Type of Ownership:				
Voluntary	1,902	1,183	1,221	3.2
Proprietary	724	1,094	1,132	3.5
Government	406	1,284	1,326	3.3
Medicare Utilization as a Percent of Inpatient Days:				
0–25	1,548	1,247	1,290	3.4
25–50	1,388	1,117	1,151	3.0
50–65	65	1,117	1,161	3.9
Over 65	13	936	988	5.6
Medicaid Utilization as a Percent of Inpatient Days:				
0–25	1,917	1,084	1,120	3.3
25–50	992	1,337	1,381	3.3
50–65	91	1,512	1,549	2.4
Over 65	32	1,565	1,589	1.5
FY 2026 Reclassifications:				
All Reclassified Hospitals	1,093	1,231	1,272	3.3
Non-Reclassified Hospitals	1,940	1,126	1,161	3.1
Urban Hospitals Reclassified	979	1,282	1,327	3.5
Urban Non-Reclassified Hospitals	1,407	1,112	1,145	3.0
Rural Hospitals Reclassified Full Year	268	833	860	3.2
Rural Non-Reclassified Hospitals Full Year	379	784	810	3.3
All Section 401 Rural Reclassified Hospitals	811	1,297	1,343	3.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	50	830	856	3.1

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section IX. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2026. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2026, and present rationales for our provisions as well as alternatives that were considered. In this section, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 329 LTCHs included in this impact analysis. We note that, although there are currently approximately 336 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 IX.B.3. of the preamble of this final rule). Moreover, in the claims data used for this final rule, two of the 329 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 payment rate, factors, and policies presented in this final rule, the 2.7 percent annual update to the LTCH PPS standard Federal payment rate, the update to the MS–LTC–DRG classifications and relative weights, the 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 329 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2026 will increase by approximately 3.3 percent (or approximately $83 million) based on the rates and factors presented in section IX. of the preamble and section V. of the Addendum to this final rule.

Based on the FY 2024 LTCH cases that were used for the analysis in this final rule, approximately 9 percent of those cases were classified as site neutral payment rate cases (that is, 9 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). In section IX.B.3.b of the preamble of this final rule, 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 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 10.0 percent (or approximately $10 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the updates to the IPPS rates and 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 charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this final rule. We note that we estimate payments to site neutral payment rate cases in FY 2026 will represent approximately 4.1 percent of estimated aggregate FY 2026 LTCH PPS payments.

Based on the FY 2024 LTCH cases that were used for the analysis in this final rule, approximately 91 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 3.0 percent (or approximately $73 million). This estimated increase in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2026 is primarily due to the 2.7 percent annual update to the LTCH PPS standard Federal payment rate and a projected 0.4 percent increase 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 329 LTCHs that were represented in the FY 2024 LTCH cases that were used for the analyses in this final rule presented in this appendix, we estimate that aggregate FY 2026 LTCH PPS payments will be approximately $2.583 billion, as compared to estimated aggregate FY 2025 LTCH PPS payments of approximately $2.500 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $83 million. We note that the estimated $83 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 policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2025 is $49,383.26. For FY 2026, we are establishing an LTCH PPS standard Federal payment rate of $50,824.51 which reflects the 2.7 percent annual update to the LTCH PPS standard Federal payment rate and the budget neutrality factor for updates to the area wage level adjustment of 1.0021275 (discussed in section V.B.6. of the Addendum to this final 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 establishing an LTCH PPS standard Federal payment rate of $49,834.74. This LTCH PPS standard Federal payment rate reflects the 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 annual update of 2.7 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.6 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 2.6 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 2.6 percent.

For FY 2026, we are updating 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 establishing a labor-related share of 72.9 percent for FY 2026, based on the most recent available data (IGI's second quarter 2025 forecast) of the relative importance of the labor-related share of operating and capital costs of the 2022-based LTCH market basket. We are also applying an area wage level budget neutrality factor of 1.0021275 to ensure that the 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 increase from FY 2025 to FY 2026. Based on the FY 2024 LTCH cases that were used for the analyses in this final 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 be less than the 7.975 percent target. Specifically, using those FY 2024 cases we currently estimate that high-cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 7.6 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 increase in high-cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 0.4 percentage point 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 charge inflation factor described in section V.D.3.b. of the Addendum to this final 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 finalized methodology described in section V.D.3.b. of the Addendum to this final rule.

Table IV shows the estimated impact of the 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.

Comment: A commenter expressed concern whether the proposed payment rate update will adequately support the operational and clinical demands faced by LTCHs. The commenter stated that these facilities provide extended inpatient care for patients with severe and complex conditions that often require prolonged mechanical ventilation, intensive wound management, or post-sepsis recovery. The commenter stated that unlike general acute care hospitals, LTCHs must sustain high staffing ratios and specialized clinical protocols for weeks or months at a time, yet are reimbursed under models that

assume tighter, episodic cost predictability. The commenter urged CMS to assess whether the current MS–LTC–DRG weighting methodology and outlier thresholds capture the intensity and unpredictability of extended LTCH care.

Response: We appreciate commenters' concerns about the proposed 2.2 percent increase in payment to LTCH PPS standard Federal payment rate cases. As explained in the proposed rule (89 FR 36635), that estimated increase of approximately 2.2 percent was 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 payment. We received several comments on the proposed annual update to the LTCH PPS standard Federal payment rate which we have summarized and responded to in sections IX.C. of the preamble to this final rule. We also received several comments on the proposed fixed-loss amount for high-cost outlier cases which we have summarized and responded to in section V.D.3. of the Addendum to this final rule.

Based on the finalized payment rates and factors in this final rule, we now project a 3.0 percent increase in payments to LTCH PPS standard Federal payment rate cases for FY 2026 (as compared to our projection of 2.2 percent in the proposed rule). This increase in our projected percentage change in payments is partially being driven by an increase to the annual update for FY 2026 based on the updated data available for this final rule. The final annual update factor of 2.7 percent is 0.1 percentage point higher than the proposed annual update factor. As discussed in section IX.C.2. of the preamble to this final rule, we believe this LTCH market basket increase appropriately reflects the input price growth that LTCHs will incur providing medical services in FY 2026. The increase in our projected percentage change in payments is also partially being driven by a downward revision in this final rule to our estimate of FY 2025 high cost outlier payments to LTCH PPS standard Federal payment rate cases. In this final rule, after incorporating into our payment model more recent data, as discussed in section V.D.3. of the Addendum to this final rule, we now estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will increase payments by approximately 0.4 percentage point (rather than decrease payments by approximately 0.3 percentage points as projected in the proposed rule based on the best data available at that time).

As we discuss in detail throughout this final rule, based on the best available data, we believe that the provisions of this final 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 3.0 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 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2026, the 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 LTCH PPS Payment Rate Changes and Policy Changes

a. 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 $83 million. This estimated increase in payments reflects the projected increase in payments to LTCH PPS standard Federal payment rate cases of approximately $73 million and the projected increase in payments to site neutral payment rate cases of approximately $10 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 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 changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. 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 final 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 rates, factors, and the policies in this final rule (as discussed in section IX. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final 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 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. 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 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 FY 2026 LTCH PPS standard Federal payment rate, we used the FY 2026 standard Federal payment rate of $50,824.51 (or $49,834.74 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable 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 FY 2026 LTCH PPS payments, we used the FY 2026 LTCH PPS labor-related share (72.9 percent), the FY 2026 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2026 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $78,936 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2026 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2026 nonlabor-related share (27.1 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 charge inflation factors in section V.D.3.b. of the Addendum to this final 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 methodology described in section V.D.3.b. of the Addendum to this final 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 final 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 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 annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final 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 changes to the area wage level adjustment (that is, the updated hospital wage data and the labor-related share) and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final 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 changes.

TABLE IV—IMPACT OF 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	No. 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	43,513	55,243	56,921	2.6	0.0	3.0
BY LOCATION:							
RURAL	17	1,343	43,770	45,084	2.6	−0.1	3.0
URBAN	310	42,170	55,608	57,298	2.6	0.0	3.0
BY OWNERSHIP TYPE:							
VOLUNTARY	53	5,032	59,674	62,211	2.5	0.5	4.3
PROPRIETARY	266	37,937	54,408	55,959	2.6	−0.1	2.9
GOVERNMENT	8	544	72,473	75,072	2.6	−0.8	3.6
BY REGION:							
NEW ENGLAND	10	1,334	49,914	51,487	2.7	0.8	3.2
MIDDLE ATLANTIC	20	3,018	63,843	66,684	2.6	0.5	4.5
SOUTH ATLANTIC	60	9,465	53,164	54,968	2.6	0.5	3.4
EAST NORTH CENTRAL	46	5,490	56,164	58,382	2.6	0.3	3.9
EAST SOUTH CENTRAL	32	3,288	48,779	50,813	2.6	0.7	4.2
WEST NORTH CENTRAL	21	2,369	51,090	53,305	2.6	1.0	4.3
WEST SOUTH CENTRAL	90	10,627	49,756	50,513	2.6	−0.7	1.5
MOUNTAIN	25	2,143	56,880	58,407	2.6	0.0	2.7
PACIFIC	23	5,779	69,371	71,080	2.5	−0.9	2.5
BY BED SIZE:							
BEDS: 0–24	37	2,272	54,222	55,441	2.6	−0.3	2.2
BEDS: 25–49	153	16,905	49,188	50,704	2.6	0.4	3.1
BEDS: 50–74	75	10,868	56,321	58,181	2.6	0.1	3.3
BEDS: 75–124	42	8,179	63,707	65,674	2.6	−0.3	3.1

TABLE IV—IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2026—Continued

[Estimated FY 2025 payments compared to estimated FY 2026 payments]

LTCH Classification	No. 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)
BEDS: 125+	20	5,289	59,727	61,304	2.6	−0.5	2.6

[1] Estimated FY 2026 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final 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 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 changes to the area wage level adjustment under § 412.525(c) (that is, the updated hospital wage data and the 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 changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge due to all changes, does not equal the sum of the percent changes in estimated payments per discharge due to the annual update to the LTCH PPS standard Federal payment rate (Column 6) and due to the 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 final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final 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 3.0 percent, on average, for all LTCHs from FY 2025 to FY 2026 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 3.0 percent increase in LTCH PPS payments per discharge was determined by comparing estimated FY 2026 LTCH PPS payments (using the payment rates and factors discussed in this final 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 finalizing an annual update to the LTCH PPS standard Federal payment rate for FY 2026 of 2.7 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 budget neutrality factor for changes to the area wage level adjustment of 1.0021275 (discussed in section V.B.6. of the Addendum to this final rule), based on the best available data at this time, to ensure that any 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 rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 2.7 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.6 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 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 average percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2025 to FY 2026 is 3.0 percent for LTCHs located in both urban and rural areas.

(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 2.9 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 4.3 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 3.6 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 1.5 percent in the West South Central region to 4.5 percent in the Middle Atlantic region. These regional variations are primarily due to the 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 3.3 percent. The remaining bed size categories are projected to experience an increase in payments in the range of 2.2 to 3.1 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final 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 $73 million (or approximately 3.0 percent) for the 329 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 final 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 $10 million (or approximately 10.0 percent) for the 329 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2026 will represent approximately 4.1 percent of total estimated FY 2026 LTCH PPS payments.) Therefore, we project that the provisions of

this final 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 $83 million (or approximately 3.3 percent) for the 329 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 final 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 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 final rule, we discuss the finalized requirements for hospitals reporting quality data under the Hospital IQR Program to receive the full annual percentage increase for the FY 2026 payment determination and subsequent years.

In this final rule, we are: (1) modifying 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) modifying 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) modifying 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) modifying 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) removing the Hospital Commitment to Health Equity measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (6) removing the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (7) removing the Screening for Social Drivers of Health measure beginning with the CY 2024 reporting period/FY 2026 payment determination; and (8) removing 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 final rule, we estimate a decrease of 627,027 hours at a savings of $16,116,129 in information collection burden associated with the finalized 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 finalized 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 final rule, we are modifying reporting requirements of the Hybrid HWR and HWM measures beginning with the FY 2028 payment determination. This modification will 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 will result in reducing the overall administrative burden required by hospitals to report these measures.

Regarding the remaining proposals, we do not believe any of these proposals will result in any additional economic impact beyond those discussed in section XIII.B.4. of the preamble of this final 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.

We received no comments on our assumptions regarding these effects.

L. Effects of New Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section X.D. of the preamble of this final rule, we discuss finalized 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 this final rule, we are: (1) removing the Hospital Commitment to Health Equity measure beginning with the FY 2026 program year; (2) removing the Screening for Social Drivers of Health measure beginning with the FY 2026 program year; and (3) removing the Screen Positive Rate for Social Drivers of Health measure beginning with the FY 2026 program year. We are also modifying 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 final rule, we estimate a decrease of 107 hours at a savings of $2,921 in information collection burden associated with the finalized 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 policies will result in any additional economic impact beyond those discussed in section XIII.B.5. of the preamble of this final rule (Collection of Information).

We received no comments on our assumptions regarding these effects.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section X.E.3. of this final rule, we are finalizing our proposal 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 this final rule, we are finalizing 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. Additionally, we are finalizing our proposal 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 proposed rule, we sought 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 final 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 ESTIMATE

Occupational title	Occupation code	Median hourly wage ($/hr)	Other indirect costs and fringe benefits ($/hr)	Adjustes hourly wage ($/hr)
Medical Records Specialist	29–2072	$23.45	$23.45	$49.60

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 this final 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 this final 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.

We have summarized the comments we received about modifying reporting requirements for the Patient/Resident COVID–19 Vaccination Measure in section X.E.3. of this final rule, removing four standardized patient assessment data elements collected under the SDOH category in section X.E.4. of this final rule, and amending the reconsideration policy and process in X.E.5. of this final rule, and provided responses. We did not receive comments specific to the estimates. After consideration of the public comments, we are finalizing these proposals without modification.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section X.F. of the preamble of this final rule, we discuss finalized 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 this final rule, we are: (1) adopting 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) modifying 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) modifying 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 by the HIPAA Security Rule beginning with the EHR reporting period in CY 2026; and (4) defining the 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 making corresponding revisions at 42 CFR 495.4.

As discussed in section XIII.B.7. of the preamble of this final 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 final 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 final rule, we are adopting 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 to set up and technically validate the functioning of the information exchange. 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 or other entities through which they participate in TEFCA. However, because each eligible hospital, CAH, and health IT vendor or other entity 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 final rule, we are modifying 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 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 final rule, we are modifying the Security Risk Analysis measure to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management as required by the HIPAA Security Rule at 45 CFR 164.308(a)(1)(ii)(B) beginning with the EHR reporting period in CY 2026. While we proposed to require eligible hospitals and CAHs to attest ''yes'' to having conducted security risk management, the costs associated with performing security risk management required by 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 final rule. We received no comments on our assumptions regarding these effects.

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the 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 final 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 final 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 final 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 reduce Medicare expenditures. This is because all the options considered give some financial protection to low volume hospitals. 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 solicited and welcomed comments on our proposals, on the alternatives we have identified, and on other alternatives that we should consider. In each section of the final rule that we received comments on alternatives considered we have addressed them accordingly, including the policy for low volume hospitals.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $5.0 billion in FY 2026, including operating, capital, and the effects of: (1) new technology add-on payment changes; (2) the 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 $4.97 billion (discussed in sections I.F. of this Appendix). The estimated change in capital payments is approximately $0.25 billion (discussed in section I.I. of this Appendix). The estimated change in the combined effects of other 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 −$0.18 billion as discussed in sections I.F. and I.G. of the Appendix of this final rule. Totals may differ from the sum of the components due to rounding.

Table I. of section I.F. of the Appendix of this final rule also demonstrates the estimated redistributional impacts of the FY 2026 changes on IPPS payments relative to FY 2025.

We estimate that hospitals will experience a 3.2 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 $251 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 final 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 final 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 329 LTCHs included in our analysis, we estimate that overall FY 2026 LTCH PPS payments would increase approximately $83 million relative to FY 2025, primarily due to the 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 would review the final rule, we assumed that the total number of timely pieces of correspondence on this year's proposed rule would be the number of reviewers of the final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed this 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 the final 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 5,409 number of timely pieces of correspondence on the FY 2026 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of the final 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.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $132.44 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 24.56 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $3,252.73 (24.56 hours × $132.44). Therefore, we estimate that the total cost of reviewing this final rule is $17,594,017 ($3,252.73 × 5,409 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 final 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 changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of the Appendix of this final rule, the net costs to the Federal Government associated with the policies in this final rule are estimated at $5.0 billion.

TABLE V—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2025 TO FY 2026

Category	Trannsfers
Annualized Monetized Transfers.	$5.0 billion.
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of the Appendix of this final rule, the impact analysis of the payment rates and factors presented in this final 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 $83 million based on the data for 329 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 the Appendix of this final rule, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final 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 final rule based on the data for the 329 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of the Appendix of this final rule, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $83 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.	$83 million.
From Whom to Whom	Federal Government to LTCH Medicare Providers.

C. HTI–2

We estimate that the total annual cost to developers of certified health IT for this final rule for the first year after it is finalized (including one-time costs), based on the cost estimates outlined previously and throughout, would result in $50.3 million. The total undiscounted cost over a 10-year period to developers for this final rule (starting in year two), based on cost estimates outlined previously, would result in $177.6 million. We estimate the total costs to developers over a 10-year period for this final rule to be $228 million.

We estimate the total annual benefit across all entities for progress toward interoperability (progress initiated by adoption of the criteria and standards set forth in this final rule, then implemented with intermediate activities that connect such adoption with the generation of benefits) beginning in 2027, when the associated policies are required to be implemented and expected benefits to be realized, would be on average $1.0 billion. We estimate the total benefits across all entities to be $19.2 billion. This benefits estimate is not comparable with the quantification of costs (totaling $228 million) because the cost of some intermediate activities has not been estimated and the cost of other intermediate activities has been attributed to other regulatory provisions, such as the ones finalized by CMS at 89 FR 8758.

TABLE VII—E.O. 12866 SUMMARY TABLE (IN $ MILLIONS, 2024 DOLLARS): HTI

	Primary (3%)	Primary (7%)
Present Value of Quantified Costs	$210,331,976.62	$190,350,533.75
Annualized Quantified Costs	24,657,324.17	27,101,633.64

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 final 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 final 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 final rule is expected to have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,033 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2026,'' on average are expected to see increases in the range of 4.3 percent, primarily due to the hospital rate update and uncompensated care payments, as discussed in section I.F. of the Appendix of this final rule. On average, the rate update for these hospitals is estimated to be 2.5 percent and

uncompensated care payments are estimated to increase payments in FY 2026 by 1.7 percent for all hospitals.

The 327 LTCH PPS hospitals included in the impact analysis shown in ''Table IV: Impact of 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)'' on average are expected to see an increase of approximately 3.0 percent, primarily due to the annual standard Federal rate update for FY 2026 (2.7 percent) and a projected 0.4 percent increase in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of the Appendix of this final rule.

This final rule contains a range of policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized 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 final rule constitutes our regulatory flexibility analysis. We sought public comments on our estimates and analysis of the impact of our policies 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 the Appendix of this final rule, rural IPPS hospitals with 0–49 beds (313 hospitals) are expected to experience an increase in payments from FY 2025 to FY 2026 of 3.0 percent and rural IPPS hospitals with 50–99 beds (180 hospitals) are expected to experience an increase in payments from FY 2025 to FY 2026 of 1.7 percent. These changes are primarily driven by the hospital rate update and the increase in estimated uncompensated care payment offset by the statutory expiration of the MDH program and the budget neutral changes to the MS–DRGs and relative weights. We refer readers to Table I. in section I.F. of the Appendix of this final rule for additional information on the quantitative effects of the policy changes under the IPPS for operating costs.

All rural LTCHs (17 hospitals) shown in Table IV. in section I.J. of the Appendix of this final rule have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2025 to FY 2026 of 3.0 percent. This increase is primarily due to the combination of the 2.7 percent annual update to the LTCH PPS standard Federal payment rate for FY 2026, the changes to the area wage level adjustment, and estimated changes in outlier payments as discussed in section I.J. of the Appendix of this final rule.

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 final 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 final 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 final 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 use input received from these consultations, as well as the comments on the proposed rule, to inform our 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.

IX. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

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. FY 2026 Inpatient Hospital Update

As discussed in section VI.B. of the preamble to this final 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 percentage increase 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 percentage increase 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 final rule, we are replacing the 2018-based IPPS operating and capital market baskets with the rebased and revised 2023-based IPPS operating and capital market baskets beginning in FY 2026.

In the FY 2026 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed 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 was 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 the FY 2026 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2024 forecast, we proposed a productivity adjustment of 0.8 percentage point for FY 2026. We also proposed that if more recent data subsequently became 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.

In the FY2026 IPPS/LTCH proposed rule, 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 presented four possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentages increase for the FY 2026 updates based on IGI's second quarter 2025 forecast of the 2023-based IPPS market basket percentage increase of 3.3 percent and the productivity adjustment of 0.7 percentage point, as discussed in section VI.B of the preamble of this final rule, 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, as shown in the table that follows.

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
IPPS Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	−0.825	−0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	−2.475	0.0	−2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	−0.7	−0.7	−0.7	−0.7
Applicable Percentage Increase Applied to Standardized Amount	2.6	0.125	1.775	−0.7

B. 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 final 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 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 final 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 establishing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs.

C. 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 final rule.

In addition, as discussed in section VI.B.2. of the preamble of this final 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 the 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 proposed 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, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we proposed 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 proposed 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 proposed 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 proposed that if more recent data subsequently became 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.

As discussed in section VI.B.1. of the preamble of this final rule, based on more recent data available for this FY 2026 IPPS/LTCH PPS final rule, we estimate that the FY 2026 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent less a productivity adjustment of 0.7 percentage point. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket rate-of-increase is 3.3 percent reduced by a productivity adjustment of 0.7 percentage point. 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 determined 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, an applicable percentage increase to the FY 2026 operating standardized amount of 2.6 percent (that is, the FY 2026 estimate of the market basket rate-of-increase of 3.3 percent reduced by 0.7 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 0.125 percent (that is, the FY 2026 estimate of the market basket rate-of-increase of 3.3 percent, less an adjustment of 2.475 percentage point (the market basket rate-of-increase of 3.3 percent $\times$ 0.75 for failure to be a meaningful EHR user), and reduced by 0.7 percentage point for the productivity adjustment).

D. 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 final rule, we are finalizing to use the percentage increase in the 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 2023-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2026 is 3.3 percent.

E. 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 final rule, we are updating the LTCH PPS standard Federal payment rate for FY 2026 by 2.7 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 QRP under section 1886(m)(5) of the Act, we are reducing 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 establishing an update factor of 1.027 in determining the LTCH PPS standard Federal rate for FY 2026. For LTCHs that fail to submit quality data for FY 2026, we are establishing an annual update to the LTCH PPS standard Federal rate of 0.7 percent (that is, the annual market basket update for FY 2026 of 2.7 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 an update factor of 1.007 in determining the LTCH PPS standard Federal rate for FY 2026. (We note that, as discussed in section IX.C. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 2.7 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 3.3 percent.

For FY 2026, consistent with policy set forth in section IX.C. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 2.7 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 0.7 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 establishing an applicable percentage increase for FY 2026 of 2.6 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 final 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 the preamble of this final rule for further discussion of Medicare DSH and uncompensated care payments.

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