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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 410, 412, 413, 415, 416, and 419

Office of the Secretary

45 CFR Part 180

[CMS-1834-P]

RIN 0938-AV51

Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

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

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the Medicare Hospital Outpatient Prospective Payment System (OPPS) and the Medicare Ambulatory Surgical Center (ASC) payment system for calendar year 2026 based on our continuing experience with these systems. We also describe the changes to the amounts and factors used to determine the payment rates for Medicare services paid under the OPPS and those paid under the ASC payment systems. This proposed rule would also update and refine the requirements for the Hospital Outpatient Quality Reporting Program, Rural Emergency Hospital Quality Reporting Program, Ambulatory Surgical Center Quality Reporting Program, Overall Hospital Quality Star Rating, and hospitals to make public their standard charge information and enforcement of hospital price transparency. This rule also contains requests for information on measure concepts regarding Well-Being and Nutrition for consideration in future years for all three programs (OQR, REHQR, and ASCQR; expanding the method to control for unnecessary increases in the volume of covered OPD services to on-

campus clinic visits; software as a service; and adjusting payment under the OPPS for services predominately performed in the ambulatory surgical center or physician office settings.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, by **[**Insert date 60 days after date of filing for public inspection at the **Federal Register**].

ADDRESSES: In commenting, please refer to file code CMS-1834-P.

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

1. *Electronically*. You may submit electronic comments on this regulation to ***http://www.regulations.gov***. Follow the "Submit a comment" instructions.

2. *By regular mail*. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1834-P,

P.O. Box 8010,

Baltimore, MD 21244-8010.

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

3. *By express or overnight mail*. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-1834-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Regulation coordination questions, contact Gina Aughenbaugh via email at *OutpatientPPS@cms.hhs.gov*.

Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m) Derived from Domestically Produced Molybdenum-99, contact Au'Sha Washington via email at *ausha.washington@cms.hhs.gov* or Leone Kisler at *leone.kisler@cms.hhs.gov*.

Adjusting Payment under the OPPS for Services Predominantly Performed in the ASC or Physician Office Settings Request for Information, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

Advisory Panel on Hospital Outpatient Payment (HOP Panel), contact the HOP Panel mailbox at *APCPanel@cms.hhs.gov*.

Ambulatory Surgical Center Covered Procedures List (ASC CPL), contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program measures, contact Marsha Hertzberg via email at *Marsha.Hertzberg@cms.hhs.gov*.

Ambulatory Surgical Center Quality Reporting (ASCQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service (IHS) and Tribal Facilities, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

Blood and Blood Products, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

Cancer Hospital Payments, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

CMS Web Posting of the OPPS and ASC Payment Files, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*.

Composite APCs (Multiple Imaging and Mental Health) and Comprehensive APCs (C-APCs), contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov.*

Device-Intensive Status and No Cost/Full Credit and Partial Credit Devices, contact Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

Graduate Medical Education (GME) Accreditation, contact *DAC@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program policies, contact Kimberly Go via email at *Kimberly.Go@cms.hhs.gov*.

Hospital Outpatient Quality Reporting (OQR) Program measures, contact Kristina Rabarison via email at *Kristina.Rabarison@cms.hhs.gov*.

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Hospital Price Transparency, contact Sarah Wheat via email at *PriceTransparencyHospitalCharges@cms.hhs.gov.*

Inpatient Only (IPO) Procedures List, contact Abigail Cesnik via email at *Abigail.Cesnik@cms.hhs.gov.*

Market-Based Data Collection and Market-Based MS–DRG Relative Weight Methodology Issues, contact *DAC@cms.hhs.gov*.

Medical Review of Certain Inpatient Hospital Admissions under Medicare Part A for CY 2026 and Subsequent Years (2-Midnight Rule), contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

Medicare OPPS Drug Acquisition Cost Survey, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* or Gil Ngan at *Gil.Ngan@cms.hhs.gov* or Nate Vercauteren at *Nathan.Vercauteren@cms.hhs.gov*.

Method to Control Unnecessary Increases in the Volume of Outpatient Services, contact Elise Barringer via email at *Elise.Barringer@cms.hhs.gov*.

New Technology Intraocular Lenses (NTIOLs), contact Scott Talaga via email at Scott.Talaga@cms.hhs.gov.

Non-Opioid Policy or Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov* or Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

OPPS Brachytherapy, contact Cory Duke via email at Cory.Duke@cms.hhs.gov and Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Data (APC Weights, Conversion Factor, Copayments, Cost-to-Charge Ratios (CCRs), Data Claims, Geometric Mean Calculation, Outlier Payments, and Wage Index), contact Erick Chuang via email at *Erick.Chuang@cms.hhs.gov* or Scott Talaga via email at *Scott.Talaga@cms.hhs.gov*.

OPPS Drugs, Radiopharmaceuticals, Biologicals, and Biosimilar Products, contact Gil Ngan via email at *Gil.Ngan@cms.hhs.gov*, Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

OPPS New Technology Procedures/Services, contact the New Technology APC mailbox at *NewTechAPCapplications@cms.hhs.gov*.

OPPS Packaged Items/Services, contact Cory Duke via email at *Cory.Duke@cms.hhs.gov*.

OPPS Pass-Through Devices, contact the Device Pass-Through mailbox at *DevicePTapplications@cms.hhs.gov*.

OPPS Status Indicators (SI) and Comment Indicators (CI), contact Marina Kushnirova via email at *Marina.Kushnirova@cms.hhs.gov* or Tonya Gierke at *Tonya.Gierke@cms.hhs.gov.*

Overall Hospital Quality Star Rating policies, contact Tyson Nakashima Sr. via email *Tyson.Nakashima@cms.hhs.gov*.

Partial Hospitalization Program (PHP), Intensive Outpatient (IOP), and Community Mental Health Center (CMHC) Issues, contact the PHP Payment Policy Mailbox at *PHPPaymentPolicy@cms.hhs.gov*.

Remote Services, contact Elise Barringer via email at Elise.Barringer@cms.hhs.gov or Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program policies, contact Anita Bhatia via email at *Anita.Bhatia@cms.hhs.gov*.

Rural Emergency Hospital Quality Reporting (REHQR) Program measures, contact Melissa Hager via email at *Melissa.Hager@cms.hhs.gov*.

Skin Substitute Products, contact Susan Janeczko via email at *Susan.Janeczko@cms.hhs.gov*, Cory Duke via email at *Cory.Duke@cms.hhs.gov*, or Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

Software as a Service, contact Nicole Marcos via email at *Nicole.Marcos@cms.hhs.gov*.

Virtual Direct Supervision of Outpatient Therapeutic and Diagnostic Services in Hospitals and CAHs, contact Nate Vercauteren via email at *Nathan.Vercauteren@cms.hhs.gov*.

All Other Issues Related to Hospital Outpatient Payments Not Previously Identified, contact the OPPS mailbox at *OutpatientPPS@cms.hhs.gov*.

All Other Issues Related to the Ambulatory Surgical Center Payments Not Previously Identified, contact the ASC mailbox at *ASCPPS@cms.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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

acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

Plain Language Summary: In accordance with 5 U.S.C. 553(b)(4), a plain language summary of this rule may be found at *https://www.regulations.gov/*.

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

Addenda Available Only Through the Internet on the CMS Website

In the past, a majority of the Addenda referred to in our OPPS/ASC proposed and final rules were published in the **Federal Register** as part of the annual rulemakings. However, beginning with the calendar year (CY) 2012 OPPS/ASC proposed rule, all of the Addenda no longer appear in the **Federal Register** as part of the annual OPPS/ASC proposed and final rules to decrease administrative burden and reduce costs associated with publishing lengthy tables. Instead, these Addenda are published and available only on the CMS website. The Addenda relating to the OPPS are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. The Addenda relating to the ASC payment system are available at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices*.

Current Procedural Terminology (CPT) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2025 American Medical Association (AMA). All Rights Reserved. CPT is a registered trademark of the AMA. Applicable Federal Acquisition Regulations and Defense Federal Acquisition Regulations apply.

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I. Summary and Background

A. Executive Summary of this Document

1. Purpose

We propose to update the payment policies and payment rates for services furnished to Medicare beneficiaries in hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs), beginning January 1, 2026. Section 1833(t) of the Social Security Act (the Act) requires us to annually review and update the payment rates for services payable under the

Hospital Outpatient Prospective Payment System (OPPS). Specifically, section 1833(t)(9)(A) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) to review certain components of the OPPS not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practice, changes in technology, and the addition of new services, new cost data, and other relevant information and factors. In addition, under section 1833(i)(D)(v) of the Act, we annually review and update the ASC payment rates. This proposed rule also includes additional policy changes made in accordance with our experience with the OPPS and the ASC payment system and recent changes in our statutory authority. We describe these and various other statutory authorities in the relevant sections of this proposed rule. In addition, this proposed rule would update the requirements for the Hospital Outpatient Quality Reporting (OQR), the Rural Emergency Hospital Quality Reporting (REHQR), the Ambulatory Surgical Center Quality Reporting (ASCQR) Programs, and Overall Hospital Quality Star Rating. Finally, we would also update and refine the requirements for hospitals to make public their standard charges and CMS enforcement of hospital price transparency (HPT) regulations.

Please note, some sections of this proposed rule contain a request for information (RFI). In accordance with the implementing regulations of the Paperwork Reduction Act of 1995 (PRA), specifically 5 CFR 1320.3(h)(4), these general solicitations are exempt from the PRA. Facts or opinions submitted in response to general solicitations of comments from the public, published in the **Federal Register** or other publications, regardless of the form or format thereof, provided that no person is required to supply specific information pertaining to the commenter, other than that necessary for self-identification, as a condition of the agency's full consideration, are not generally considered information collections and therefore not subject to the PRA.

Respondents are encouraged to provide complete but concise responses. These RFIs are issued solely for information and planning purposes; they do not constitute a Request for Proposal (RFP), applications, proposal abstracts, or quotations. These RFIs do not commit the

U.S. Government to contract for any supplies or services or make a grant award. Further, CMS is not seeking proposals through these RFIs and will not accept unsolicited proposals. Responders are advised that the U.S. Government will not pay for any information or administrative costs incurred in response to these RFIs; all costs associated with responding to these RFIs will be solely at the interested party's expense. Not responding to these RFIs does not preclude participation in any future procurement, if conducted. It is the responsibility of the potential responders to monitor these RFI announcements for additional information pertaining to these requests.

Please note that CMS will not respond to questions about the policy issues raised in these RFIs. CMS may or may not choose to contact individual responders. Such communications would only serve to further clarify written responses. Contractor support personnel may be used to review RFI responses. Responses to this notice are not offers and cannot be accepted by the U.S. Government to form a binding contract or issue a grant. Information obtained as a result of these RFIs may be used by the U.S. Government for program planning on a non-attribution basis. Respondents should not include any information that might be considered proprietary or confidential. These RFIs should not be construed as a commitment or authorization to incur cost for which reimbursement would be required or sought. All submissions become U.S. Government property and will not be returned. CMS may publicly post the comments received, or a summary thereof.

2. Summary of the Major Provisions

- *OPPS Update*: For CY 2026, we propose to increase the payment rates under the OPPS by an Outpatient Department (OPD) fee schedule increase factor of 2.4 percent. This increase factor is based on the proposed inpatient hospital market basket percentage increase of 3.2 percent for inpatient services paid under the hospital inpatient prospective payment system (IPPS) reduced by a proposed productivity adjustment of 0.8 percentage point. Based on this update, we estimate that total payments to OPPS providers (including beneficiary cost sharing

and estimated changes in enrollment, utilization, and case mix) for calendar year (CY) 2026 will be approximately $100.0 billion, an increase of approximately $8.1 billion compared to estimated CY 2025 OPPS payments.

We are continuing to implement the statutory 2.0 percentage point reduction in payments for hospitals that fail to meet the hospital outpatient quality reporting requirements by applying a reporting factor of 0.9805 to the OPPS payments and copayments for all applicable services. We note that under the proposed 340B remedy offset, payments for services at hospitals subject to the 340B remedy offset will be reduced by 2.0 percentage points.

- *ASC Payment Update*: For CYs 2019 through 2023, we adopted a policy to update the ASC payment system using the hospital market basket update. In light of the impact of the COVID-19 public health emergency (PHE) on healthcare utilization, we extended our policy to update the ASC payment system using the hospital market basket update an additional 2 years – through CYs 2024 and 2025. In this proposed rule, we propose to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for 1 additional year (through CY 2026). Using the hospital market basket update, for CY 2026, we propose to increase payment rates under the ASC payment system by 2.4 percent for ASCs that meet the quality reporting requirements under the ASCQR Program. This increase is based on a proposed hospital market basket percentage increase of 3.2 percent reduced by a proposed productivity adjustment of 0.8 percentage point. Based on this proposed update, we estimate that total payments to ASCs (including beneficiary cost sharing and estimated changes in enrollment, utilization, and case-mix) for CY 2026 will be approximately $9.2 billion, an increase of approximately $480 million compared to estimated CY 2025 Medicare payments.

- *Device Pass-Through Payment Applications*: For CY 2026, we received 7 complete applications for device pass-through payments. We solicit public comment on these applications and will make final determinations on these applications in the CY 2026 OPPS/ASC final rule with comment period.

- *Changes to the List of ASC Covered Surgical Procedures and Ancillary Services Lists:* For CY 2026, we propose to expand the ASC CPL by revising the criteria under § 416.166 to modify the general standard criteria and to eliminate five of the general exclusion criteria, moving them into a new section as nonbinding physician considerations for patient safety. We also propose to add 276 procedures to the ASC CPL based on these criteria changes and add an additional 271 codes to the ASC CPL that are proposed for removal from the IPO list for CY 2026.

- *Changes to the Inpatient Only (IPO) List*: For CY 2026, we propose to phase out the IPO list over 3 years, beginning with the removal of 285 mostly musculoskeletal services for CY 2026.

- *Add-on Payment for Radiopharmaceutical Technetium-99m (Tc-99m) Derived from Domestically Produced Molybdenum-99 (Mo-99):* In the CY 2025 OPPS/ASC final rule with comment period, we finalized that for CY 2026 the add-on payment for radiopharmaceuticals produced without the use of Tc-99m derived from non-Highly Enriched Uranium sources would be replaced with an add-on payment for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99. For CY 2026, we propose a $10 per dose amount for this add-on payment, and that at least 50 percent of the Mo-99 used in the Tc-99m generator that produces a dose of Tc-99m must be domestically produced for the dose to qualify for the add-on payment. We also propose to codify our definition for domestically produced Mo-99, and to establish new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose).

- *Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs:* We propose to remove: (1) the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure from the Hospital OQR and ASCQR Program measure sets beginning with the CY 2024 reporting period/CY 2026 payment

determination; (2) the Hospital Commitment to Health Equity (HCHE) measure from the Hospital OQR and REHQR Program measure sets and the Facility Commitment to Health Equity (FCHE) measure from the ASCQR Program measure set beginning with the CY 2025 reporting period/CY 2027 payment or program determination; and (3) the Screening for Social Drivers of Health (SDOH) measure and the Screen Positive Rate for SDOH measure from the Hospital OQR, REHQR, and ASCQR Program measure sets beginning with the CY 2025 reporting period. Additionally, we seek comments regarding measured concepts related to well-being and nutrition for future consideration in the Hospital OQR, REHQR, and ASCQR Programs. We also propose to update and codify the Extraordinary Circumstance Exception (ECE) policy to clarify that CMS has the discretion to grant an extension in response to an ECE request for the Hospital OQR, REHQR, and ASCQR Programs.

- *Hospital Outpatient Quality Reporting (OQR) Program:* In addition to the cross-program measures and policies, we propose to: (1) adopt the Emergency Care Access & Timeliness eCQM with one year of voluntary reporting for the CY 2027 reporting period followed by mandatory reporting for the CY 2028 reporting period/CY 2030 payment determination and subsequent years; (2) remove the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients and the Left Without Being Seen measures beginning with the CY 2028 reporting period/2030 payment determination, contingent upon finalization of adoption of the Emergency Care Access and Timeliness eCQM; and (3) modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) measure (Excessive Radiation eCQM) from mandatory reporting beginning with the CY 2027 reporting period to continue voluntary reporting in the CY 2027 reporting period and subsequent years.

- *Rural Emergency Hospital Quality Reporting (REHQR) Program:* In addition to the cross-program measures and policies, we propose to: (1) adopt the Emergency Care Access & Timeliness eCQM beginning with the CY 2027 reporting period/CY 2029 program

determination; and (2) establish related eCQM data submission and reporting requirements, including that REHs would be provided the option of reporting either the Emergency Care Access and Timeliness eCQM or the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2027 reporting period/CY 2029 program determination.

- *Ambulatory Surgical Center Quality Reporting (ASCQR) Program:* In addition to the cross-program measures and policies, we propose to: (1) adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) beginning with voluntary reporting for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination.

- *Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group:* We propose updating the methodology that will be used to calculate the Overall Hospital Quality Star Rating through implementation of a 2-stage methodologic update. We are updating the methodology to emphasize the importance of the Safety of Care measure group, particularly to address the issue of hospitals receiving a high Star Rating despite performing in the lowest quartile of the Safety of Care measure group. The first-stage methodology update would be a narrow but focused transitional step that would limit hospitals to a maximum of four out of five stars (based on at least three Safety of Care measure scores) if they performed in the lowest quartile of the Safety of Care measure group in the 2026 Overall Hospital Quality Star Rating. The second stage of the methodology update would replace the first-stage update and reduce the Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three Safety of Care measure scores) by one star, to a minimum 1-star rating for the 2027 Overall Hospital Quality Star Rating and later years. These changes will prioritize safety for both patients and healthcare workers and reflect CMS' fundamental

commitment to ensuring high-quality, safe care as a central component of health system performance.

● *Partial Hospitalization and Intensive Outpatient:* We propose to calculate the CY 2026 Community Mental Health Center (CMHC) Partial Hospitalization Program (PHP), and Intensive Outpatient Program (IOP) costs based on 40 percent of the corresponding proposed hospital-based PHP and IOP costs. This change would resolve a cost inversion in CMHC cost data that resulted in higher geometric mean costs for 3-service days than for 4-service days. It would also stabilize rates for CMHCs by basing them on data from a much larger set of providers while preserving the adjustment for the structural differences between CMHC and hospital costs.

● *Notice of Intent to Conduct a Medicare OPPS Drugs Acquisition Cost Survey:* Section 1833(t)(14)(D)(ii) of the Act requires the Secretary to periodically conduct surveys of hospital acquisition costs for each specified covered outpatient drug for use in setting the payment rates for such drugs. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First." Section 5 of the E.O., "Appropriately Accounting for Acquisition Costs of Drugs in Medicare," which directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments. Accordingly, we will be conducting a survey, with the survey submission window opening by early CY 2026, of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS. We intend for the survey to be completed in time for the survey results to be used to inform policymaking beginning with the CY 2027 OPPS/ASC proposed rule.

- *Two-Midnight Rule Medical Review Activities Exemptions*: For CY 2026, we propose to continue our existing policy exempting procedures that are removed from the inpatient only (IPO) list under the OPPS from certain medical review activities related to the two-midnight

policy. Under this policy, procedures removed from the IPO list are exempted from site-of-service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization (BFCC-QIO) referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service) until claims data demonstrates that the procedures are more commonly billed in the outpatient setting than the inpatient setting. We also propose to revise 42 CFR 412.3(d)(2) for clarity.

● *Virtual Direct Supervision of Pulmonary Rehabilitation (PR), Coronary Rehabilitation (CR), Intensive Coronary Rehabilitation and Diagnostic Services*. For CY 2026, we propose to revise § 410.27(a)(1)(iv)(B)(*1*) and § 410.28(e)(2)(iii) to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) permanent, except for diagnostic services that have a global period indicator of 010 or 090.

● *Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy.* For CY 2026, we propose to revise the reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(12) used to determine the payment amounts for non-drug items and services for hospitals for whom this adjustment applies from 0.5 percent to 2 percent. The Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (88 FR 77150) codified a 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services, excluding hospitals that enrolled in Medicare after January 1, 2018. This 0.5 percent reduction would remain in effect until the estimated payment reduction reached the estimated $7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022, which we estimated would occur in CY 2041. This prospective offset aimed to balance the goal of restoring hospitals to their financial position had the original 340B policy never existed, while avoiding burdening them with an immediate single

year recovery. After subsequent reconsideration of balancing these two goals, we have determined a shorter timeframe to be more appropriate. This proposed 2 percent reduction would remain in effect for certain hospitals until the estimated payment reduction reaches $7.8 billion, which we estimate will occur in CY 2031.

● *Payment for Skin Substitute Products under the OPPS.* For CY 2026, we propose to separately pay for the provision of certain groups of skin substitute products as supplies when they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. We propose to group skin substitutes that are not drugs or biologicals using three FDA regulatory categories (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. To effectuate this categorization into a payment policy under the OPPS, we propose to create three new APCs for HCPCS codes that describe skin substitute products organized by clinical and resource similarity. These three APCs will divide skin substitutes by their FDA regulatory pathway. Specifically, we propose to create: APC 6000 (PMA Skin Substitute Products); APC 6001 (510(k) Skin Substitute Products); and APC 6002 (361 HCT/P Skin Substitute Products). This proposal would result in an initial payment rate of $125.38 for each of the new proposed APCs. We propose implementing this policy in both the non-facility, ambulatory surgical center setting, and outpatient hospital settings.

● *Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)*: For CY 2026, we propose to use our authority under section 1833(t)(2)(F) of the Act to apply the Physician Fee Schedule equivalent rate for any HPCPCs codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. We propose to exempt rural Sole Community Hospitals from this method to control the unnecessary volume of drug administration services. Finally, we are requesting information on expanding our volume control method to on-campus clinic visits.

● *Request for information on Adjusting Payment under the OPPS for Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings*: For CY 2026, we are requesting information for future rulemaking on the development of a systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity and adjusting payments according.

● *Request for information on Software as a Service:* We are issuing a request for information on alternative and consistent payment methods for software as a service (SaaS) services under the OPPS to consider for future rulemaking. We intend to identify whether specific adjustments to our payment policies for SaaS services are needed to more accurately and appropriately pay for these products and services across settings of care.

● *Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System*: As discussed in section XX. of the proposed rule, in order to reduce the Medicare program's reliance on the hospital chargemaster, and to support the development of a market-based approach to payment under the Medicare FFS system, we propose that hospitals would be required to report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2026, to be used in a proposed change to the methodology for calculating the IPPS MS–DRG relative weights to reflect relative market-based pricing. Specifically, the market-based rate information we propose to collect on the Medicare cost report would be the median of the payer-specific negotiated charges by MS–DRG, for a hospital's MA organizations (MAOs). As described further in section XX.C.2. of this proposed rule, we specifically propose that for the purposes of reporting the data on the cost report, hospitals would report the median of the payer-specific negotiated charges for an MS-DRG that the hospital has disclosed for all of its MAOs on the most recent version of the machine-readable file (MRF) that the hospital is required to disclose under the hospital price

transparency regulations at 45 CFR Part 180. We also propose a change to the methodology for calculating the IPPS MS–DRG relative weights to incorporate this market-based rate information, beginning in FY 2029. This proposed MS–DRG relative weight methodology would utilize the proposed median payer-specific negotiated charge information, collected on the cost report, for calculating the MS–DRG relative weights.

● *Graduate Medical Education (GME) Accreditation:* In order to ensure that accreditation for approved medical residency programs is in compliance with applicable laws related to race-based admission policies and to improve the accreditation process, we propose that accreditors may not require as part of accreditation, or otherwise encourage institutions to put in place, diversity, equity, and inclusion programs that encourage unlawful discrimination on the basis of race or other violations of Federal law. We also note that the Secretary may recognize other organizations that meet or exceed Medicare's requirements as accreditors in order to increase the potential for competition in the accreditation space and improve the quality of the accreditation process. The effective date of this proposal would be January 1, 2026.

● *Proposed Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges*: We propose amendments to the hospital price transparency (HPT) regulations to enhance clarity and standardization in hospital pricing disclosures. Specifically, we propose revisions to § 180.20 to add definitions for "tenth (10^{th}) percentile allowed amount," "median allowed amount," and "ninetieth (90^{th}) percentile allowed amount," to more accurately reflect the distribution of actual amounts that the hospital has received for an item or service. In tandem with this, we propose revisions to § 180.50 to remove the requirement for hospitals to encode the estimated allowed amount and instead require hospitals, beginning January 1, 2026, to disclose the 10th percentile, median, and 90th percentile allowed amounts in machine-readable files (MRFs) when standard charges are based on percentages or algorithms, as well as the count of allowed amounts. We also propose that hospitals should use EDI 835 transaction remittance advice (ERA) transaction data to calculate and encode these values, and we propose specific

instructions to hospitals with regard to the methodology, including lookback period, that should be used to calculate these amounts. We propose revisions to § 180.50(a)(3) to update the attestation language hospitals must include in the MRF and to require hospitals to encode the name of the chief executive officer, president or senior hospital official designated to oversee the encoding of true, accurate, and complete data in the MRF. We also propose revisions to § 180.50(b)(2)(i)(A) to require hospitals, beginning January 1, 2026, to encode in a newly created general data element in the MRF their Type 2 (organizational) National Provider Identifier(s) (NPI). Finally, to encourage faster resolution and payment of CMPs and in exchange for a hospital's admission of having violated HPT requirements, we propose to update § 180.90 to allow hospitals, under certain circumstances, the opportunity to have the amount of a CMP reduced by 35 percent where the hospital waives its right to an ALJ hearing. These proposed changes aim to improve price transparency, facilitate efficient enforcement, and empower consumers with actionable pricing information.

3. Summary of Costs and Benefits

In section XXV. of this proposed rule, we set forth a detailed analysis of the regulatory and Federalism impacts that the proposed changes would have on affected entities and beneficiaries. Key estimated impacts are described below.

a. Impacts of all OPPS Changes

Table 112 in section XXV.C. of this proposed rule displays the distributional impact of all the OPPS changes on various groups of hospitals and CMHCs for CY 2026 compared to all estimated OPPS payments in CY 2025. We estimate that the proposed policies in this proposed rule would result in a 1.9 percent increase in OPPS payments to providers for services prior to the 340B remedy offset. We estimate that total OPPS payments for CY 2026, including beneficiary cost-sharing, to the approximately 4,000 facilities paid under the OPPS (including general acute care hospitals, children's hospitals, cancer hospitals, and CMHCs) would increase by approximately $1.61 billion compared to CY 2025 payments due to the OPD update,

excluding changes in enrollment, utilization, and case-mix. However, for providers subject to the 340B remedy offset, the 340B remedy offset is estimated to reduce payments by $1.1 billion in CY 2026.

We estimated the isolated impact of our OPPS policies on CMHCs because CMHCs have historically only been paid for partial hospitalization services under the OPPS. Beginning CY 2024, they are also paid for IOP services under the OPPS. Based on our proposal to calculate CMHC PHP and IOP costs based on 40 percent of the corresponding proposed hospital-based PHP and IOP costs, we estimate a 0.6 percent increase in CY 2026 payments to CMHCs relative to their CY 2025 payments.

b. Impacts of the Updated Wage Indexes

We estimate that our update of the wage indexes based on the fiscal year (FY) 2026 IPPS proposed rule wage indexes will result in a 0.1 percent increase for urban hospitals under the OPPS and a 0.4 percent increase for rural hospitals. These wage indexes include continued implementation of the Office of Management and Budget (OMB) labor market area delineations based on 2020 Decennial Census data, with updates, as discussed in section II.C. of this proposed rule.

c. Impacts of the Rural Adjustment and the Cancer Hospital Payment Adjustment

For CY 2026, we proposed to continue to provide additional payments to cancer hospitals so that a cancer hospital's payment-to-cost ratio (PCR) after the additional payments is equal to the weighted average PCR for the other OPPS hospitals using the most recently submitted or settled cost report data. Section 16002(b) of the 21st Century Cures Act requires that this weighted average PCR be reduced by 1.0 percentage point. In light of the COVID-19 PHE impact on claims and cost data used to calculate the target PCR, we maintained the CY 2021 target PCR of 0.89 through CYs 2022 and 2023. However, in CY 2024, we finalized a policy to reduce the target PCR by 1.0 percentage point each calendar year until the target PCR equals the PCR of non-cancer hospitals using the most recently submitted or settled cost report data. For

CY 2025, we finalized a target PCR of 0.87. For CY 2026, we propose a target PCR of 0.87, the same PCR of non-cancer hospitals using the most recently submitted or settled cost report data, to determine the CY 2026 cancer hospital payment adjustment to be paid at cost report settlement. That is, the payment adjustments would be the additional payments needed to result in a PCR equal to 0.87 for each cancer hospital.

d. Impacts of the OPD Fee Schedule Increase Factor

For the CY 2026 OPPS/ASC, we are establishing an OPD fee schedule increase factor of 2.4 percent and applying that increase factor to the conversion factor for CY 2025. As a result of the OPD fee schedule increase factor and other budget neutrality adjustments, we estimate that urban hospitals would experience an increase in payments of approximately 2.6 percent and that rural hospitals would experience an increase in payments of 2.5 percent. Classifying hospitals by teaching status, we estimate non-teaching hospitals would experience an increase in payments of 2.6 percent, minor teaching hospitals would experience an increase in payments of 2.8 percent, and major teaching hospitals would experience an increase in payments of 2.3 percent. We also classified hospitals by the type of ownership. We estimate that hospitals with voluntary ownership would experience an increase of 2.5 percent in payments, while hospitals with government ownership would experience an increase of 2.5 percent in payments. We estimate that hospitals with proprietary ownership will experience an increase of 3.0 percent in payments.

e. Impacts of the ASC Payment Update

For impact purposes, the surgical procedures on the ASC covered surgical procedure list are aggregated into surgical specialty groups using CPT and HCPCS code range definitions. The percentage change in estimated total payments by specialty groups under the proposed CY 2026 payment rates, compared to estimated CY 2025 payment rates, generally ranges between an increase of 1 percent and an increase of 3 percent, depending on the service, with some exceptions from expected utilization changes with new CY 2026 AMA CPT codes.

f. Impacts of the Proposed Market-Based MS–DRG Relative Weight Data Collection and Change in Methodology for Calculating MS–DRG Relative Weights Under the Inpatient Prospective Payment System.

In section XX. of this proposed rule, we seek comment on a proposed methodology for estimating the MS–DRG relative weights beginning in FY 2029 based on the median payer-specific negotiated charge information we propose to collect on the cost report. We note that the estimated total annual burden hours for this proposal are as follows: 3,038 hospitals times 20 hours per hospital equals 60,760 annual burden hours and $4,857,458.20. We refer readers to section XXII.E. of this proposed rule for further analysis of this assessment.

g. Impacts of Hospital Price Transparency

We propose to require hospitals to report four new data elements when the payer-specific negotiated charge is based on a percentage or algorithm – the median allowed amount (which would replace the estimated allowed amount data element), the 10th percentile allowed amount, the 90th percentile allowed amount, and the count of allowed amounts. We also propose to update the attestation language hospitals must include in the MRF and to require hospitals to encode the name of the chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data in the MRF. Additionally, we propose to require hospitals to add their National Provider Identifiers (NPIs) to the MRF. The proposals would advance the comparability of standard charge information across hospitals and of the HPT data with other healthcare data, including health plan transparency data from the Transparency in Coverage (TiC) MRFs. These proposals include a one-time burden of $478.08 per hospital, and a total national cost of $3,545,441.28 ($478.08 × 7,416 hospitals). As discussed in detail in section XIX. of this proposed rule, we believe that the benefits to the public (and to hospitals themselves) outweigh the burden imposed on hospitals.

B. Legislative and Regulatory Authority for the Hospital OPPS

When Title XVIII of the Act was enacted, Medicare payment for hospital outpatient services was based on hospital-specific costs. In an effort to ensure that Medicare and its beneficiaries pay appropriately for services and to encourage more efficient delivery of care, the Congress mandated replacement of the reasonable cost-based payment methodology with a prospective payment system (PPS). The Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33) added section 1833(t) to the Act, authorizing implementation of a PPS for hospital outpatient services. The OPPS was first implemented for services furnished on or after August 1, 2000. Implementing regulations for the OPPS are located at 42 CFR parts 410 and 419.

The Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113) made major changes in the hospital OPPS. The following Acts made additional changes to the OPPS: the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106-554); the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173); the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109-171), enacted on February 8, 2006; the Medicare Improvements and Extension Act under Division B of Title I of the Tax Relief and Health Care Act of 2006 (MIEA-TRHCA) (Pub. L. 109-432), enacted on December 20, 2006; the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173), enacted on December 29, 2007; the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275), enacted on July 15, 2008; the Patient Protection and Affordable Care Act (Pub. L. 111-148), enacted on March 23, 2010, as amended by the Health Care and Education Reconciliation Act of 2010 (HCERA, Pub. L. 111-152), enacted on March 30, 2010 (these two public laws are collectively known as the Affordable Care Act); the Medicare and Medicaid Extenders Act of 2010 (MMEA, Pub. L. 111-309); the Temporary Payroll Tax Cut Continuation Act of 2011 (TPTCCA, Pub. L. 112-78), enacted on December 23, 2011; the Middle Class Tax Relief and Job Creation Act of 2012 (MCTRJCA, Pub. L. 112-96), enacted on February 22, 2012; the

American Taxpayer Relief Act of 2012 (Pub. L. 112-240), enacted January 2, 2013; the Pathway for SGR Reform Act of 2013 (Pub. L. 113-67) enacted on December 26, 2013; the Protecting Access to Medicare Act of 2014 (PAMA, Pub. L. 113-93), enacted on March 27, 2014; the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 (Pub. L. 114-10), enacted April 16, 2015; the Bipartisan Budget Act of 2015 (Pub. L. 114-74), enacted November 2, 2015; the Consolidated Appropriations Act, 2016 (Pub. L. 114-113), enacted on December 18, 2015, the 21st Century Cures Act (Pub. L. 114-255), enacted on December 13, 2016; the Consolidated Appropriations Act, 2018 (Pub. L. 115–141), enacted on March 23, 2018; the Substance Use Disorder- Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (Pub. L. 115-271), enacted on October 24, 2018; the Further Consolidated Appropriations Act, 2020 (Pub. L. 116-94), enacted on December 20, 2019; the Coronavirus Aid, Relief, and Economic Security Act (Pub. L. 116-136), enacted on March 27, 2020; the Consolidated Appropriations Act, 2021 (Pub. L. 116–260), enacted on December 27, 2020; the Inflation Reduction Act, 2022 (Pub. L. 117-169), enacted on August 16, 2022; and the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-238), enacted December 29, 2022.

Under the OPPS, we generally pay for hospital Part B services on a rate-per-service basis that varies according to the APC group to which the service is assigned. We use the Healthcare Common Procedure Coding System (HCPCS) (which includes certain Current Procedural Terminology (CPT) codes) to identify and group the services within each APC. The OPPS includes payment for most hospital outpatient services, except those identified in section I.C of this proposed rule. Section 1833(t)(1)(B) of the Act provides for payment under the OPPS for hospital outpatient services designated by the Secretary (which includes partial hospitalization services furnished by CMHCs), and certain inpatient hospital services that are paid under Medicare Part B.

The OPPS rate is an unadjusted national payment amount that includes the Medicare payment and the beneficiary copayment. This rate is divided into a labor-related amount and a

nonlabor-related amount. The labor-related amount is adjusted for area wage differences using the hospital inpatient wage index value for the locality in which the hospital or CMHC is located.

All services and items within an APC group are comparable clinically and with respect to resource use, as required by section 1833(t)(2)(B) of the Act. In accordance with section 1833(t)(2)(B) of the Act, subject to certain exceptions, items and services within an APC group cannot be considered comparable with respect to the use of resources if the highest median cost (or mean cost, if elected by the Secretary) for an item or service in the APC group is more than 2 times greater than the lowest median cost (or mean cost, if elected by the Secretary) for an item or service within the same APC group (referred to as the "2 times rule"). In implementing this provision, we generally use the cost of the item or service assigned to an APC group.

For new technology items and services, special payments under the OPPS may be made in one of two ways. section 1833(t)(6) of the Act provides for temporary additional payments, which we refer to as "transitional pass-through payments," for at least 2 but not more than 3 years for certain drugs, biological agents, brachytherapy devices used for the treatment of cancer, and categories of other medical devices. For new technology services that are not eligible for transitional pass-through payments, and for which we lack sufficient clinical information and cost data to appropriately assign them to a clinical APC group, we have established special APC groups based on costs, which we refer to as New Technology APCs. These New Technology APCs are designated by cost bands which allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data. Similar to pass-through payments, an assignment to a New Technology APC is temporary; that is, we retain a service within a New Technology APC until we acquire sufficient data to assign it to a clinically appropriate APC group.

C. Excluded OPPS Services and Hospitals

Section 1833(t)(1)(B)(i) of the Act authorizes the Secretary to designate the hospital outpatient services that are paid under the OPPS. While most hospital outpatient services are

payable under the OPPS, section 1833(t)(1)(B)(iv) of the Act excludes payment for ambulance, physical and occupational therapy, and speech-language pathology services, for which payment is made under a fee schedule. It also excludes screening mammography, diagnostic mammography, and effective January 1, 2011, an annual wellness visit providing personalized prevention plan services. The Secretary exercises the authority granted under the statute to also exclude from the OPPS certain services that are paid under fee schedules or other payment systems. Such excluded services include, for example, the professional services of physicians and nonphysician practitioners paid under the Medicare Physician Fee Schedule (MPFS); certain laboratory services paid under the Clinical Laboratory Fee Schedule (CLFS); services for beneficiaries with end-stage renal disease (ESRD) that are paid under the ESRD prospective payment system; and services and procedures that require an inpatient stay that are paid under the hospital IPPS. In addition, section 1833(t)(1)(B)(v) of the Act does not include applicable items and services (as defined in subparagraph (A) of paragraph (21)) that are furnished on or after January 1, 2017, by an off-campus outpatient department of a provider (as defined in subparagraph (B) of paragraph (21)). We set forth the services that are excluded from payment under the OPPS in regulations at 42 CFR 419.22.

Under § 419.20(b) of the regulations, we specify the types of hospitals that are excluded from payment under the OPPS. These excluded hospitals are:

- Critical access hospitals (CAHs);
- Hospitals located in Maryland and paid under Maryland's All-Payer or Total Cost of Care Model;
- Hospitals located outside of the 50 States, the District of Columbia, and Puerto Rico;
- Indian Health Service (IHS) hospitals; and
- Rural emergency hospitals (REH).

D. Prior Rulemaking

On April 7, 2000, we published in the **Federal Register** a final rule with comment period (65 FR 18434) to implement a prospective payment system for hospital outpatient services. The hospital OPPS was first implemented for services furnished on or after August 1, 2000. Section 1833(t)(9)(A) of the Act requires the Secretary to review certain components of the OPPS, not less often than annually, and to revise the groups, the relative payment weights, and the wage and other adjustments to take into account changes in medical practices, changes in technology, the addition of new services, new cost data, and other relevant information and factors.

Since initially implementing the OPPS, we have published final rules in the **Federal Register** annually to implement statutory requirements and changes arising from our continuing experience with this system. These rules can be viewed on the CMS website at: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

E. Advisory Panel on Hospital Outpatient Payment (the HOP Panel or the Panel)

1. Authority of the Panel

Section 1833(t)(9)(A) of the Act, as amended by section 201(h) of Pub. L. 106-113, and redesignated by section 202(a)(2) of Pub. L. 106-113, requires that we consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to annually review (and advise the Secretary concerning) the clinical integrity of the payment groups and their weights under the OPPS. In CY 2000, based on section 1833(t)(9)(A) of the Act, the Secretary established the Advisory Panel on Ambulatory Payment Classification Groups (APC Panel) to fulfill this requirement. In CY 2011, based on section 222 of the Public Health Service Act (the PHS Act), which gives discretionary authority to the Secretary to convene advisory councils and committees, the Secretary expanded the panel's scope to include the supervision of hospital outpatient therapeutic services in addition to the APC groups and weights. To reflect this new role of the panel, the Secretary changed the panel's name to the

Advisory Panel on Hospital Outpatient Payment (the HOP Panel). The HOP Panel is not restricted to using data compiled by CMS, and in conducting its review, it may use data collected or developed by organizations outside the Department.

2. Establishment of the Panel

On November 21, 2000, the Secretary signed the initial charter establishing the Panel, and, at that time, named the APC Panel. This expert panel is composed of appropriate representatives of providers (currently employed full-time, not as consultants, in their respective areas of expertise) who review clinical data and advise CMS about the clinical integrity of the APC groups and their payment weights. Since CY 2012, the Panel also is charged with advising the Secretary on the appropriate level of supervision for individual hospital outpatient therapeutic services. The Panel is technical in nature, and it is governed by the provisions of the Federal Advisory Committee Act (FACA). The current charter specifies, among other requirements, that the Panel--

- May advise on the clinical integrity of Ambulatory Payment Classification (APC) groups and their associated weights;
- May advise on the appropriate supervision level for hospital outpatient services;
- May advise on OPPS APC rates for ASC covered surgical procedures;
- Continues to be technical in nature;
- Is governed by the provisions of the FACA;
- Has a Designated Federal Official (DFO); and
- Is chaired by a Federal Official designated by the Secretary.

The Panel's charter was amended on November 15, 2011, renaming the Panel and expanding the Panel's authority to include supervision of hospital outpatient therapeutic services and to add critical access hospital (CAH) representation to its membership. The Panel's charter was also amended on November 6, 2014 (80 FR 23009), and the number of members was

revised from up to 19 to up to 15 members. The Panel's current charter was approved on November 21, 2024, for a 2-year period.

The current Panel membership and other information pertaining to the Panel, including its charter, **Federal Register** notices, membership, meeting dates, agenda topics, and meeting reports, can be viewed on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonAmbulatoryPaymentClassificationGroups.html*.

3. Panel Meetings and Organizational Structure

The Panel has held many meetings, with the last meeting taking place on August 26, 2024. The recommendations of the Panel for the most recent meeting are available on the CMS website at *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment*. Prior to each meeting, we publish a notice in the **Federal Register** to announce the meeting, new members, and any other changes of which the public should be aware. Beginning in CY 2017, we have transitioned to one meeting per year (81 FR 31941). In CY 2022, we published a **Federal Register** notice requesting nominations to fill vacancies on the Panel (87 FR 68499). We are currently accepting nominations at: *https://mearis.cms.gov*.

In addition, the Panel has established an administrative structure that, in part, currently includes the use of three subcommittee workgroups to provide preparatory meeting and subject support to the larger panel. The three current subcommittees include the following:

- APC Groups and Status Indicator Assignments Subcommittee, which advises and provides recommendations to the Panel on the appropriate status indicators to be assigned to HCPCS codes, including but not limited to whether a HCPCS code or a category of codes should be packaged or separately paid, as well as the appropriate APC assignment of HCPCS codes regarding services for which separate payment is made.

- Data Subcommittee, which is responsible for studying the data issues confronting the Panel and for recommending options for resolving them; and

● Visits and Observation Subcommittee, which reviews and makes recommendations to the Panel on all technical issues pertaining to observation services and hospital outpatient visits paid under the OPPS.

Each of these workgroup subcommittees was established by a majority vote from the full Panel during a scheduled Panel meeting, and the Panel recommended at the August 26, 2024, meeting that the subcommittees continue. We accepted this recommendation.

For discussions of earlier Panel meetings and recommendations, we refer readers to previously published OPPS/ASC proposed and final rules, the CMS website mentioned earlier in this section, and the FACA database at *https://facadatabase.gov*.

F. Public Comments Received on the CY 2025 OPPS/ASC Final Rule with Comment Period

We received approximately 29 timely pieces of correspondence on the CY 2025 OPPS/ASC final rule with comment period that appeared in the **Federal Register** on November 27, 2024 (88 FR 93912).

II. Updates Affecting OPPS Payments

A. Recalibration of APC Relative Payment Weights

1. Database Construction

a. Database Source and Methodology

Section 1833(t)(9)(A) of the Act requires that the Secretary review not less often than annually and revise the relative payment weights for Ambulatory Payment Classifications (APCs). In the April 7, 2000, OPPS final rule with comment period (65 FR 18482), we explained in detail how we calculated the relative payment weights that were implemented on August 1, 2000, for each APC group.

For the CY 2026 OPPS, we propose to recalibrate the APC relative payment weights for services furnished on or after January 1, 2026, and before January 1, 2027 (CY 2026), using the same basic methodology that we described in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93921 through 93922), using CY 2024 claims data. That is, we propose to

recalibrate the relative payment weights for each APC based on claims and cost report data for hospital outpatient department (HOPD) services to construct a database for calculating APC group weights.

For the purpose of recalibrating the proposed APC relative payment weights for CY 2026, we began with approximately 143 million final action claims (claims for which all disputes and adjustments have been resolved and payment has been made) for HOPD services furnished on or after January 1, 2024, and before January 1, 2025, before applying our exclusionary criteria and other methodological adjustments. After the application of those data processing changes, we used approximately 76 million final action claims to develop the proposed CY 2026 OPPS payment weights. For exact numbers of claims used and additional details on the claims accounting process, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

Addendum N to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) includes the proposed list of bypass codes for CY 2026. The proposed list of bypass codes contains codes that are reported on claims for services in CY 2024 and, therefore, includes codes that were in effect in CY 2024 and used for billing. We propose to retain these deleted bypass codes on the proposed CY 2026 bypass list because these codes existed in CY 2024 and were covered HOPD services in that period, and CY 2024 claims data were used to calculate proposed CY 2026 payment rates. Keeping these deleted bypass codes on the bypass list potentially allows us to create more "pseudo" single procedure claims for ratesetting purposes. "Overlap bypass codes" that are members of the proposed multiple imaging composite APCs are identified by asterisks (*) in the third column of Addendum N to this proposed rule. HCPCS codes that we propose to add for CY 2026 are identified by asterisks (*) in the fourth column of Addendum N.

b. Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs)

For CY 2026, we propose to continue to use the hospital-specific overall ancillary and departmental cost-to-charge ratios (CCRs) to convert charges to estimated costs through application of a revenue code-to-cost center crosswalk. To calculate the APC costs on which the proposed CY 2026 APC payment rates are based, we calculated hospital-specific departmental CCRs for each hospital for which we had CY 2024 claims data by comparing these claims data to the most recently available hospital cost reports, which, in most cases, are from CY 2023. For the proposed CY 2026 OPPS payment rates, we used the set of claims processed during CY 2024. We applied the hospital-specific CCR to the hospital's charges at the most detailed level possible, based on a revenue code-to-cost center crosswalk that contains a hierarchy of CCRs used to estimate costs from charges for each revenue code. To ensure the completeness of the revenue code-to-cost center crosswalk, we reviewed changes to the list of revenue codes for CY 2024 (the year of claims data we used to calculate the proposed CY 2026 OPPS payment rates) and updates to the National Uniform Billing Committee (NUBC) 2024 Data specifications Manual. That crosswalk is available for review and continuous comment on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

In accordance with our longstanding policy, similar to our finalized policy for CY 2025 OPPS ratesetting, we propose to calculate CCRs for the standard cost centers – cost centers with a predefined label – and nonstandard cost centers – cost centers defined by a hospital – accepted by the electronic cost report database. In general, the most detailed level at which we calculate CCRs is the hospital-specific departmental level.

While we generally view the use of additional cost data as improving our OPPS ratesetting process, we have historically not included cost report lines for certain nonstandard cost centers in the OPPS ratesetting database construction when hospitals have reported these nonstandard cost centers on cost report lines that do not correspond to the cost center number. We believe it is important to further investigate the accuracy of these cost report data before

including such data in the ratesetting process. Further, we believe it is appropriate to gather additional information from the public as well before including the data in OPPS ratesetting. For CY 2026, we propose not to include the nonstandard cost centers reported in this way in the OPPS ratesetting database construction.

2. Proposed Data Development and Calculation of Costs Used for Ratesetting

In this section of this proposed rule, we discuss the use of claims to calculate the OPPS payment rates for CY 2026. The Hospital OPPS page on the CMS website on which this proposed rule is posted (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient)* provides an accounting of claims used in the development of the proposed payment rates. That accounting provides additional detail regarding the number of claims derived at each stage of the process. In addition, later in this section we discuss the file of claims that comprises the data set that is available upon payment of an administrative fee under a CMS data use agreement. The CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*, includes information about obtaining the "OPPS Limited Data Set," which now includes the additional variables previously available only in the OPPS Identifiable Data Set, including International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes and revenue code payment amounts. This file is derived from the CY 2024 claims that are used to calculate the proposed payment rates for this proposed rule.

Previously, the OPPS established the scaled relative weights on which payments are based using APC median costs, a process described in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74188). However, as discussed in more detail in section II.A.2.f. of the CY 2013 OPPS/ASC final rule with comment period (77 FR 68259 through 68271), we finalized the use of geometric mean costs to calculate the relative weights on which the CY 2013 OPPS payment rates were based. While this policy changed the cost metric on which the relative payments are based, the data process in general remained the same under the methodologies that

we used to obtain appropriate claims data and accurate cost information in determining estimated service cost.

We used the methodology described in sections II.A.2.a. through II.A.2.c. of this proposed rule to calculate the costs we used to establish the proposed relative payment weights used in calculating the OPPS payment rates for CY 2026 shown in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). We refer readers to section II.A.4. of this proposed rule for a discussion of the conversion of APC costs to scaled payment weights.

We note that under the OPPS, CY 2019 was the first year in which the claims data used for setting payment rates (CY 2017 data) contained lines with the modifier "PN," which indicates nonexcepted items and services furnished and billed by off-campus provider-based departments (PBDs) of hospitals. Because nonexcepted items and services are not paid under the OPPS, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58832), we finalized a policy to remove those claim lines reported with modifier "PN" from the claims data used in ratesetting for the CY 2019 OPPS and subsequent years. For the CY 2026 OPPS, we propose to continue to remove claim lines with modifier "PN" from the ratesetting process.

For details of the claims accounting process used in this CY 2026 OPPS/ASC proposed rule, we refer readers to the claims accounting narrative under supporting documentation for this proposed rule on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

a. Calculation of Single Procedure APC Criteria-Based Costs

(1) Blood and Blood Products

Since the implementation of the OPPS in August 2000, we have made separate payments for blood and blood products through APCs rather than packaging payment for them into payments for the procedures with which they are administered. Hospital payments for the costs

of blood and blood products, as well as for the costs of collecting, processing, and storing blood and blood products, are made through the OPPS payments for specific blood product APCs. We propose to continue to establish payment rates for blood and blood products using our blood-specific CCR methodology (88 FR 49562), which utilizes actual or simulated CCRs from the most recently available hospital cost reports to convert hospital charges for blood and blood products to costs. This methodology has been our standard ratesetting methodology for blood and blood products since CY 2005. It was developed in response to data analysis indicating that there was a significant difference in CCRs for those hospitals with and without blood-specific cost centers and past public comments indicating that the former OPPS policy of defaulting to the overall hospital CCR for hospitals not reporting a blood-specific cost center often resulted in an underestimation of the true hospital costs for blood and blood products. To address the differences in CCRs and to better reflect hospitals' costs, our methodology simulates blood CCRs for each hospital that does not report a blood cost center by calculating the ratio of the blood-specific CCRs to hospitals' overall CCRs for those hospitals that do report costs and charges for blood cost centers and applies this mean ratio to the overall CCRs of hospitals not reporting costs and charges for blood cost centers on their cost reports. We propose to calculate the costs upon which the proposed payment rates for blood and blood products are based using the actual blood-specific CCR for hospitals that reported costs and charges for a blood cost center and a hospital-specific, simulated, blood-specific CCR for hospitals that did not report costs and charges for a blood cost center.

We continue to believe that the hospital-specific, simulated, blood-specific CCR methodology takes into account the unique charging and cost accounting structure of each hospital, as it better responds to the absence of a blood-specific CCR for a hospital than alternative methodologies, such as defaulting to the overall hospital CCR or applying an average blood-specific CCR across hospitals. This methodology also yields more accurate estimated costs for these products and results in payment rates for blood and blood products that

appropriately reflect the relative estimated costs of these products for hospitals without blood cost centers and for these blood products in general.

We refer readers to Addendum B to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) for the proposed CY 2026 payment rates for blood and blood products (which are generally identified with status indicator "R").

For a more detailed discussion of payments for blood and blood products through APCs, we refer readers to:

- the CY 2005 OPPS proposed rule (69 FR 50524 and 50525) for a more comprehensive discussion of the blood-specific CCR methodology;
- the CY 2008 OPPS/ASC final rule with comment period (72 FR 66807 through 66810) for a detailed history of the OPPS payment for blood and blood products; and
- the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795 and 66796) for additional discussion of our policy not to make separate payments for blood and blood products when they appear on the same claims as services assigned to a C-APC.

(2) Brachytherapy Sources

Section 1833(t)(2)(H) of the Act mandates the creation of additional groups of covered OPD services that classify devices of brachytherapy – cancer treatment through solid source radioactive implants – consisting of a seed or seeds (or radioactive source) ("brachytherapy sources") separately from other services or groups of services. The statute provides certain criteria for the additional groups. For the history of OPPS payment for brachytherapy sources, we refer readers to prior OPPS final rules, such as the CY 2012 OPPS/ASC final rule with comment period (77 FR 68240 and 68241). As we have stated in prior OPPS updates, we believe that adopting the general OPPS prospective payment methodology for brachytherapy sources is appropriate for several reasons (77 FR 68240). The general OPPS methodology uses costs based on claims data to set the relative payment weights for hospital outpatient services.

This payment methodology results in more consistent, predictable, and equitable payment amounts per source across hospitals by averaging the extremely high and low values, in contrast to payment based on hospitals' charges adjusted to costs. We believe that the OPPS methodology, as opposed to payment based on hospitals' charges adjusted to cost, also would provide hospitals with incentives for efficiency in the provision of brachytherapy services to Medicare beneficiaries. Moreover, this approach is consistent with our payment methodology for most items and services paid under the OPPS. We refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70323 through 70325) for further discussion of the history of OPPS payment for brachytherapy sources.

For CY 2026, except where otherwise indicated, we propose to continue our policy and use the costs derived from CY 2024 claims data to set the proposed CY 2026 payment rates for brachytherapy sources because we propose to use CY 2024 data to set the proposed payment rates for most other items and services that would be paid under the CY 2026 OPPS. With the exception of the proposed payment rate for brachytherapy source C2645 (Brachytherapy planar source, palladium-103, per square millimeter) and the proposed payment rates for low-volume brachytherapy APCs discussed in section III.D. of this proposed rule, we propose to base the payment rates for brachytherapy sources on the geometric mean unit costs for each source, consistent with the methodology that we propose for other items and services paid under the OPPS, as discussed in section II.A.2. of this proposed rule. We also propose for CY 2026 and subsequent years to continue the other payment policies for brachytherapy sources that we finalized and first implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537). For CY 2026 and subsequent years, we propose to pay for the stranded and nonstranded not otherwise specified (NOS) codes, HCPCS codes C2698 (Brachytherapy source, stranded, not otherwise specified, per source) and C2699 (Brachytherapy source, non-stranded, not otherwise specified, per source), at a rate equal to the lowest stranded or nonstranded prospective payment rate for such sources, respectively, on a per-source basis (as opposed to, for

example, per mCi), which is based on the policy we established in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66785). For CY 2026 and subsequent years, we also propose to continue the policy we implemented in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60537) regarding payment for new brachytherapy sources for which we have no claims data, for the same reasons we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66786; which was delayed until January 1, 2010, by section 142 of Pub. L. 110-275). Specifically, this policy is intended to enable us to assign new HCPCS codes for new brachytherapy sources to their own APCs, with prospective payment rates set based on our consideration of external data and other relevant information regarding the expected costs of the sources to hospitals. The proposed CY 2026 payment rates for brachytherapy sources are included in Addendum B to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) and identified with status indicator "U (Brachytherapy Sources, Paid under OPPS; separate APC payment)."

For CY 2018, we assigned status indicator "U" to HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) in the absence of claims data and established a payment rate using external data (invoice price) at $4.69 per mm^2 for the brachytherapy source's APC – APC 2648 (Brachytx planar, p-103) (82 FR 49233 through 49244). For CY 2019, in the absence of sufficient claims data, we continued to establish a payment rate for C2645 at $4.69 per mm^2 for APC 2648 (Brachytx planar, p-103) (83 FR 58834 through 58836). Our CY 2018 claims data available for the CY 2020 OPPS/ASC final rule with comment period (84 FR 61142) included two claims with a geometric mean cost for HCPCS code C2645 of $1.02 per mm^2. In response to comments from interested parties, we agreed that, given the limited claims data available and a new outpatient indication for C2645, a payment rate for HCPCS code C2645 based on the geometric mean cost of $1.02 per mm^2 may not adequately reflect the cost of HCPCS code C2645. In the CY 2020 OPPS/ASC final rule with comment

period, we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act, which states that the Secretary shall establish, in a budget neutral manner, other adjustments as determined to be necessary to ensure equitable payments, to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CY 2020. Similarly, in the absence of sufficient claims data to establish an APC payment rate, in the CY 2021, CY 2022, CY 2023, CY 2024, and CY 2025 OPPS/ASC final rules with comment period (85 FR 85879 through 85880, 86 FR 63469, 87 FR 71760-71761, 88 FR 81553, and 89 FR 93925), we finalized our policy to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2019 payment rate of $4.69 per mm^2 for HCPCS code C2645 for CYs 2021 through 2025.

There are no CY 2024 claims available that reported HCPCS code C2645 for this proposed rule. Therefore, in the absence of claims data, we propose to continue to use our equitable adjustment authority under section 1833(t)(2)(E) of the Act to maintain the CY 2025 payment rate of $4.69 per mm^2 for HCPCS code C2645, which we propose to be assigned to APC 2648 (Brachytx planar, p-103), for CY 2026.

Additionally, for CY 2022 and subsequent calendar years, we adopted a Universal Low Volume APC policy for clinical and brachytherapy APCs. As discussed in further detail in section X.C. of the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted this policy to mitigate wide variation in payment rates that occur from year to year for APCs with low utilization. Such volatility in payment rates from year to year can result in even lower utilization and potential barriers to access. Brachytherapy APCs that have fewer than 100 single claims used for ratesetting purposes are designated as Low Volume APCs unless an alternative payment rate is applied, such as the use of our equitable adjustment authority under section 1833(t)(2)(E) of the Act in the case of APC 2648 (Brachytx planar, p-103), for which HCPCS code C2645 (Brachytherapy planar source, palladium-103, per square millimeter) is the only code assigned as discussed previously in this section.

For CY 2026, we propose to designate six brachytherapy APCs as Low Volume APCs as these APCs meet our criteria to be designated as Low Volume APCs. For more information on the brachytherapy APCs we propose to designate as Low Volume APCs, see section III.D. of this proposed rule.

We invite interested parties to submit recommendations for new codes to describe new brachytherapy sources. Such recommendations should be directed via email to outpatientpps@cms.hhs.gov. We will continue to add new brachytherapy source codes and descriptors to our systems for payment on a quarterly basis.

b. Comprehensive APCs (C-APCs) for CY 2026

(1) Background

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861 through 74910), we finalized a comprehensive payment policy that packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. The policy was finalized in CY 2014, but the effective date was delayed until January 1, 2015, to allow additional time for further analysis, opportunity for public comment, and systems preparation. The comprehensive APC (C-APC) policy was implemented effective January 1, 2015, with modifications and clarifications in response to public comments received regarding specific provisions of the C-APC policy (79 FR 66798 through 66810).

A C-APC is defined as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. We established C-APCs as a category broadly for OPPS payment and implemented 25 C-APCs beginning in CY 2015 (79 FR 66809 and 66810). We have gradually added new C-APCs since the policy was implemented beginning in CY 2015, with the number of C-APCs now totaling 72 (80 FR 70332; 81 FR 79584 and 79585; 83 FR 58844 through 58846; 84 FR 61158 through 61166; 85 FR 85885; 86 FR 63474; 87 FR 71769; 88 FR 81562; and 89 FR 93926).

Under our C-APC policy, we designate a service described by a HCPCS code assigned to a C-APC as the primary service when the service is identified by OPPS status indicator "J1." When such a primary service is reported on a hospital outpatient claim, taking into consideration the few exceptions that are discussed below, we make payment for all other items and services reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service (hereinafter collectively referred to as "adjunctive services") and representing components of a complete comprehensive service (78 FR 74865 and 79 FR 66799). Payments for adjunctive services are packaged into the payments for the primary services. This results in a single prospective payment for each of the primary, comprehensive services based on the costs of all reported services at the claim level. One example of a primary service would be a partial mastectomy, and an example of a secondary service packaged into that primary service would be a radiation therapy procedure.

Services excluded from the C-APC policy under the OPPS include services that are not covered OPD services, services that cannot, by statute, be paid for under the OPPS, and services that are required by statute to be separately paid. This includes certain mammography and ambulance services that are not covered OPD services in accordance with section 1833(t)(1)(B)(iv) of the Act; brachytherapy seeds, which also are required by statute to receive separate payment under section 1833(t)(2)(H) of the Act; pass-through payment drugs and devices, which also require separate payment under section 1833(t)(6) of the Act; self-administered drugs (SADs) that are not otherwise packaged as supplies because they are not covered under Medicare Part B under section 1861(s)(2)(B) of the Act; and certain preventive services (78 FR 74865 and 79 FR 66800 and 66801). A list of services excluded from the C-APC policy is included in Addendum J to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*). If a service does not appear on this list of

excluded services, payment for it will be packaged into the payment for the primary C-APC service when it appears on an outpatient claim with a primary C-APC service.

The C-APC policy payment methodology set forth in the CY 2014 OPPS/ASC final rule with comment period and modified and implemented beginning in CY 2015 is summarized as follows (78 FR 74887 and 79 FR 66800):

Basic Methodology. As stated in the CY 2015 OPPS/ASC final rule with comment period, we define the C-APC payment policy as including all covered OPD services on a hospital outpatient claim reporting a primary service that is assigned to status indicator "J1,"[1] excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS. Services and procedures described by HCPCS codes assigned to status indicator "J1" are assigned to C-APCs based on our usual APC assignment methodology by evaluating the geometric mean costs of the primary service claims to establish resource similarity and the clinical characteristics of each procedure to establish clinical similarity within each APC.

In the CY 2016 OPPS/ASC final rule with comment period, we expanded the C-APC payment methodology to qualifying extended assessment and management encounters through the "Comprehensive Observation Services" C–APC (C–APC 8011). Services within this APC are assigned status indicator "J2."[2] Specifically, we make a payment through C–APC 8011 for a claim that:

- Does not contain a procedure described by a HCPCS code to which we have assigned status indicator "T[3];"
- Contains 8 or more units of services described by HCPCS code G0378 (Hospital observation services, per hour);

[1] Status indicator "J1" denotes Hospital Part B Services Paid Through a Comprehensive APC. Further information can be found in CY 2026 Addendum D1.
[2] Status indicator "J2" denotes Hospital Part B Services That May Be Paid Through a Comprehensive APC. Further information can be found in CY 2026 Addendum D1.
[3] Status Indicator "T" is defined as a "Procedure or Service, Multiple Procedure Reduction Applies" the OPPS payment status is "Paid under OPPS; separate APC payment." Definitions to all OPPS payment status indicators are available in Addenda D1 to this proposed rule.

• Contains services provided on the same date of service or one day before the date of service for HCPCS code G0378 that are described by one of the following codes: HCPCS code G0379 (Direct admission of patient for hospital observation care) on the same date of service as HCPCS code G0378; CPT code 99281 (Emergency department visit for the evaluation and management of a patient (Level 1)); CPT code 99282 (Emergency department visit for the evaluation and management of a patient (Level 2)); CPT code 99283 (Emergency department visit for the evaluation and management of a patient (Level 3)); CPT code 99284 (Emergency department visit for the evaluation and management of a patient (Level 4)); CPT code 99285 (Emergency department visit for the evaluation and management of a patient (Level 5)) or HCPCS code G0380 (Type B emergency department visit (Level 1)); HCPCS code G0381 (Type B emergency department visit (Level 2)); HCPCS code G0382 (Type B emergency department visit (Level 3)); HCPCS code G0383 (Type B emergency department visit (Level 4)); HCPCS code G0384 (Type B emergency department visit (Level 5)); CPT code 99291 (Critical care, evaluation and management of the critically ill or critically injured patient; first 30-74 minutes); or HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient); and

● Does not contain services described by a HCPCS code to which we have assigned status indicator "J1."

The assignment of status indicator "J2" to a specific set of services performed in combination with each other allows for all other OPPS payable services and items reported on the claim (excluding services that are not covered OPD services or that cannot by statute be paid for under the OPPS) to be deemed adjunctive services representing components of a comprehensive service and resulting in a single prospective payment for the comprehensive service based on the costs of all reported services on the claim (80 FR 70333 through 70336).

Services included under the C-APC payment packaging policy, that is, services that are typically adjunctive to the primary service and provided during the delivery of the

comprehensive service, include diagnostic procedures, laboratory tests, and other diagnostic tests and treatments that assist in the delivery of the primary procedure; visits and evaluations performed in association with the procedure; uncoded services and supplies used during the service; durable medical equipment as well as prosthetic and orthotic items and supplies when provided as part of the outpatient service; and any other components reported by HCPCS codes that represent services that are provided during the complete comprehensive service (78 FR 74865 and 79 FR 66800).

In addition, payment for hospital outpatient department services that are similar to therapy services, such as speech language pathology, and delivered either by therapists or nontherapists is included as part of the payment for the packaged complete comprehensive service. These services that are provided during the perioperative period are adjunctive services and are deemed not to be therapy services as described in section 1834(k) of the Act, regardless of whether the services are delivered by therapists or other nontherapist health care workers. We have previously noted that therapy services are those provided by therapists under a plan of care in accordance with section 1835(a)(2)(C) and section 1835(a)(2)(D) of the Act and are paid for under section 1834(k) of the Act, subject to annual therapy caps as applicable (78 FR 74867 and 79 FR 66800). However, certain other services similar to therapy services are considered and paid for as hospital outpatient department services. Payment for these nontherapy outpatient department services that are reported with therapy codes and provided with a comprehensive service is included in the payment for the packaged complete comprehensive service. We note that these services, even though they are reported with therapy codes, are hospital outpatient department services and not therapy services. We refer readers to the July 2016 OPPS Change Request 9658 (Transmittal 3523)[4] for further instructions on reporting these services in the context of a C-APC service.

[4] *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r3523cp.pdf.*

Items included in the packaged payment provided in conjunction with the primary service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and SADs, unless they function as packaged supplies (78 FR 74868, 74869, and 74909 and 79 FR 66800). We refer readers to Section 50.2M, Chapter 15, of the Medicare Benefit Policy Manual for a description of our policy on SADs treated as hospital outpatient supplies, including lists of SADs that function as supplies and those that do not function as supplies.[5]

We define each hospital outpatient claim reporting a single unit of a single primary service assigned to status indicator "J1" as a single "J1" unit procedure claim (78 FR 74871 and 79 FR 66801). Line-item charges for services included on the C-APC claim are converted to line-item costs, which are then summed to develop the estimated APC costs. These claims are then assigned one unit of the service with status indicator "J1" and later used to develop the geometric mean costs for the C-APC relative payment weights. (We note that we use the term "comprehensive" to describe the geometric mean cost of a claim reporting "J1" service(s) or the geometric mean cost of a C-APC, inclusive of all the items and services included in the C-APC service payment bundle.) Charges for services that would otherwise be separately payable are added to the charges for the primary service. This process differs from our traditional cost accounting methodology only in that all such services on the claim are packaged (except certain services as described above). We apply our standard data trims, which exclude claims with extremely high primary units or extreme costs.

The comprehensive geometric mean costs are used to establish resource similarity and, along with clinical similarity, dictate the assignment of the primary services to the C-APCs. We establish a ranking of each primary service (single unit only) to be assigned to status indicator "J1" according to its comprehensive geometric mean costs. For the minority of claims reporting more than one primary service assigned to status indicator "J1" or units thereof, we identify one

[5] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.*

"J1" service as the primary service for the claim based on our cost-based ranking of primary services. We then assign these multiple "J1" procedure claims to the C-APC to which the service designated as the primary service is assigned. If the reported "J1" services on a claim map to different C-APCs, we designate the "J1" service assigned to the C-APC with the highest comprehensive geometric mean cost as the primary service for that claim. If the reported multiple "J1" services on a claim map to the same C-APC, we designate the most costly service (at the HCPCS code level) as the primary service for that claim. This process results in initial assignments of claims for the primary services assigned to status indicator "J1" to the most appropriate C-APCs based on both single and multiple procedure claims reporting these services and clinical and resource homogeneity.

Complexity Adjustments. We use complexity adjustments to provide increased payment for certain comprehensive services. We apply a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and certain add-on codes (as described further below) from the originating C-APC (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. We apply this type of complexity adjustment when the paired code combination represents a complex, costly form or version of the primary service according to the following criteria:

- Frequency of 25 or more claims reporting the code combination (frequency threshold); and
- Violation of the 2 times rule, as stated in section 1833(t)(2) of the Act and section III.B.2. of this proposed rule, in the originating C-APC (cost threshold).

These criteria identify paired code combinations that occur commonly and exhibit materially greater resource requirements than the primary service. The CY 2017 OPPS/ASC final rule with comment period (81 FR 79582) included a revision to the complexity adjustment eligibility criteria. Specifically, we finalized a policy to discontinue the requirement that a code

combination (that qualifies for a complexity adjustment by satisfying the frequency and cost criteria thresholds described above) also not create a 2 times rule violation in the higher level or receiving APC.

After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim assigned to status indicator "J1" (or certain add-on codes) to determine if there are paired code combinations that meet the complexity adjustment criteria. For a new HCPCS code, we determine initial C-APC assignment and qualification for a complexity adjustment using the best available information, crosswalking the new HCPCS code to a predecessor code(s) when appropriate.

Once we have determined that a particular code combination of "J1" services (or combinations of "J1" services reported in conjunction with certain add-on codes) represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described above, we promote the claim including the complex version of the primary service as described by the code combination to the next higher cost C-APC within the clinical family, unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

We package payment for all add-on codes into the payment for the C-APC. However, certain primary service add-on combinations may qualify for a complexity adjustment. As noted in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70331), all add-on codes that can be appropriately reported in combination with a base code that describes a primary "J1" service are evaluated for a complexity adjustment.

To determine which combinations of primary service codes reported in conjunction with an add-on code may qualify for a complexity adjustment for CY 2026, we apply the frequency and cost criteria thresholds discussed above, testing claims reporting one unit of a single primary service assigned to status indicator "J1" and any number of units of a single add-on code for the primary "J1" service. If the frequency and cost criteria thresholds for a complexity adjustment are met and reassignment to the next higher cost APC in the clinical family is appropriate (based on meeting the criteria outlined above), we make a complexity adjustment for the code combination; that is, we reassign the primary service code reported in conjunction with the add-on code to the next higher cost C-APC within the same clinical family of C-APCs. As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and is not reassigned to the next higher cost C-APC. We list the proposed complexity adjustments for "J1" and add-on code combinations for CY 2026, along with all the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

Addendum J to this proposed rule includes the cost statistics for each code combination that would qualify for a complexity adjustment (including primary code and add-on code combinations). Addendum J to this proposed rule also contains summary cost statistics for each of the paired code combinations that describe a complex code combination that would qualify for a complexity adjustment and be reassigned to the next higher cost C-APC within the clinical family. The combined statistics for all proposed reassigned complex code combinations are represented by an alphanumeric code with the first four digits of the designated primary service followed by a letter. For example, the proposed geometric mean cost listed in Addendum J for

the code combination described by complexity adjustment assignment 3320R, which is assigned to C-APC 5224 (Level 4 Pacemaker and Similar Procedures), includes all paired code combinations that will be reassigned to C-APC 5224 when CPT code 33208 is the primary code. Providing the information contained in Addendum J to this proposed rule allows interested parties the opportunity to better assess the impact associated with the assignment of claims with each of the paired code combinations eligible for a complexity adjustment.

(2) Comment Solicitation on C-APC Complexity Adjustment Criteria

We have received a variety of requests from interested parties as well, as public comments in past rulemaking, related to our C-APC complexity adjustment criteria. Interested parties and commenters have requested that CMS modify the established C-APC complexity adjustment eligibility criteria of 25 or more claims reporting the code combination (frequency threshold) and a violation of the 2 times rule in the originating C-APC (cost threshold) to allow additional code combinations to qualify for complexity adjustments. Interested parties and commenters have also requested expanding the qualifying code combinations for complexity adjustments to allow clusters of procedures, consisting of a "J1" code pair and multiple other associated add-on codes, to be used in combination with that "J1" code pair to qualify. These interested parties and commenters have noted these expanded combinations may allow for a more accurate reflection of medical practice when multiple procedures are performed together or there are certain complex procedures that include numerous add-on codes.

For CY 2026, we are soliciting comments on potential refinements to our C-APC complexity adjustment criteria. Under this solicitation, we are seeking comment on expanding code combinations that qualify for complexity adjustments, including any specifications related to determining specific combination types and how they represent a complex, costly subset of the primary service. We are seeking comment on how CMS could identify service pairings or clusters of services for complexity adjustments that are clinically appropriate but are currently not evaluated for complexity adjustments. Additionally, if we were to expand our complexity

adjustment criteria to allow for clusters of codes, we are seeking comment on what the appropriate cost and frequency thresholds could be used to identify which code clusters truly reflect complex and resource-intensive code combinations that are commonly performed in the hospital outpatient department setting.

We are seeking comment on which services are clinically integral to the provision of "J1" services that would qualify for a complexity adjustment under an expanded evaluation framework. Specifically, we are seeking comment on what criteria we could add, reflecting clinical practice, that would determine the costly additional components that are often associated with other high-cost packaged items and services. Finally, we are seeking comment on how we might address the unintended consequences of granular coding on the mechanics of the complexity adjustment criteria and if highly specific coding truly reflects clinical practice in hospital outpatient departments.

(3) Exclusion of Procedures Assigned to New Technology APCs from the C-APC Policy

Services that are assigned to New Technology APCs are typically new procedures that do not have sufficient claims history to establish an accurate payment for them. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected (82 FR 59277).

The C-APC payment policy packages payment for adjunctive and secondary items, services, and procedures into the most costly primary procedure under the OPPS at the claim level. Prior to CY 2019, when a procedure assigned to a New Technology APC was included on the claim with a primary procedure, identified by OPPS status indicator "J1," payment for the new technology service was typically packaged into the payment for the primary procedure.

Because the new technology service was not separately paid in this scenario, the overall number of single claims available to determine an appropriate clinical APC for the new service was reduced. This was contrary to the objective of the New Technology APC payment policy, which is to gather sufficient claims data to enable us to assign the service to an appropriate clinical APC.

To address this issue and ensure that there are sufficient claims data for services assigned to New Technology APCs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58847), we finalized excluding payment for any procedure that is assigned to a New Technology APC (APCs 1491 through 1599 and APCs 1901 through 1908) from being packaged when included on a claim with a "J1" service assigned to a C-APC. In the CY 2020 OPPS/ASC final rule with comment period, we finalized that beginning in CY 2020, payment for services assigned to a New Technology APC would be excluded from being packaged into the payment for comprehensive observation services assigned status indicator "J2" when they are included on a claim with a "J2" service (84 FR 61167).

(4) Exclusion of Drugs and Biologicals Described by HCPCS Code C9399 (Unclassified drugs or biologicals) from the C-APC Policy

Section 1833(t)(15) of the Act, as added by section 621(a)(1) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173), provides for payment under the OPPS for new drugs and biologicals until HCPCS codes are assigned. Under this provision, we are required to make payment for a covered outpatient drug or biological that is furnished as part of covered outpatient department services but for which a HCPCS code has not yet been assigned in an amount equal to 95 percent of average wholesale price (AWP) for the drug or biological.

In the CY 2005 OPPS/ASC final rule with comment period (69 FR 65805), we implemented section 1833(t)(15) of the Act by instructing hospitals to bill for a drug or biological that is newly approved by the Food and Drug Administration (FDA) and that does not

yet have a HCPCS code by reporting the National Drug Code (NDC) for the product along with the newly created HCPCS code C9399 (Unclassified drugs or biologicals). We explained that when HCPCS code C9399 appears on a claim, the Outpatient Code Editor (OCE) suspends the claim for manual pricing by the Medicare Administrative Contractor (MAC). The MAC prices the claim at 95 percent of the drug or biological's AWP, using Red Book or an equivalent recognized compendium, and processes the claim for payment. We emphasized that this approach enables hospitals to bill and receive payment for a new drug or biological concurrent with its approval by the FDA. The hospital does not have to wait for the next quarterly release or for approval of a product specific HCPCS code to receive payment for a newly approved drug or biological or to resubmit claims for adjustment. We instructed that hospitals would discontinue billing HCPCS code C9399 and the NDC upon implementation of a product specific HCPCS code, status indicator, and appropriate payment amount with the next quarterly update. We also note that HCPCS code C9399 is paid in a similar manner in the ASC setting, as 42 CFR 416.171(b) outlines that certain drugs and biologicals for which separate payment is allowed under the OPPS are considered covered ancillary services for which the OPPS payment rate, which is 95 percent of AWP for HCPCS code C9399, applies. Since the implementation of the C-APC policy in 2015, payment for drugs and biologicals described by HCPCS code C9399 had been included in the C-APC payment when these products appear on a claim with a primary C-APC service. Packaging payment for these drugs and biologicals that appear on a hospital outpatient claim with a primary C-APC service is consistent with our C-APC packaging policy under which we make payment for all items and services, including all non-pass-through drugs, reported on the hospital outpatient claim as being integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a complete comprehensive service, with certain limited exceptions (78 FR 74869). It was our position that the total payment for the C-APC with which payment for a drug or biological described by HCPCS code C9399 is packaged includes payment for the drug or biological at 95 percent of its AWP.

However, we determined that in certain instances, drugs and biologicals described by HCPCS code C9399 are not being paid at 95 percent of their AWPs when payment for them is packaged with payment for a primary C-APC service. In order to ensure payment for new drugs and biologicals described by HCPCS code C9399 at 95 percent of their AWP, for CY 2023 and subsequent years, we finalized our proposal to exclude any drug or biological described by HCPCS code C9399 from packaging when the drug or biological is included on a claim with a "J1" service, which is the status indicator assigned to a C-APC, and a claim with a "J2" service, which is the status indicator assigned to comprehensive observation services. See Addendum J to this proposed rule for the proposed CY 2026 C-APC payment policy exclusions.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized the proposal in section XI., "CY 2023 OPPS Payment Status and Comment Indicators", to add a new definition to status indicator "A" to include unclassified drugs and biologicals that are reportable with HCPCS code C9399 (87 FR 72051). The current definition, as finalized in the CY 2023 OPPS/ASC final rule with comment period, can be found in Addendum D1 of this proposed rule, would ensure the MAC prices claims for drugs or biologicals billed with HCPCS code C9399 at 95 percent of the drug or biological's AWP and pays separately for the drug or biological under the OPPS when it appears on the same claim as a primary C-APC service.

(5) Exclusion of Cell and Gene Therapies from the C-APC Policy

As previously discussed in this section, and in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74865), the C-APC policy packages payment for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to the primary service and provided during the delivery of the comprehensive service, including diagnostic procedures, laboratory tests and other diagnostic tests and treatments that assist in the delivery of the primary procedure. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74861), we finalized defining a comprehensive APC as a classification for the provision of a primary service and all adjunctive services provided to support the delivery of the primary service. Because a

comprehensive APC treats all individually reported codes as representing components of the comprehensive service, we make a single prospective payment based on the cost of all individually reported codes that represent the provision of a primary service and all adjunctive services provided to support that delivery of the primary service.

As discussed in the CY 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204), we generally treat all items and services reported on a C-APC claim as integral, ancillary, supportive, dependent, and adjunctive to the primary service and representing components of a comprehensive service. Historically, items packaged for payment provided in conjunction with the primary C-APC service also include all drugs, biologicals, and radiopharmaceuticals, regardless of cost, except those drugs with pass-through payment status and those drugs that are usually self-administered (SADs), unless they function as supplies (78 FR 74868 through 74869 and 74909).

However, we recognized in the 2025 OPPS/ASC proposed rule (89 FR 59201 through 59204) that there are rare instances in which cell and gene therapies appear on the same claim as a primary C-APC service and therefore, have their payment packaged with payment for the primary C-APC service. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93932 through 93938), given the unique nature of these therapies, we do not believe they function as integral, ancillary, supportive, dependent, or adjunctive to any of the current primary C-APC services. Additionally, we stated that when these products are administered, they are the primary treatment being administered to a patient and thus, are not integral, ancillary, supportive, dependent, or adjunctive to any primary C-APC services.

Therefore, we finalized a policy for CY 2025 and subsequent years (89 FR 93932 through 93938), to not package payment for cell and gene therapies into C-APCs, when those cell and gene therapies are not functioning as integral, ancillary, supportive, dependent, or adjunctive to the primary C-APC service. For new cell and gene therapy products that are not integral, ancillary, supportive, dependent, or adjunctive to any C-APC primary service, we will

continue to add their product specific HCPCS codes, when created, to the C-APC exclusion list. The current list of qualifying products can be found in Table 1.

We list all proposed C-APC exclusion categories for CY 2026 in Addendum J to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

TABLE 1: CELL AND GENE THERAPIES PROPOSED FOR EXCLUSION FROM C-APC PACKAGING FOR CY 2026

Trade Name	HCPCS Code	Long Descriptor
Yescarta	Q2041	Axicabtagene ciloleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Kymriah	Q2042	Tisagenlecleucel, up to 600 million car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Provenge	Q2043	Sipuleucel-t, minimum of 50 million autologous cd54+ cells activated with pap-gm-csf, including leukapheresis and all other preparatory procedures, per infusion
Tecartus	Q2053	Brexucabtagene autoleucel, up to 200 million autologous anti-cd19 car positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Breyanzi	Q2054	Lisocabtagene maraleucel, up to 110 million autologous anti-cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Abecma	Q2055	Idecabtagene vicleucel, up to 510 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
Luxturna	J3398	Injection, voretigene neparvovec-rzyl, 1 billion vector genomes
Zolgensma	J3399	Injection, onasemnogene abeparvovec-xioi, per treatment, up to 5x10^15 vector genomes
CASGEVY	J3392	Injection, exagamglogene autotemcel, per treatment

(6) Exclusion of Non-Opioid Products for Pain Relief under Section 4135 of the Consolidated Appropriations Act, 2023 from the C-APC Policy

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled “Access to Non-

Opioid Treatments for Pain Relief," amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount. As stated earlier in this section, our current policy is to exclude from the packaged C-APC payment those items and services that are required by statute to be separately paid.

Accordingly, in the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to exclude the non-opioid treatments for pain relief identified as satisfying the required criteria for payment under section 4135 of the CAA, 2023 from the C-APC policy to ensure payment is not packaged into any C-APC and that separate payment is made in accordance with the statute (89 FR 93938 through 93939).

(7) C-APCs for CY 2026

For CY 2026 and subsequent years, we propose to continue to apply the C-APC payment policy methodology. We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79583) for a discussion of the C-APC payment policy methodology and revisions.

Each year, in accordance with section 1833(t)(9)(A) of the Act, we review and revise the services within each APC group and the APC assignments under the OPPS. As a result of our annual review of the services and the APC assignments under the OPPS, we are not proposing to convert any standard APCs to C-APCs in CY 2026; thus, we propose that the number of C-APCs for CY 2026 would be the same as the number for CY 2025, which is 72 C-APCs.

Table 2 lists the proposed C-APCs for CY 2026, all of which were established in past rules. All C-APCs are displayed in Addendum J to this proposed rule. Addendum J to this proposed rule also contains all the data related to the C-APC payment policy methodology, including the list of complexity adjustments and other information.

TABLE 2: PROPOSED CY 2026 C-APCs

C-APC	CY 2026 APC Group Title	Clinical Family
5072	Level 2 Excision/Biopsy/Incision and Drainage	EBIDX
5073	Level 3 Excision/Biopsy/Incision and Drainage	EBIDX
5091	Level 1 Breast/Lymphatic Surgery and Related Procedures	BREAS
5092	Level 2 Breast/Lymphatic Surgery and Related Procedures	BREAS
5093	Level 3 Breast/Lymphatic Surgery and Related Procedures	BREAS
5094	Level 4 Breast/Lymphatic Surgery and Related Procedures	BREAS
5112	Level 2 Musculoskeletal Procedures	ORTHO
5113	Level 3 Musculoskeletal Procedures	ORTHO
5114	Level 4 Musculoskeletal Procedures	ORTHO
5115	Level 5 Musculoskeletal Procedures	ORTHO
5116	Level 6 Musculoskeletal Procedures	ORTHO
5153	Level 3 Airway Endoscopy	AENDO
5154	Level 4 Airway Endoscopy	AENDO
5155	Level 5 Airway Endoscopy	AENDO
5163	Level 3 ENT Procedures	ENTXX
5164	Level 4 ENT Procedures	ENTXX
5165	Level 5 ENT Procedures	ENTXX
5166	Cochlear Implant Procedure	COCHL
5182	Level 2 Vascular Procedures	VASCX
5183	Level 3 Vascular Procedures	VASCX
5184	Level 4 Vascular Procedures	VASCX
5191	Level 1 Endovascular Procedures	EVASC
5192	Level 2 Endovascular Procedures	EVASC
5193	Level 3 Endovascular Procedures	EVASC
5194	Level 4 Endovascular Procedures	EVASC
5200	Implantation Wireless PA Pressure Monitor	WPMXX
5211	Level 1 Electrophysiologic Procedures	EPHYS
5212	Level 2 Electrophysiologic Procedures	EPHYS
5213	Level 3 Electrophysiologic Procedures	EPHYS
5222	Level 2 Pacemaker and Similar Procedures	AICDP
5223	Level 3 Pacemaker and Similar Procedures	AICDP
5224	Level 4 Pacemaker and Similar Procedures	AICDP
5231	Level 1 ICD and Similar Procedures	AICDP
5232	Level 2 ICD and Similar Procedures	AICDP
5244	Level 4 Blood Product Exchange and Related Services	SCTXX
5302	Level 2 Upper GI Procedures	GIXXX
5303	Level 3 Upper GI Procedures	GIXXX
5313	Level 3 Lower GI Procedures	GIXXX
5331	Complex GI Procedures	GIXXX
5341	Level 1 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5342	Level 2 Abdominal/Peritoneal/Biliary and Related Procedures	GIXXX
5361	Level 1 Laparoscopy and Related Services	LAPXX
5362	Level 2 Laparoscopy and Related Services	LAPXX

C-APC	CY 2026 APC Group Title	Clinical Family
5372	Level 2 Urology and Related Services	UROXX
5373	Level 3 Urology and Related Services	UROXX
5374	Level 4 Urology and Related Services	UROXX
5375	Level 5 Urology and Related Services	UROXX
5376	Level 6 Urology and Related Services	UROXX
5377	Level 7 Urology and Related Services	UROXX
5378	Level 8 Urology and Related Services	UROXX
5414	Level 4 Gynecologic Procedures	GYNXX
5415	Level 5 Gynecologic Procedures	GYNXX
5416	Level 6 Gynecologic Procedures	GYNXX
5431	Level 1 Nerve Procedures	NERVE
5432	Level 2 Nerve Procedures	NERVE
5461	Level 1 Neurostimulator and Related Procedures	NSTIM
5462	Level 2 Neurostimulator and Related Procedures	NSTIM
5463	Level 3 Neurostimulator and Related Procedures	NSTIM
5464	Level 4 Neurostimulator and Related Procedures	NSTIM
5465	Level 5 Neurostimulator and Related Procedures	NSTIM
5471	Implantation of Drug Infusion Device	PUMPS
5491	Level 1 Intraocular Procedures	INEYE
5492	Level 2 Intraocular Procedures	INEYE
5493	Level 3 Intraocular Procedures	INEYE
5494	Level 4 Intraocular Procedures	INEYE
5495	Level 5 Intraocular Procedures	INEYE
5496	Level 6 Intraocular Procedures	INEYE
5503	Level 3 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5504	Level 4 Extraocular, Repair, and Plastic Eye Procedures	EXEYE
5627	Level 7 Radiation Therapy	RADTX
5881	Ancillary Outpatient Services When Patient Dies	N/A
8011	Comprehensive Observation Services	N/A

C-APC Clinical Family Descriptor Key:
AENDO = Airway Endoscopy
AICDP = Automatic Implantable Cardiac Defibrillators, Pacemakers, and Related Devices.
BREAS = Breast Surgery
COCHL = Cochlear Implant
EBIDX = Excision/ Biopsy/Incision and Drainage
ENTXX = ENT Procedures
EPHYS = Cardiac Electrophysiology/
EVASC = Endovascular Procedures
EXEYE = Extraocular Ophthalmic Surgery
GIXXX = Gastrointestinal Procedures
GYNXX = Gynecologic Procedures
INEYE = Intraocular Surgery
LAPXX = Laparoscopic Procedures
NERVE = Nerve Procedures
NSTIM = Neurostimulators
ORTHO = Orthopedic Surgery
PUMPS = Implantable Drug Delivery Systems
RADTX = Radiation Oncology
SCTXX = Stem Cell Transplant
UROXX = Urologic Procedures
VASCX = Vascular Procedures
WPMXX = Wireless PA Pressure Monitor

c. Calculation of Composite APC Criteria-Based Costs

As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613), we believe it is important that the OPPS enhance incentives for hospitals to provide necessary,

high-quality care as efficiently as possible. For CY 2008, we developed composite APCs to provide a single payment for groups of services that are typically performed together during a single clinical encounter and that result in the provision of a complete service. Combining payment for multiple, independent services into a single OPPS payment in this way enables hospitals to manage their resources with maximum flexibility by monitoring and adjusting the volume and efficiency of services themselves. An additional advantage to the composite APC model is that we can use data from correctly coded multiple procedure claims to calculate payment rates for the specified combinations of services, rather than relying upon single procedure claims which may be low in volume and/or incorrectly coded. Under the OPPS, we currently have composite policies for mental health services and multiple imaging services. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66611 through 66614 and 66650 through 66652) for a full discussion of the development of the composite APC methodology, and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74163) and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59241, 59242, and 59246 through 52950) for further background.

(1) Mental Health Services Composite APC

For CY 2026, we propose to continue our longstanding policy of limiting the aggregate payment for specified less resource-intensive mental health services furnished on the same date to the payment for a day of partial hospitalization services provided by a hospital, which we consider to be the most resource-intensive of all outpatient mental health services (88 FR 49572). We refer readers to the April 7, 2000, OPPS final rule with comment period (65 FR 18452 through 18455) for the initial discussion of this longstanding policy and the CY 2012 OPPS/ASC final rule with comment period (76 FR 74168) for further background.

In the CY 2018 OPPS/ASC proposed rule and final rule with comment period (82 FR 33580 and 33581 and 82 FR 59246 and 59247), we proposed and finalized the policy for CY 2018 and subsequent years that, when the aggregate payment for specified mental health

services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the maximum per diem payment rate for partial hospitalization services provided by a hospital, those specified mental health services will be paid through composite APC 8010 (Mental Health Services Composite). In addition, we set the payment rate for composite APC 8010 for CY 2018 at the same payment rate for APC 5863, which was the maximum partial hospitalization per diem payment rate for a hospital, and finalized a policy that the hospital would continue to be paid the payment rate for composite APC 8010. This policy applied in CYs 2018 through 2023.

In the CY 2024 OPPS/ASC proposed rule, we stated that APC 5863 was no longer the maximum partial hospitalization per diem payment rate for a hospital due to the creation of APC 5864, which is four or more hospital-based PHP services per day (88 FR 49572). We solicited comment on whether APC 5864 would be appropriate to use as the daily mental health cap, as we have historically set the daily mental health cap for composite APC 8010 at the maximum partial hospitalization per diem payment rate for a hospital (88 FR 49572). Based on public comments received and our longstanding policy, in CY 2024 OPPS/ASC final rule, we finalized APC 5864, four hospital-based PHP services per day, as the daily mental health cap (88 FR 81566).

We continue to believe that the costs associated with administering a partial hospitalization program represent the most resource intensive of all outpatient mental health services. For CY 2026 and subsequent years, we propose to continue this policy that when the aggregate payment for specified mental health services provided by one hospital to a single beneficiary on a single date of service, based on the payment rates associated with the APCs for the individual services, exceeds the per diem payment rate for 4 partial hospitalization services provided in a day by a hospital (the payment amount for APC 5864), those specified mental health services would be paid through composite APC 8010. In addition, we propose to continue to set the payment rate for composite APC 8010 at the same payment rate that we propose for

APC 5864, which is a partial hospitalization per diem payment rate for 4 partial hospitalization services furnished in a day by a hospital.

Under the proposed policy, the Integrated OCE (I/OCE) would continue to determine whether to pay for these specified mental health services individually, or to make a single payment at the same payment rate established for APC 5864 for all the specified mental health services furnished by the hospital on that single date of service by paying for the services through composite APC 5863.

(2) Multiple Imaging Composite APCs (APCs 8004, 8005, 8006, 8007, and 8008)

Effective January 1, 2009, we provide a single payment each time a hospital submits a claim for more than one imaging procedure within an imaging family on the same date of service, to reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session (73 FR 41448 through 41450). We utilize three imaging families based on imaging modality for purposes of this methodology: (1) ultrasound; (2) computed tomography (CT) and computed tomographic angiography (CTA); and (3) magnetic resonance imaging (MRI) and magnetic resonance angiography (MRA). The HCPCS codes subject to the multiple imaging composite policy and their respective families are listed in Table 3.

While there are three imaging families, there are five multiple imaging composite APCs due to the statutory requirement under section 1833(t)(2)(G) of the Act that we differentiate payment for OPPS imaging services provided with and without contrast. While the ultrasound procedures included under the policy do not involve contrast, both CT/CTA and MRI/MRA scans can be provided either with or without contrast. The five multiple imaging composite APCs established in CY 2009 are:

- APC 8004 (Ultrasound Composite);
- APC 8005 (CT and CTA without Contrast Composite);

● APC 8006 (CT and CTA with Contrast Composite);

● APC 8007 (MRI and MRA without Contrast Composite); and

● APC 8008 (MRI and MRA with Contrast Composite).

We define the single imaging session for the "with contrast" composite APCs as having at least one or more imaging procedures from the same family performed with contrast on the same date of service. For example, if the hospital performs an MRI without contrast during the same session as at least one other MRI with contrast, the hospital will receive payment based on the payment rate for APC 8008, the "with contrast" composite APC.

We make a single payment for those imaging procedures that qualify for payment based on the composite APC payment rate, which includes any packaged services furnished on the same date of service. The standard (noncomposite) APC assignments continue to apply for single imaging procedures and multiple imaging procedures performed across families. For a full discussion of the development of the multiple imaging composite APC methodology, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68559 through 68569).

For CY 2026, we propose to continue to pay for all multiple imaging procedures within an imaging family performed on the same date of service using the multiple imaging composite APC payment methodology. We continue to believe that this policy would reflect and promote the efficiencies hospitals can achieve when performing multiple imaging procedures during a single session.

For CY 2026, except where otherwise indicated, we propose to use the costs derived from CY 2024 claims data to set the proposed CY 2026 payment rates. Therefore, for CY 2026, the proposed payment rates for the five multiple imaging composite APCs (APCs 8004, 8005, 8006, 8007, and 8008) were based on proposed geometric mean costs calculated from CY 2024 claims available for the CY 2026 OPPS/ASC proposed rule that qualify for composite payment under the current policy (that is, those claims reporting more than one procedure within the same

family on a single date of service). To calculate the proposed geometric mean costs, we used the same methodology that we used to calculate the geometric mean costs for these composite APCs since CY 2014, as described in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918). The imaging HCPCS codes referred to as "overlap bypass codes" that we removed from the bypass list for purposes of calculating the proposed multiple imaging composite APC geometric mean costs, in accordance with our established methodology as stated in the CY 2014 OPPS/ASC final rule with comment period (78 FR 74918), are identified by asterisks in Addendum N to this proposed rule (which is available via the Internet on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) and are discussed in more detail in section II.A.1.a. of this proposed rule.

For this proposed rule, we were able to identify approximately 0.98 million "single session" claims out of an estimated 2.2 million potential claims for payment through composite APCs from our ratesetting claims data, which represents approximately 44.0 percent of all eligible claims, to calculate the proposed CY 2026 geometric mean costs for the multiple imaging composite APCs. Table 3 lists the proposed HCPCS codes that would be subject to the multiple imaging composite APC policy and their respective families and approximate composite APC final geometric mean costs for CY 2026.

TABLE 3: OPPS IMAGING FAMILIES AND MULTIPLE IMAGING PROCEDURE COMPOSITE APCS

Family 1 – Ultrasound	
CY 2026 APC 8004 (Ultrasound Composite)	**CY 2026 Approximate APC Geometric Mean Cost = $307.79**
76700	Us exam, abdom, complete
76705	Echo exam of abdomen
76770	Us exam abdo back wall, comp
76776	Us exam k transpl w/Doppler
76831	Echo exam, uterus
76856	Us exam, pelvic, complete
76857	Us exam, pelvic, limited
76981	Us parenchyma

76982	Us 1st target lesion
Family 2 - CT and CTA with and without Contrast	
CY 2026 APC 8005 (CT and CTA without Contrast Composite) *	**CY 2026 Approximate APC Geometric Mean Cost = $229.60**
0633T	Ct breast w/3d uni c-
0636T	Ct breast w/3d bi c-
70450	Ct head/brain w/o dye
70480	Ct orbit/ear/fossa w/o dye
70486	Ct maxillofacial w/o dye
70490	Ct soft tissue neck w/o dye
71250	Ct thorax w/o dye
72125	Ct neck spine w/o dye
72128	Ct chest spine w/o dye
72131	Ct lumbar spine w/o dye
72192	Ct pelvis w/o dye
73200	Ct upper extremity w/o dye
73700	Ct lower extremity w/o dye
74150	Ct abdomen w/o dye
74176	Ct angio abd & pelvis
74261	Ct colonography, w/o dye
CY 2026 APC 8006 (CT and CTA with Contrast Composite)	**CY 2026 Approximate APC Geometric Mean Cost = $445.99**
0634T	Ct breast w/3d uni c+
0635T	Ct breast w/3d uni c-/c+
0637T	Ct breast w/3d bi c+
0638T	Ct breast w/3d bi c-/c+
70460	Ct head/brain w/dye
70470	Ct head/brain w/o & w/dye
70481	Ct orbit/ear/fossa w/dye
70482	Ct orbit/ear/fossa w/o & w/dye
70487	Ct maxillofacial w/dye
70488	Ct maxillofacial w/o & w/dye
70491	Ct soft tissue neck w/dye
70492	Ct sft tsue nck w/o & w/dye
70496	Ct angiography, head
70498	Ct angiography, neck
71260	Ct thorax w/dye
70XX1	Cta h&n c+ w/noncontrast img
70XX3	Ct cere prfu aly c+wo ct/cta
71270	Ct thorax w/o & w/dye
71275	Ct angiography, chest
72126	Ct neck spine w/dye
72127	Ct neck spine w/o & w/dye
72129	Ct chest spine w/dye

72130	Ct chest spine w/o & w/dye
72132	Ct lumbar spine w/dye
72133	Ct lumbar spine w/o & w/dye
72191	Ct angiograph pelv w/o & w/dye
72193	Ct pelvis w/dye
72194	Ct pelvis w/o & w/dye
73201	Ct upper extremity w/dye
73202	Ct uppr extremity w/o & w/dye
73206	Ct angio upr extrm w/o & w/dye
73701	Ct lower extremity w/dye
73702	Ct lwr extremity w/o & w/dye
73706	Ct angio lwr extr w/o & w/dye
74160	Ct abdomen w/dye
74170	Ct abdomen w/o & w/dye
74175	Ct angio abdom w/o & w/dye
74177	Ct angio abd & pelv w/contrast
74178	Ct angio abd & pelv 1+ regns
74262	Ct colonography, w/dye
75635	Ct angio abdominal arteries
* If a “without contrast” CT or CTA procedure is performed during the same session as a “with contrast” CT or CTA procedure, the I/OCE assigns the procedure to APC 8006 rather than APC 8005.	
Family 3 - MRI and MRA with and without Contrast	
CY 2026 APC 8007 (MRI and MRA without Contrast Composite) *	**CY 2026 Approximate APC Geometric Mean Cost = $553.17**
0609T	Mrs disc pain acquisj data
70336	Magnetic image, jaw joint
70540	Mri orbit/face/neck w/o dye
70544	Mr angiography head w/o dye
70547	Mr angiography neck w/o dye
70551	Mri brain w/o dye
70554	Fmri brain by tech
71550	Mri chest w/o dye
72141	Mri neck spine w/o dye
72146	Mri chest spine w/o dye
72148	Mri lumbar spine w/o dye
72195	Mri pelvis w/o dye
73218	Mri upper extremity w/o dye
73221	Mri joint upr extrem w/o dye
73718	Mri lower extremity w/o dye
73721	Mri jnt of lwr extre w/o dye
74181	Mri abdomen w/o dye
75557	Cardiac mri for morph
75559	Cardiac mri w/stress img
76391	Mr elastography
77046	Mri breast c- unilateral

77047	Mri breast c- bilateral
C8901	MRA w/o cont, abd
C8910	MRA w/o cont, chest
C8913	MRA w/o cont, lwr ext
C8919	MRA w/o cont, pelvis
C8932	MRA, w/o dye, spinal canal
C8935	MRA, w/o dye, upper extr
C9762	Cardiac MRI seg dys strain
C9763	Cardiac MRI seg dys stress
CY 2026 APC 8008 (MRI and MRA with Contrast Composite)	**CY 2026 Approximate APC Geometric Mean Cost = $888.59**
70542	Mri orbit/face/neck w/dye
70543	Mri orbt/fac/nck w/o & w/dye
70545	Mr angiography head w/dye
70546	Mr angiograph head w/o & w/dye
70547	Mr angiography neck w/o dye
70548	Mr angiography neck w/dye
70549	Mr angiograph neck w/o & w/dye
70552	Mri brain w/dye
70553	Mri brain w/o & w/dye
71551	Mri chest w/dye
71552	Mri chest w/o & w/dye
72142	Mri neck spine w/dye
72147	Mri chest spine w/dye
72149	Mri lumbar spine w/dye
72156	Mri neck spine w/o & w/dye
72157	Mri chest spine w/o & w/dye
72158	Mri lumbar spine w/o & w/dye
72196	Mri pelvis w/dye
72197	Mri pelvis w/o & w/dye
73219	Mri upper extremity w/dye
73220	Mri uppr extremity w/o & w/dye
73222	Mri joint upr extrem w/dye
73223	Mri joint upr extr w/o & w/dye
73719	Mri lower extremity w/dye
73720	Mri lwr extremity w/o & w/dye
73722	Mri joint of lwr extr w/dye
73723	Mri joint lwr extr w/o & w/dye
74182	Mri abdomen w/dye
74183	Mri abdomen w/o & w/dye
75561	Cardiac mri for morph w/dye
75563	Card mri w/stress img & dye
C8900	MRA w/cont, abd
C8902	MRA w/o fol w/cont, abd

C8903	MRI w/cont, breast, uni
C8905	MRI w/o fol w/cont, brst, un
C8906	MRI w/cont, breast, bi
C8908	MRI w/o fol w/cont, breast,
C8909	MRA w/cont, chest
C8911	MRA w/o fol w/cont, chest
C8912	MRA w/cont, lwr ext
C8914	MRA w/o fol w/cont, lwr ext
C8918	MRA w/cont, pelvis
C8920	MRA w/o fol w/cont, pelvis
C8931	MRA, w/dye, spinal canal
C8933	MRA, w/o&w/dye, spinal canal
C8934	MRA, w/dye, upper extremity
C8936	MRA, w/o&w/dye, upper extr

***** If a "without contrast" MRI or MRA procedure is performed during the same session as a "with contrast" MRI or MRA procedure, the I/OCE assigns the procedure to APC 8008 rather than APC 8007.

3. Proposed Changes to Packaged Items and Services

a. Background and Rationale for Packaging in the OPPS

Like other prospective payment systems, the OPPS relies on the concept of averaging to establish a payment rate for services. The payment may be more or less than the estimated cost of providing a specific service or a bundle of specific services for a particular beneficiary. The OPPS packages payments for multiple interrelated items and services into a single payment to create incentives for hospitals to furnish services most efficiently and to manage their resources with maximum flexibility. Our packaging policies support our strategic goal of using larger payment bundles in the OPPS to maximize hospitals' incentives to provide care in the most efficient manner. For example, where there are a variety of devices, drugs, items, and supplies that could be used to furnish a service, some of which are more costly than others, packaging encourages hospitals to use the most cost-efficient item that meets the patient's needs, rather than to routinely use a more expensive item, which may occur if separate payment is provided for the item.

Packaging also encourages hospitals to effectively negotiate with manufacturers and suppliers to reduce the purchase price of items and services or to explore alternative group purchasing arrangements, thereby encouraging the most economical health care delivery.

Similarly, packaging encourages hospitals to establish protocols that ensure that necessary services are furnished, while scrutinizing the services ordered by practitioners to maximize the efficient use of hospital resources. Packaging payments into larger payment bundles promotes the predictability and accuracy of payment for services over time. Finally, packaging may reduce the importance of refining service-specific payments because packaged payments include costs associated with higher cost cases requiring many ancillary items and services and lower cost cases requiring fewer ancillary items and services. Packaging encourages efficiency and is an essential component of a prospective payment system; therefore, packaging payments for items and services that are typically integral, ancillary, supportive, dependent, or adjunctive to a primary service has been a fundamental part of the OPPS since its implementation in August 2000. As we continue to develop larger payment groups that more broadly reflect services provided in an encounter or episode of care, we have expanded the OPPS packaging policies. Most, but not necessarily all, categories of items and services currently packaged in the OPPS are listed in 42 CFR 419.2(b). Our overarching goal is to make payments for all services under the OPPS more consistent with those of a prospective payment system and less like those of a per-service fee schedule, which pays separately for each coded item. As a part of this effort, we have continued to examine the payment for items and services provided under the OPPS to determine which OPPS services can be packaged to further achieve the objective of advancing the OPPS toward a more prospective payment system.

b. Proposed CY 2026 Policy on Packaged Items and Services

For CY 2026, we examined the items and services currently provided under the OPPS, reviewing categories of integral, ancillary, supportive, dependent, or adjunctive items and services for which we believe payment would be appropriately packaged into payment for the primary service that they support. Specifically, we examined the HCPCS code definitions (including CPT code descriptors) and hospital outpatient department billing patterns to determine whether there were categories of codes for which packaging would be appropriate according to

existing OPPS packaging policies or a logical expansion of those existing OPPS packaging policies.

For CY 2026, we are not proposing any changes to the overall packaging policy discussed. We propose to continue to conditionally package the costs of selected newly identified ancillary services into payment for a primary service where we believe that the packaged item or service is integral, ancillary, supportive, dependent, or adjunctive to the provision of care that was reported by the primary service HCPCS code.

c. Payment for Diagnostic Radiopharmaceuticals

(1) Background on OPPS Packaging Policy for Diagnostic Radiopharmaceuticals

Under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in § 419.2(b), we refer to them as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. In particular, under § 419.2(b)(15), payment for drugs, biologicals, and, prior to CY 2025, all radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure are packaged with the payment for the related procedure or service. Packaging costs into a single aggregate payment for a service, encounter, or episode of care is a fundamental principle that distinguishes a prospective payment system from a fee schedule. In general, packaging the costs of supportive items and services into the payment for the primary procedure or service with which they are associated encourages hospital efficiencies and enables hospitals to manage their resources with maximum flexibility.

In the CY 2008 OPPS/ASC final rule with comment period, we finalized the packaging status of diagnostic radiopharmaceuticals as part of our overall enhanced packaging approach for the CY 2008 OPPS and subsequent years (72 FR 66635 through 66641). Importantly, we noted that we believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, making it appropriate to package the payment for the diagnostic radiopharmaceutical into the

payment for the related nuclear medicine procedure. Higher cost diagnostic radiopharmaceuticals were one specific type of product that, prior to CY 2025, was policy packaged under the category described by § 419.2(b)(15). Since we implemented this policy in CY 2008, interested parties raised concerns regarding policy packaging of diagnostic radiopharmaceuticals.

In the CY 2025 OPPS/ASC proposed rule (89 FR 59213 through 59222), we stated that we continue to believe diagnostic radiopharmaceuticals are always intended to be used with a diagnostic nuclear medicine procedure and function as supplies when used in a diagnostic test or procedure, generally making it appropriate to package payment for them with payment for the related nuclear medicine procedure. However, we stated there are certain situations in which the packaged payment amount attributed to the diagnostic radiopharmaceutical used in an imaging procedure assigned to a nuclear medicine APC may not adequately account for the cost of a diagnostic radiopharmaceutical that has a significantly higher cost, but lower utilization relative to the other diagnostic radiopharmaceuticals that may be used with the procedure.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963) we finalized a policy to pay separately for any diagnostic radiopharmaceutical with a per day cost greater than $630 for CY 2025. We propose to use the same methodology that was finalized in the CY 2025 OPPS/ASC final rule with comment period in order to calculate the per day costs for diagnostic radiopharmaceuticals for CY 2026 and future years (89 FR 93953 through 93955). We noted that any diagnostic radiopharmaceutical with a per day cost at or below that threshold will continue to be policy packaged under our longstanding policy at § 419.2(b)(15). Additionally, we finalized the policy that starting in CY 2026 and for subsequent years, we will update the threshold amount of $630 by a forecast of the Producer Price Index (PPI) for Pharmaceuticals for Human Use, Prescription (Bureau of Labor Statistics (BLS) series code WPUSI07003) from IHS Global, Inc (IGI) (89 FR 93955).

In the CY 2025 OPPS/ASC final rule with comment period, we also finalized a policy to pay for nonpass-through, separately payable diagnostic radiopharmaceuticals with per day costs above the designated threshold based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. As we found that the ASP data we had was not usable for the purpose of paying for diagnostic radiopharmaceuticals, we finalized a policy to pay for qualifying nonpass-through diagnostic radiopharmaceuticals with claims data based on mean unit cost data derived from hospital claims. Additionally, we finalized corresponding modifications to the regulation text at § 419.2(b)(15) and § 419.41 to codify our finalized payment policy for diagnostic radiopharmaceuticals and our existing policy for therapeutic radiopharmaceuticals. For additional information regarding the policy finalized for CY 2025, reference 89 FR 93948 through 93963.

(2) Proposed Diagnostic Radiopharmaceutical Packaging Threshold

For CY 2026, we propose to continue the policy finalized in CY 2025. Specifically, we propose to continue to calculate the per day cost of diagnostic radiopharmaceuticals based on the methodology described in section V.B.1.b. of this proposed rule, which relies on the methodology finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638).

As finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955), starting in the OPPS/ASC rulemaking for CY 2026 and for subsequent years, we stated we would update the proposed threshold amount of $630 by a forecast of the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) from IHS Global, Inc (IGI) by using most recently available four-quarter moving average PPI levels to trend from the third quarter of the year 2 years prior to the applicable calendar year to the third quarter of the year prior to the applicable calendar year (for example, from the third quarter of 2024 to the third quarter of 2025 for CY 2026). We propose a technical refinement to this policy. We propose to use the most recently available four-quarter moving average PPI levels to trend the

CY 2025 final threshold forward from the third quarter of the CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment. We believe using the most recently available four-quarter moving average PPI levels more appropriately updates the packaging threshold from CY 2025 for payment in CY 2026. For CY 2027 and subsequent updates, we therefore, propose to trend the CY 2025 threshold of $630 forward using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription for CY 2025 (third quarter) forward using the PPI for Pharmaceuticals for Human Use, Prescription for the applicable payment year (third quarter). This is the same as the update factor used for the OPPS drug packaging threshold, where we originally used the four-quarter moving average PPI levels for Pharmaceutical Preparations, Prescription (BLS series code WPUSI07003, formerly BLS series code 32541DRX) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108–173 mandated threshold became effective) to the third quarter of the applicable payment year (71 FR 68085 and 68086).

Therefore, for CY 2026, we propose to update the CY 2025 $630 threshold amount by the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription to trend the $630 threshold forward. Specifically, we propose to use the most recently available forecast of the four-quarter moving average PPI levels for Pharmaceutical for Human Use, Prescription from the third quarter of 2025 to the third-quarter of 2026, and to round the resulting dollar amount to the nearest $5 increment. Based on this methodology, we trended the $630 threshold forward and rounded the resulting dollar amount ($654.23) to the nearest $5 increment, which yields a proposed figure of $655 per day for CY 2026. Consistent with our methodology and practices listed in section V.B.1.b. of this proposed rule, we also propose that if more recent data are subsequently available (for example, a more recent estimate of the PPI for Pharmaceuticals for Human Use, Prescription), we would use such data, if appropriate, to determine the CY 2026 diagnostic radiopharmaceutical packaging threshold in the final rule.

(3) Amount of Separate Payment for Diagnostic Radiopharmaceuticals Exceeding the Threshold

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93955 through 93959), once we determine that the per day cost of a nonpass-through diagnostic radiopharmaceutical exceeds the cost threshold, proposed to be $655 per day for CY 2026, we will then assign that radiopharmaceutical to an APC, making it a specified covered outpatient drug (SCOD) per section 1833(t)(14)(B) of the Act. We propose to continue our current policy for CY 2026, and propose to pay for those nonpass-through, separately payable diagnostic radiopharmaceuticals based on our authority under section 1833(t)(14)(A)(iii)(II) of the Act. While, under this authority, we would ordinarily use the ASP methodology under section 1847A of the Act, we continue to find that the ASP data we have is not usable for payment purposes. We continue to believe that arithmetic Mean Unit Cost (MUC) would be an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. Therefore, we propose to continue our current policy and propose for CY 2026 to pay qualifying diagnostic radiopharmaceuticals with per day costs above the diagnostic radiopharmaceutical packaging threshold, based on their arithmetic MUC, which would be derived from calendar year 2024 claims data.

Although we propose to base payment for qualifying radiopharmaceuticals on their arithmetic MUC for CY 2026, we continue to encourage manufacturers to submit ASP information for diagnostic radiopharmaceuticals, if possible. While we propose to continue to use MUC to pay for separately payable diagnostic radiopharmaceuticals in CY 2026, manufacturers can begin, or continue, to report ASP data for potential future use in paying for diagnostic radiopharmaceuticals. For CY 2026, ASP reporting is voluntary for diagnostic radiopharmaceuticals paid under the OPPS. We encourage interested parties to submit comments regarding potential issues that may arise that prevent appropriate ASP reporting for diagnostic radiopharmaceuticals. We refer readers to the CY 2025 OPPS/ASC final rule with comment period as it discusses some of the known concerns regarding ASP reporting for diagnostic

radiopharmaceuticals (89 FR 93948 through 93963). We reiterate our stance from the CY 2025 OPPS/ASC final rule with comment period, that if we were to use average sales price as the basis of calculating a payment, we believe there must be more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology (89 FR 93961).

We also reiterate, as we stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93957), that there could be potential value in the use of ASP data for payment purposes for diagnostic radiopharmaceuticals when reported correctly and by all manufacturers who manufacture a product that is described by a given HCPCS code. We continue to believe that the use of ASP information for OPPS payment could provide an opportunity to improve payment accuracy for separately payable diagnostic radiopharmaceuticals by applying an established methodology that has already been successfully implemented under the OPPS for other separately payable drugs and biologicals, as well as therapeutic radiopharmaceuticals.

In order to facilitate potential future payment for diagnostic radiopharmaceuticals on ASP, we are seeking comment from interested parties on how CMS can ensure more consistent, validated, and universal reporting in order for ASP to be a viable payment methodology utilized in future rulemaking. For example, we are seeking comment on how CMS may update its past guidance, *Submission of OPPS ASP Data for Nonpass-Through Separately Payable Therapeutic Radiopharmaceuticals and Radiopharmaceuticals with Pass-Through Status*[6], in order to reflect current clinical practices and to reflect ASP reporting for diagnostic radiopharmaceuticals.

Additionally, as discussed in section V.B.5. of this proposed rule (Proposed Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data), we propose to set the payment rate for new diagnostic radiopharmaceuticals that exceed the diagnostic radiopharmaceutical packaging threshold and with HCPCS codes, but which do not have pass-through status and are without claims data at

[6] *https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/opps_asp_radiopharm_guidance10302009.pdf.*

ASP plus 6 percent. If ASP data for these diagnostic radiopharmaceuticals are not available, we propose to pay WAC plus 3 percent during the product's initial sales period, consistent with our policy described in section V.B.2. of this proposed rule. If the WAC also is unavailable, we propose to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. Following the initial sales period, a payment rate of WAC plus 6 percent would apply, if ASP data for these diagnostic radiopharmaceuticals remain unavailable. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would continue to be appropriate to use ASP, WAC plus 3 or 6 percent, or 95 percent of AWP until a MUC is available. As stated in the CY 2025 OPPS/ASC final rule with comment period, we stated we believe it would be appropriate to use this payment hierarchy until a MUC is available. There is typically only one manufacturer for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, so CMS does not have to ensure all manufacturers are reporting ASP for that particular HCPCS code prior to establishing a separate payment amount based on ASP. Additionally, although reporting of ASP is not a condition of CMS approving a HCPCS application, CMS has the opportunity to actively engage with the manufacturer, or sponsor of a HCPCS application, during the HCPCS application process. This allows for ongoing dialogue and education regarding the unique ASP reporting requirements that may be associated with a particular product, including how to ensure the reported ASP aligns with the dose descriptor for the newly assigned HCPCS code (89 FR 93958). We believe the hierarchy previously specified is appropriate to determine the payment for a diagnostic radiopharmaceutical that is new and described by a HCPCS code, but without claims data, as it is consistent with the typical hierarchy associated with payment for drugs and biologicals paid under the OPPS as discussed in section V.A. and V.B. of this proposed rule.

(4) Qualifying Diagnostic Radiopharmaceuticals Above the Diagnostic Radiopharmaceutical Packaging Threshold

The HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that exceed the proposed diagnostic radiopharmaceutical packaging threshold are proposed to be assigned to a status indicator of "K", indicating separate payment to be paid based on that HCPCS code's arithmetic MUC. A proposed APC and a proposed payment rate would be assigned as shown in Addendum B to this proposed rule. HCPCS codes that describe diagnostic radiopharmaceuticals with per day costs that are at or below the proposed diagnostic radiopharmaceutical packaging threshold are proposed to continue to be assigned to a status indicator of "N", indicating packaged payment.

The proposed list of diagnostic radiopharmaceuticals that we calculated as having per day costs that exceed $655 and their proposed status indicators can be found in Table 4.

TABLE 4: PROPOSED QUALIFYING DIAGNOSTIC RADIOPHARMACEUTICALS WITH PER DAY COSTS EXCEEDING $655

HCPCS Code	Short Descriptor	Proposed CY 2026 Status Indicator Assignment
A9507	In111 capromab	K
A9508	I131 iodobenguate, dx	K
A9515	Choline c-11	K
A9521	Tc99m exametazime	K
A9532	I125 serum albumin, dx	K
A9547	In111 oxyquinoline	K
A9548	In111 pentetate	K
A9553	Cr51 chromate	K
A9554	I125 iothalamate, dx	K
A9557	Tc99m bicisate	K
A9569	Technetium tc-99m auto wbc	K
A9570	Indium in-111 auto wbc	K
A9572	Indium in-111 pentetreotide	K
A9582	Iodine i-123 iobenguane	K
A9584	Iodine i-123 ioflupane	K
A9586	Florbetapir f18	K
A9587	Gallium ga-68	K
A9588	Fluciclovine f-18	K
A9591	Fluoroestradiol f 18	K
A9592	Copper cu 64 dotatate diag	K
A9593	Gallium ga-68 psma-11 ucsf	K
A9594	Gallium ga-68 psma-11, ucla	K
A9595	Piflu f-18, dia 1 millicurie	K
A9596	Gallium illuccix 1 millicure	K
A9602	Fluorodopa f-18 diag per mci	K
A9608	Flotufolastat f18 diag 1 mci	K*
A9800	Gallium locametz 1 millicuri	K
C9067	Gallium ga-68 dotatoc	K
Q9982	Flutemetamol f18 diagnostic	K
Q9983	Florbetaben f18 diagnostic	K

* HCPCS code A9608 will be assigned to status indicator "G" until its pass through expiration on September 30, 2026. For the remainder of CY 2026, we would propose to assign it to status indicator "K" and paid based on its arithmetic MUC calculated.

Proposed definitions of status indicators can be found in Addendum D1 to this proposed rule. Addenda to this proposed rule can be found on the CMS OPPS webpage.

4. Proposed Implementation of Section 4135 of the Consolidated Appropriations Act (CAA), 2023

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended sections 1833(t)(16) and 1833(i) of the Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) of the Act provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount, respectively.

The required additional payments began on January 1, 2025, based on the policy finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94361). In section XIII.F. of this proposed rule, we propose to continue for CY 2026 the policy finalized in the CY 2025 OPPS/ASC final rule with comment period. We also propose non-opioid treatments

for pain relief that would qualify under this policy for CY 2026 and seek public comment on those product evaluations.

5. Calculation of OPPS Scaled Payment Weights

We established a policy in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68283) of using geometric mean-based APC costs to calculate relative payment weights under the OPPS. In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93964 through 93965), we applied this policy and calculated the relative payment weights for each APC for CY 2025 that were shown in Addenda A and B of the CY 2025 OPPS/ASC final rule with comment period (which were made available via the Internet on the CMS website) using the APC costs discussed in sections II.A.1. and II.A.2. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 93921 through 93947). For CY 2026, as we did for CY 2025, we propose to continue to apply the policy established in CY 2013 and calculate relative payment weights for each APC for CY 2026 using geometric mean-based APC costs.

For CY 2012 and CY 2013, outpatient clinic visits were assigned to one of five levels of clinic visit APCs, with APC 0606 representing a mid-level clinic visit. In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75036 through 75043), we finalized a policy that created alphanumeric HCPCS code G0463 (Hospital outpatient clinic visit for assessment and management of a patient), representing all clinic visits under the OPPS. HCPCS code G0463 was assigned to APC 0634 (Hospital Clinic Visits). We also finalized a policy to use CY 2012 claims data to develop the CY 2014 OPPS payment rates for HCPCS code G0463 based on the total geometric mean cost of the levels one through five CPT Evaluation or Assessment and Management (E/M) codes for clinic visits previously recognized under the OPPS (CPT codes 99201 through 99205 and 99211 through 99215). In addition, we finalized a policy to no longer recognize a distinction between new and established patient clinic visits.

For CY 2016, we deleted APC 0634 and reassigned the outpatient clinic visit HCPCS code G0463 to APC 5012 (Level 2 Examinations and Related Services) (80 FR 70372). For

CY 2026, as we did for CY 2025, we propose to continue to standardize all the relative payment weights to APC 5012. We believe that standardizing relative payment weights to the geometric mean of the APC to which HCPCS code G0463 is assigned maintains consistency in calculating unscaled weights that represent the cost of some of the most frequently provided OPPS services. For CY 2026, as we did for CY 2025, we propose to assign APC 5012 a relative payment weight of 1.00 and to divide the geometric mean cost of each APC by the geometric mean cost for APC 5012 to derive the unscaled relative payment weight for each APC. The choice of the APC on which to standardize the relative payment weights does not affect payments made under the OPPS because we scale the weights for budget neutrality.

Section 1833(t)(9)(B) of the Act requires that APC reclassification and recalibration changes, wage index changes, and other adjustments be made in a budget neutral manner. Budget neutrality ensures that the estimated aggregate weight under the OPPS for CY 2026 is neither greater than nor less than the estimated aggregate weight that would have been calculated without the changes. To comply with this requirement concerning the APC changes, we propose to compare the estimated aggregate weight using the CY 2025 scaled relative payment weights to the estimated aggregate weight using the proposed CY 2026 unscaled relative payment weights.

For CY 2025, we multiplied the CY 2025 scaled APC relative payment weight applicable to a service paid under the OPPS by the volume of that service from CY 2024 claims to calculate the total relative payment weight for each service. We then added together the total relative payment weight for each of these services to calculate an estimated aggregate weight for the year. For CY 2026, we propose to apply the same process using the estimated CY 2026 unscaled relative payment weights rather than scaled relative payment weights. We propose to calculate the weight scalar by dividing the CY 2025 estimated aggregate weight by the unscaled CY 2026 estimated aggregate weight.

For a detailed discussion of the weight scalar calculation, we refer readers to the OPPS claims accounting document available on the CMS website at

https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices. Click on the link labeled "Hospital Outpatient Prospective Payment System Proposed Rule" for 2026, which can be found under the heading "Hospital Outpatient Regulations and Notices" and open the claims accounting document link, which is labeled "2026 Proposed Rule OPPS Claims Accounting (PDF)."

We propose to compare the estimated unscaled relative payment weights in CY 2026 to the estimated total relative payment weights in CY 2025 using CY 2024 claims data, holding all other components of the payment system constant to isolate changes in total weight. Based on this comparison, we propose to adjust the calculated CY 2026 unscaled relative payment weights for purposes of budget neutrality. We propose to adjust the estimated CY 2026 unscaled relative payment weights by multiplying them by a proposed weight scalar of 1.4624 to ensure that the proposed CY 2026 relative payment weights are scaled to be budget neutral. The proposed CY 2026 relative payment weights listed in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*) are scaled and incorporate the recalibration adjustments discussed in sections II.A.1. and II.A.2. of this proposed rule.

Section 1833(t)(14) of the Act provides the methodology for payment rates for certain specified covered outpatient drugs (SCODs). Section 1833(t)(14)(H) of the Act provides that additional expenditures resulting from this paragraph shall not be taken into account in establishing the conversion factor, weighting, and other adjustment factors for 2004 and 2005 under paragraph (9) but shall be taken into account for subsequent years. Therefore, the cost of those SCODs (as discussed in section V.B.2. of this proposed rule) is included in the budget neutrality calculations for the CY 2026 OPPS.

B. Proposed Conversion Factor Update

1. OPD Fee Schedule Increase Factor

Section 1833(t)(3)(C)(ii) of the Act requires the Secretary to update the conversion factor used to determine the payment rates under the OPPS on an annual basis by applying the OPD fee schedule increase factor. For purposes of section 1833(t)(3)(C)(iv) of the Act, subject to sections 1833(t)(17) and 1833(t)(3)(F) of the Act, the OPD fee schedule increase factor is equal to the hospital inpatient market basket percentage increase applicable to hospital discharges of the Act (or an amount that is computed and applied with respect to covered OPD services). In the FY 2026 IPPS/Long Term Care Hospital (LTCH) PPS proposed rule (90 FR 18266), consistent with current law, based on IHS Global, Inc.'s fourth quarter 2024 forecast, the proposed FY 2026 IPPS market basket percentage increase was 3.2 percent. We note that under our regular process for the CY 2026 OPPS/ASC final rule with comment period, we would use the market basket update for the FY 2026 IPPS/LTCH PPS final rule. If that forecast is different than the IPPS market basket percentage increase used for this proposed rule, the CY 2026 OPPS/ASC final rule with comment period OPD fee schedule increase factor would reflect that updated forecast of the market basket percentage increase.

For CY 2026, we propose to use the estimate of the hospital inpatient market basket percentage increase of 3.2 percent as one component to calculate the OPD fee schedule increase factor.

2. Productivity Adjustment

Section 1833(t)(3)(F)(i) of the Act requires that, for 2012 and subsequent years, the OPD fee schedule increase factor under subparagraph (C)(iv) be reduced 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 defines the productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (MFP) (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 “productivity adjustment”). 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. 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 IHS Global, Inc.'s (IGI) 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. In the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18266), the proposed productivity adjustment for FY 2026 was 0.8 percentage point.

Therefore, we propose that the productivity adjustment for the CY 2026 OPPS/ASC would be 0.8 percentage point. We also propose that if more recent data subsequently become available after the publication of the CY 2026 OPPS/ASC proposed rule (for example, a more recent estimate of the market basket percentage increase and/or the productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 hospital inpatient market basket update and the productivity adjustment for the final rule, which are components in calculating

the OPD fee schedule increase factor under sections 1833(t)(3)(C)(iv) and 1833(t)(3)(F) of the Act.

We note that section 1833(t)(3)(F) of the Act provides that application of this subparagraph may result in the OPD fee schedule increase factor under section 1833(t)(3)(C)(iv) of the Act being less than 0.0 percent for a year and may result in OPPS payment rates being less than rates for the preceding year. As described in further detail below, we proposed for CY 2026 an OPD fee schedule increase factor of 2.4 percent for the CY 2026 OPPS/ASC (which is the proposed estimate of the hospital inpatient market basket percentage increase of 3.2 percent, less the proposed 0.8 percentage point productivity adjustment).

3. Other Conversion Factor Adjustments

To set the OPPS conversion factor for 2026, we propose to increase the CY 2025 conversion factor of $89.169 by 2.4 percent. In accordance with section 1833(t)(9)(B) of the Act, we propose to further adjust the conversion factor for CY 2026 to ensure that any revisions made to the wage index and rural adjustment are made on a budget neutral basis. We propose to apply an overall budget neutrality factor of 1.0116 for wage index changes by comparing proposed total estimated payments from our simulation model using the proposed FY 2026 IPPS wage indexes to those payments using the CY 2025 OPPS wage indexes. We further propose to calculate an additional budget neutrality factor of 0.9955 to account for our proposed policy to cap wage index reductions for hospitals at 5 percent on an annual basis and the CY 2026 proposed transitional exception.

For CY 2026, we propose to maintain the current rural adjustment policy, as discussed in section II.E. of this proposed rule with comment period. Therefore, the proposed budget neutrality factor for the rural adjustment is 1.0000.

We propose to calculate a CY 2026 budget neutrality adjustment factor for the cancer hospital payment adjustment. We previously finalized transitioning from the target PCR of 0.89 for CYs 2020 through 2023 (which included the 1.0 percentage point reduction as required by

section 16002(b) of the 21st Century Cures Act) and incrementally reducing the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0 percentage point as required by section 16002(b) of the 21st Century Cures Act. Based on the most recent data available for this proposed rule, the target PCR now equals the PCR of non-cancer hospitals. We propose a CY 2026 target PCR equal to 0.87 for the cancer hospital payment adjustment, which includes the 1.0 percentage point reduction as required by section 16002(b) of the 21st Century Cures Act. We note that this proposed target PCR is the same as the final target PCR established in the CY 2025 OPPS (89 FR 93979). Therefore, we propose to apply a budget neutrality adjustment factor of 1.0000 to the conversion factor for the cancer hospital payment adjustment.

For the CY 2026 OPPS/ASC proposed rule, we estimate that proposed pass-through spending for drugs, biologicals, and devices for CY 2026 will equal approximately $587 million, which represents 0.59 percent of total projected CY 2026 OPPS spending. Therefore, we state that the proposed conversion factor would be adjusted by the difference between the 0.37 percent estimate of pass-through spending for CY 2025 and the 0.59 percent estimate of proposed pass-through spending for CY 2026, resulting in a proposed decrease to the conversion factor for CY 2026 of 0.22 percentage point.

We propose that estimated payments for outliers would be 1.0 percent of total OPPS payments for CY 2026. We estimate for the proposed rule that outlier payments will be approximately 0.92 percent of total OPPS payments in CY 2025; the 1.00 percent for proposed outlier payments in CY 2026 would constitute a 0.08 percentage point increase in payment in CY 2026 relative to CY 2025.

For CY 2026, we propose to use a conversion factor of $91.747 in the calculation of the national unadjusted payment rates for those items and services for which payment rates are calculated using geometric mean costs; that is, the proposed OPD fee schedule increase factor of

1.024 (2.4 percent for CY 2026), the required proposed wage index budget neutrality adjustment of approximately 1.0116, the proposed 5 percent annual cap for individual hospital wage index reductions adjustment and the proposed transitional exception of approximately 0.9955, the proposed cancer hospital payment adjustment of 1.0000, and the proposed adjustment factor of 0.9978 (a decrease of 0.22 percentage point) for the difference in pass-through spending, and a 0.08 percentage point increase in projected OPPS spending for the projected increase in outlier payments, which resulted in a proposed conversion factor for CY 2026 of $91.747

For CY 2026, we also propose that hospitals that fail to meet the reporting requirements of the Hospital OQR Program would continue to be subject to a further reduction of 2.0 percentage points to the OPD fee schedule increase factor. For hospitals that fail to meet the requirements of the Hospital OQR Program, we propose to make all other adjustments discussed above and apply an adjustment factor of 0.9805 to the proposed CY 2026 conversion factor of $91.747. We propose that the hospitals that fail to meet the requirements of the Hospital OQR Program will use a reduced OPD fee schedule update factor of 0.4 percent (that is, the proposed OPD fee schedule increase factor of 2.4 percent further reduced by 2.0 percentage points).

For CY 2026, as previously discussed in section V.B.7. of this proposed rule, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies with a 2 percentage point reduction to the OPD fee schedule increase factor, explained in more detail in section XIV.D. of this proposed rule. This would result in a proposed reduced conversion factor for CY 2026 of approximately $89.958 for this group of hospitals. The calculations we performed to determine the CY 2026 proposed conversion factor are shown in Table 5.

TABLE 5: CALCULATION OF CY 2026 FINAL OPPS CONVERSION FACTOR

Start: CY 2025 Final OPPS Conversion Factor = **$89.169**
Step 1a: Adjust the conversion factor to temporarily account for additional drug and device pass-through spending and outlier spending in CY 2025. This action causes an increase in the conversion factor. So, the amount of both drug and device pass-through spending (0.0037) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2025.

- 1.0000 – (0.0037 + 0.01) = 0.9863

Step 1b: Divide $89.169 by 0.9863

- $89.169/0.9863 = **$90.408**

Step 2: Adjust the conversion factor by the required wage index budget neutrality adjustment of approximately 1.0116. This adjustment increases the amount of OPPS outpatient hospital spending and is multiplied with $90.408.

- $90.408* 1.0116 = **$91.456**

Step 3: Adjust the conversion factor by the 5 percent annual cap for individual hospital wage index reductions adjustment of approximately 0.9955. This adjustment reduces the amount of OPPS outpatient hospital spending and is multiplied with $91.456.

- $91.456* 0.9955 = **$91.045**

Step 4: Adjust the conversion factor by the cancer hospital payment adjustment of 1.0000. Because the PCR for cancer hospitals is the same between CY 2025 and CY 2026, there would be no change to the OPPS conversion factor.

- $91.045*1.0000 = **$91.045**

Step 5: Adjust the conversion factor by rural SCH adjustment policy of 1.0000. Since we propose to maintain our current policy, there is no impact on the conversion factor by this policy.

- $91.045*1.0000 = **$91.045**

Step 6a: Adjust the conversion factor by the OPD fee schedule increase factor of 0.024 for CY 2025. The OPD fee schedule increase factor increases outpatient hospital spending in CY 2026 over CY 2025 and is added to 1.0000 which represents total outpatient hospital OPPS spending in CY 2024.

- 1.0000+0.024 = 1.0240

Step 6b: Multiply $91.045 by 1.0240.

- $91.045*1.0240 = **$93.230**

Step 7a: Adjust the conversion factor to remove additional drug and device pass-through spending and outlier spending for CY 2026. This action causes a decrease in the conversion factor. So, the amount of both drug and device pass-through spending (0.0059) and the percentage of outlier spending (0.01) as a share of total OPPS outpatient hospital spending is subtracted from 1.0000, which represents total OPPS outpatient hospital spending for CY 2026.

- 1.0000 – (0.0059+0.01) = 0.9841

Step 7b: Multiply $93.230 by 0.9841 to get the CY 2026 final OPPS conversion factor.

$93.230*0.9841 = **$91.747**

Finish: **CY 2026 OPPS Conversion Factor = $91.747**

* *Reduction for Providers Subject to the 340B Remedy Offset*

Step 8: Multiply $91.747 by 0.9805 to get the CY 2026 proposed OPPS conversion factor for the providers subject to the 340B remedy offset.

$91.747*0.9805 = **$89.958**

Please note rounding may affect the numbers in the calculations above.

C. Proposed Wage Index Changes

Section 1833(t)(2)(D) of the Act requires the Secretary to determine a wage adjustment factor to adjust the portion of payment and coinsurance attributable to labor-related costs for relative differences in labor and labor-related costs across geographic regions in a budget neutral manner (codified at 42 CFR 419.43(a)). This portion of the OPPS payment rate is called the OPPS labor-related share. Budget neutrality is discussed in section II.A.5. of this proposed rule.

The OPPS labor-related share is 60 percent of the national OPPS payment. This labor-related share is based on a regression analysis that determined that, for all hospitals, approximately 60 percent of the costs of services paid under the OPPS were attributable to wage costs. We confirmed that this labor-related share for outpatient services is appropriate during our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553). We propose to continue this policy for the CY 2026 OPPS/ASC. We refer readers to section II.C. of this proposed rule for a description and an example of how the wage index for a particular hospital is used to determine payment for the hospital.

As discussed in the claims accounting narrative included with the supporting documentation for this proposed rule (which is available via the internet on the CMS website (*https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*)), for estimating APC costs, we would standardize 60 percent of estimated claims costs for geographic area wage variation using the same FY 2026 pre-reclassified wage index that we use under the IPPS to standardize costs. This standardization process removes the effects of differences in area wage levels from the determination of a national unadjusted OPPS payment rate and copayment amount.

Under §§ 419.41(c)(1) and 419.43(c) (published in the OPPS April 7, 2000, final rule with comment period (65 FR 18495 and 18545)), the OPPS adopted the final fiscal year IPPS

post-reclassified wage index as the calendar year wage index for adjusting the OPPS standard payment amounts for labor market differences. Therefore, the wage index that applies to a particular acute care, short-stay hospital under the IPPS also applies to that hospital under the OPPS. As initially explained in the September 8, 1998, OPPS/ASC proposed rule (63 FR 47576), we believe that using the IPPS wage index as the source of an adjustment factor for the OPPS is reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall. In accordance with section 1886(d)(3)(E) of the Act, the IPPS wage index is updated annually.

The Affordable Care Act contained several provisions affecting the wage index. These provisions were discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74191). Section 10324 of the Affordable Care Act added section 1886(d)(3)(E)(iii)(II) to the Act, which defines a frontier State and amended section 1833(t) of the Act to add paragraph (19), which requires a frontier State wage index floor of 1.00 in certain cases, and states that the frontier State floor shall not be applied in a budget neutral manner. We codified these requirements at § 419.43(c)(2) and (3) of our regulations. For CY 2026, we propose to implement this provision in the same manner as we have since CY 2011. Under this policy, the frontier State hospitals would receive a wage index of 1.00 if the otherwise applicable wage index (including reclassification, the rural floor, and rural floor budget neutrality) is less than 1.00. Because the HOPD receives a wage index based on the geographic location of the specific inpatient hospital with which it is associated, the frontier State wage index adjustment applicable for the inpatient hospital also would apply for any associated HOPD. We refer readers to the FY 2011 through FY 2025 IPPS/LTCH PPS final rules for discussions regarding this provision, including our methodology for identifying which areas meet the definition of “frontier States” as provided for in section 1886(d)(3)(E)(iii)(II) of the Act: for FY 2011, 75 FR 50160 through 50161; for FY 2012, 76 FR 51793, 51795, and 51825; for FY 2013, 77 FR 53369 and 53370; for FY 2014, 78 FR 50590 and 50591; for FY 2015, 79 FR 49971; for FY 2016, 80 FR 49498; for

FY 2017, 81 FR 56922; for FY 2018, 82 FR 38142; for FY 2019, 83 FR 41380; for FY 2020, 84 FR 42312; for FY 2021, 85 FR 58765; for FY 2022, 86 FR 45178; FY 2023, 87 FR 49006; FY 2024, 88 FR 58977; and for FY 2025, 89 FR 69300.

In addition to the changes required by the Affordable Care Act, we note that the proposed FY 2026 IPPS wage indexes continue to reflect a number of adjustments implemented in past years, including, but not limited to, reclassification of hospitals to different geographic areas, the rural floor provisions, the imputed floor wage index adjustment in all-urban states, an adjustment for occupational mix, an adjustment to the wage index based on commuting patterns of employees (the out-migration adjustment), and the permanent 5 percent cap on any decrease to a hospital's wage index from its wage index in a prior FY. Beginning with FY 2024, we 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 Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act (88 FR 58971 through 58973). We refer readers to the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18217 through 18236) for a detailed discussion of all proposed changes to the FY 2026 IPPS wage indexes.

We note that in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a permanent approach to smooth year-to-year decreases in hospitals' wage indexes. Specifically, for FY 2023 and subsequent years, 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. That is, a hospital's wage index for FY 2026 would not be less than 95 percent of its final wage index for FY 2025. Except for newly opened hospitals, we apply the cap for a fiscal year using the final wage index applicable to the hospital on the last day of the prior fiscal year. A newly opened hospital would be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year (subject to any reclassification),

and it would not receive a cap for that first year, because it would not have been assigned a wage index in the prior year (in accordance with 42 CFR 419.41(c)(1) and 419.43(c), as noted previously).

Consistent with the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18233), we propose to discontinue for CY 2026 and subsequent years the low wage index hospital policy under the OPPS. Under the low wage index hospital policy that we adopted for the OPPS (84 FR 61186 through 61188), we increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a calendar 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. We removed the low wage index hospital policy from the IPPS wage index calculation for FY 2025 after considering the Court of Appeals for the D.C. Circuit's decision in *Bridgeport Hosp. v. Becerra*, 108 F.4th 882 (D.C. Cir. 2024). On July 23, 2024, the court held in *Bridgeport Hosp. v. Becerra* 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 for the IPPS, and that the policy for FY 2020 and related budget neutrality adjustment in the IPPS must be vacated. After considering the court's decision, 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 and also removed the low wage index budget neutrality factor from the FY 2025 standardized amounts.

In the FY 2026 IPPS/LTCH PPS proposed rule, 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. We refer the reader to the FY 2025 IFC (89 FR 80405 through 80421) and FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18233 through

18236) for a detailed discussion regarding the removal of the low wage index hospital policy from the IPPS for FYs 2025 and 2026.

As discussed previously, from the establishment of the OPPS in 2000 through 2024, we adopted the IPPS wage index on a calendar year basis in the OPPS. From FY 2020 to FY 2024, the IPPS wage index included the low wage index hospital policy and we correspondingly adopted the low wage index hospital policy under the OPPS for CY 2020 to CY 2024. However, when the *Bridgeport* decision was issued in July 2024, the OPPS did not remove the low wage index hospital policy from the calculation of the CY 2025 wage index. As discussed in the CY 2025 OPPS/ASC final rule with comment period, this decision to continue the low wage index hospital policy under the OPPS for CY 2025 (and thus to diverge from the IPPS wage index for FY 2025) was due principally to the unique circumstances presented by the timing of the court decision and subsequent IFC and the statutory authority that CMS relied upon to implement the low wage index hospital policy under the OPPS was different than the statutory authority relied upon for the policy under the IPPS. We took this approach for the CY 2025 OPPS given the unusual circumstances wherein an appellate court ruled that CMS lacked authority under the IPPS statute for a policy under the FY 2020 IPPS wage index that the OPPS proposed rule had already proposed to include in the OPPS wage index. Under these circumstances, we concluded that continuing the low wage index hospital policy for CY 2025 would avoid unexpected and arguably unfair payment consequences for hospitals that were not plaintiffs in *Bridgeport*. Additionally, we believed that the same reasons underlying adoption of the IFC policies for the FY 2025 IPPS wage index weighed against incorporating those policies for purposes of the CY 2025 OPPS wage index. Specifically, we noted in the IFC that the intention of the policies implemented therein was to "promote certainty regarding...payments" and "provide for payment stability and promote predictability," in light of the court's decision in *Bridgeport* (89 FR 80408) and we determined that those interests would be better served by finalizing the OPPS wage index methodology as proposed, including the low wage index hospital policy. Based on these

considerations, we continued the low wage index hospital policy under the OPPS for CY 2025 as proposed but indicated that we would explore options for realigning the IPPS and OPPS wage index values through future rulemaking. We refer readers to the CY 2025 OPPS/ASC final rule with comment period for a detailed discussion regarding our retention of the low wage index hospital policy under the OPPS for CY 2025 (89 FR 93975 through 93976).

Given the proposal to discontinue the low wage index hospital policy under the IPPS in the FY 2026 IPPS/LTCH PPS proposed rule and the absence of the timing issues which compelled us to continue the low wage index hospital policy under the OPPS for CY 2025, we think it is now appropriate to return to our longstanding policy of using the IPPS wage index as the source of an adjustment factor for the OPPS. Consequently, to effectuate full realignment of the IPPS and OPPS wage index values in CY 2026, we propose to eliminate the low wage index hospital policy under the OPPS and use the IPPS wage index in CY 2026 and subsequent years.

To effectuate full realignment of the IPPS and OPPS wage index values in CY 2026, we propose that the 5 percent cap that will apply to the CY 2026 OPPS wage index will be based off the IPPS wage index for FY 2025 rather than the OPPS wage index for CY 2025. We note that because the CY 2025 OPPS wage index was different than the FY 2025 IPPS wage index (due to the continuation of the low wage index hospital policy under the OPPS), using the FY 2026 IPPS wage index for the CY 2026 OPPS wage index will result in decreases greater than 5 percent to some hospitals' wage indexes under the OPPS. Therefore, under our proposal the 5 percent cap on wage index decreases in the CY 2026 OPPS would apply in a similar manner to years prior to the CY 2025 OPPS, in which IPPS hospitals would receive the same wage index with the cap on wage index decreases as they would under the FY IPPS, and non-IPPS hospitals and CMHCs would receive a similar corresponding wage index with the cap on wage index decreases policy under the broader wage index adoption.

We note that in the FY 2026 IPPS proposed rule (90 FR 18233 through 18235) we propose, 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. As indicated in that rule, we propose this temporary payment exception "to mitigate short-term instability and payment fluctuations that can negatively impact hospitals consistent with principles of certainty and predictability under prospective payment systems." To address these same concerns under the OPPS, we correspondingly propose a transitional payment exception for CY 2026 under the OPPS using our equitable adjustment authority under section 1833(t)(2)(E) of the Act. This authority allows the Secretary to establish, in a budget neutral manner, adjustments as determined to be necessary to ensure equitable payments.

The transitional exception policy we propose would apply to hospitals that benefitted from the CY 2024 low wage index hospital policy. For those hospitals, we propose to compare the hospital's proposed CY 2026 wage index to the hospital's CY 2024 wage index. If the hospital is significantly impacted by the discontinuation of the low wage index hospital policy, meaning the hospital's proposed CY 2026 wage index is decreasing by more than 9.75 percent from the hospital's CY 2024 wage index, then the transitional payment exception for CY 2026 for that hospital would be equal to the additional CY 2026 amount the hospital would be paid under the OPPS if its CY 2026 wage index were equal to 90.25 percent of its CY 2024 wage index. 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 propose to make this policy budget neutral under the OPPS through the second wage index budget neutrality adjustment applied to the OPPS conversion factor (which currently includes the 5 percent hold harmless cap policy).

Core Based Statistical Areas (CBSAs) are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. The FY 2018 IPPS/LTCH PPS final rule (82 FR 38130) discussed the two different lists of codes to identify counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS listed and used SSA and FIPS county codes to identify

and crosswalk counties to CBSA codes for purposes of the IPPS and OPPS wage indexes. However, the SSA county codes are no longer being maintained and updated, although the FIPS codes continue to be maintained by the U.S. Census Bureau. The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2015. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), for purposes of crosswalking counties to CBSAs for the IPPS wage index, we finalized our proposal to discontinue the use of the SSA county codes and begin using only the FIPS county codes. Similarly, for the purposes of crosswalking counties to CBSAs for the OPPS wage index, in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59260), we finalized our proposal to discontinue the use of SSA county codes and begin using only the FIPS county codes. For CY 2026, under the OPPS, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs.

We propose to use the FY 2026 IPPS post-reclassified wage index for urban and rural areas as the wage index for the OPPS to determine the wage adjustments for both the OPPS payment rate and the copayment rate for CY 2026. Therefore, any policies and adjustments that are finalized for the FY 2026 IPPS post-reclassified wage index would be reflected in the final CY 2026 OPPS wage index beginning on January 1, 2026, if appropriate. We refer readers to the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18217 through 18236) and the proposed FY 2026 hospital wage index files posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page.* Regarding budget neutrality for the CY 2026 OPPS wage index, we refer readers to section II.C. of this proposed rule. We continue to believe that using the IPPS post-reclassified wage index as the source of an adjustment factor for the OPPS is

reasonable and logical, given the inseparable, subordinate status of the HOPD within the hospital overall.

Hospitals that are paid under the OPPS, but not under the IPPS, do not have an assigned hospital wage index under the IPPS. Therefore, for non-IPPS hospitals paid under the OPPS, it is our longstanding policy to assign the wage index that would be applicable if the hospital was paid under the IPPS, based on its geographic location and any applicable wage index policies and adjustments. We propose to continue this policy for CY 2026. We refer readers to the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18217 through 18236) for a detailed discussion of the proposed changes to the FY 2026 IPPS wage indexes.

It has been our longstanding policy to allow non-IPPS hospitals paid under the OPPS to qualify for the out-migration adjustment if they are located in a section 505 out-migration county (section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)) (Pub. L. 108-173). Applying this adjustment is consistent with our policy of adopting IPPS wage index policies for hospitals paid under the OPPS. We note that, because non-IPPS hospitals cannot reclassify, they are eligible for the out-migration wage index adjustment if they are located in a section 505 out-migration county. This is the same out-migration adjustment policy that would apply if the hospital were paid under the IPPS. For CY 2026, we propose to continue our policy of allowing non-IPPS hospitals paid under the OPPS to qualify for the outmigration adjustment if they are located in a section 505 out-migration county (section 505 of the MMA) (88 FR 49585 and 49586). Furthermore, we propose that the wage index that would apply for CY 2026 to non-IPPS hospitals paid under the OPPS would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index. In addition, we propose that the wage index that would apply to non-IPPS hospitals paid under the OPPS would include the 5 percent cap on wage index decreases and the previously described proposed transitional payment exception for hospitals significantly impacted by the discontinuation of the low wage index hospital policy.

For CMHCs, for CY 2026, we propose to continue to calculate the wage index by using the post-reclassification IPPS wage index based on the CBSA where the CMHC is located. Furthermore, we propose that the wage index that would apply to a CMHC for CY 2026 would continue to include the rural floor adjustment and any policies and adjustments applied to the IPPS wage index. In addition, the wage index that would apply to CMHCs would include the 5 percent cap on wage index decreases. Also, we propose that the wage index that would apply to CMHCs would not include the outmigration adjustment because that adjustment only applies to hospitals.

Table 4A associated with the FY 2026 IPPS/LTCH PPS proposed rule (available via the internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/fy-2026-ipps-proposed-rule-home-page)* identifies counties that would be eligible for the out-migration adjustment. Table 2 associated with the FY 2026 IPPS/LTCH PPS proposed rule (available for download via the website noted previously) identifies IPPS hospitals that would receive the out-migration adjustment for FY 2026. We are including the outmigration adjustment information from Table 2 associated with the FY 2026 IPPS/LTCH PPS proposed rule as Addendum L to this proposed rule, with the addition of non-IPPS hospitals that would receive the section 505 outmigration adjustment under this proposed rule. Addendum L is available via the internet on the CMS website. We refer readers to the CMS website for the OPPS at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. At this link, readers will find a link to the proposed FY 2026 IPPS wage index tables and Addendum L.

D. Proposed Statewide Average Default Cost-to-Charge Ratios (CCRs)

In addition to using CCRs to estimate costs from charges on claims for ratesetting, we use overall hospital-specific CCRs calculated from the hospital's most recent cost report (OMB control number: 0938-0050 for Form CMS–2552–10) to determine outlier payments, payments for pass-through devices, and monthly interim transitional corridor payments under the

OPPS during the PPS year. For certain hospitals, under the regulations at 42 CFR 419.43(d)(5)(iii), we use the statewide average default CCRs to determine the payments mentioned earlier if it is not possible to determine an accurate CCR for a hospital in certain circumstances. This includes hospitals that are new, hospitals that have not accepted assignment of an existing hospital's provider agreement, and hospitals that have not yet submitted a cost report. We also use the statewide average default CCRs to determine payments for hospitals whose CCR falls outside the predetermined ceiling threshold for a valid CCR or for hospitals in which the most recent cost report reflects an all-inclusive rate status (Medicare Claims Processing Manual (Pub. L. 100-04), Chapter 4, Section 10.11).

We discussed our policy for using default CCRs, including setting the ceiling threshold for a valid CCR, in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599) in the context of our adoption of an outlier reconciliation policy for cost reports beginning on or after January 1, 2009. For details on our process for calculating the statewide average CCRs, we refer readers to the Claims Accounting Narrative for this proposed rule, which is posted on the CMS website. We propose to calculate the default ratios for CY 2026 using the most recent cost report data. We will update these ratios in the final rule with comment period if more recent cost report data are available.

We no longer publish a table in the **Federal Register** containing the statewide average CCRs in the annual OPPS/ASC proposed rule and final rule with comment period. These CCRs and the upper limit CCR value at which we would apply statewide CCRs will be available for download with each OPPS/ASC CY proposed rule and final rule on the CMS website. We refer readers to our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*; click on the link on the left of the page titled "Annual Policy Files" and then select the relevant year to download the statewide CCRs and upper limits in the "Downloads" section of the webpage.

E. Proposed Adjustment for Rural Sole Community Hospitals (SCHs) and Essential Access Community Hospitals (EACHs) under Section 1833(t)(13)(B) of the Act for CY 2026

In the CY 2006 OPPS final rule with comment period (70 FR 68556), we finalized a payment increase for rural sole community hospitals (SCHs) of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act, as added by section 411 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173). Section 1833(t)(13) of the Act provides the Secretary the authority to make an adjustment to OPPS payments for rural hospitals, effective January 1, 2006, if justified by a study of the difference in costs by APC between hospitals in rural areas and hospitals in urban areas. Our analysis showed a difference in costs for rural SCHs. Therefore, for the CY 2006 OPPS, we finalized a payment adjustment for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, in accordance with section 1833(t)(13)(B) of the Act.

In the CY 2007 OPPS/ASC final rule with comment period (71 FR 68010 and 68227), for purposes of receiving this rural adjustment, we revised our regulations at § 419.43(g) to clarify that essential access community hospitals (EACHs) are also eligible to receive the rural SCH adjustment, assuming these entities otherwise meet the rural adjustment criteria. Currently, two hospitals are classified as EACHs, and as of CY 1998, under section 4201(c) of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105-33), a hospital can no longer become newly classified as an EACH.

This adjustment for rural SCHs is budget neutral and applied before calculating outlier payments and copayments. We stated in the CY 2006 OPPS final rule with comment period (70 FR 68560) that we would not reestablish the adjustment amount on an annual basis, but we

may review the adjustment in the future and, if appropriate, would revise the adjustment. We provided the same 7.1 percent adjustment to rural SCHs, including EACHs, again in CYs 2008 through 2025 (89 FR 93977).

For CY 2026, we propose to continue the current policy of a 7.1 percent payment adjustment for rural SCHs, including EACHs, for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, brachytherapy sources, items paid at charges reduced to costs, and devices paid under the pass-through payment policy, applied in a budget neutral manner.

F. Proposed Payment Adjustment for Certain Cancer Hospitals for CY 2026

1. Background

Since the inception of the OPPS, which was authorized by the BBA, Medicare has paid the 11 hospitals that meet the criteria for cancer hospitals identified in section 1886(d)(1)(B)(v) of the Act under the OPPS for covered outpatient department services. These cancer hospitals are exempted from payment under the IPPS. With the Medicare, Medicaid and SCHIP Balanced Budget Refinement Act of 1999 (Pub. L. 106-113), the Congress added section 1833(t)(7), "Transitional Adjustment to Limit Decline in Payment," to the Act, which requires the Secretary to determine OPPS payments to cancer and children's hospitals based on their pre-BBA payment amount (these hospitals are often referred to under this policy as "held harmless" and their payments are often referred to as "hold harmless" payments).

As required under section 1833(t)(7)(D)(ii) of the Act, a cancer hospital receives the full amount of the difference between payments for covered outpatient department services under the OPPS and a "pre-BBA amount." That is, cancer hospitals are permanently held harmless to their "pre-BBA amount," and they receive transitional outpatient payments (TOPs) or hold harmless payments to ensure that they do not receive a payment that is lower in amount under the OPPS than the payment amount they would have received before implementation of the OPPS, as set forth in section 1833(t)(7)(F) of the Act. The "pre-BBA amount" is the product of the hospital's

reasonable costs for covered outpatient department services occurring in the current year and the base payment-to-cost ratio (PCR) for the hospital defined in section 1833(t)(7)(F)(ii) of the Act. The "pre-BBA amount" and the determination of the base PCR are defined at § 419.70(f). TOPs are calculated on Worksheet E, Part B, of the Hospital Cost Report or the Hospital Health Care Complex Cost Report (Form CMS–2552–96 or Form CMS–2552–10 (OMB NO: 0938-0050), respectively), as applicable each year. Section 1833(t)(7)(I) of the Act exempts TOPs from budget neutrality calculations.

Section 3138 of the Affordable Care Act (Pub. L. 111-148) amended section 1833(t) of the Act by adding a new paragraph (18), which instructs the Secretary to conduct a study to determine if, under the OPPS, outpatient costs incurred by cancer hospitals described in section 1886(d)(1)(B)(v) of the Act with respect to APC groups exceed outpatient costs incurred by other hospitals furnishing services under section 1833(t) of the Act, as determined appropriate by the Secretary. Section 1833(t)(18)(A) of the Act requires the Secretary to take into consideration the cost of drugs and biologicals incurred by cancer hospitals and other hospitals. Section 1833(t)(18)(B) of the Act provides that, if the Secretary determines that cancer hospitals' costs are higher than those of other hospitals, the Secretary shall provide an appropriate adjustment under section 1833(t)(2)(E) of the Act to reflect these higher costs. In 2011, after conducting the study required by section 1833(t)(18)(A) of the Act, we determined that outpatient costs incurred by the 11 specified cancer hospitals were greater than the costs incurred by other OPPS hospitals. For a complete discussion regarding the cancer hospital cost study, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74200 and 74201).

Based on these findings, we finalized a policy to provide a payment adjustment to the 11 specified cancer hospitals that reflects their higher outpatient costs, as discussed in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74202 through 74206). Specifically, we adopted a policy to provide additional payments to the cancer hospitals so that

each cancer hospital's final PCR for services provided in a given calendar year is equal to the weighted average PCR (which we refer to as the "target PCR") for other hospitals paid under the OPPS. The target PCR is set in advance of the calendar year and is calculated using the most recently submitted or settled cost report data that are available at the time of final rulemaking for the calendar year. The amount of the payment adjustment is made on an aggregate basis at cost report settlement. We note that the changes made by section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs are assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period. Table 6 displays the target PCR for purposes of the cancer hospital adjustment for CY 2012 through CY 2025.

TABLE 6: CANCER HOSPITAL ADJUSTMENT TARGET PAYMENT-TO-COST RATIOS (PCRS), CY 2012 THROUGH CY 2025

Calendar Year	Target PCR
2012	0.91
2013	0.91
2014	0.90
2015	0.90
2016	0.92
2017	0.91
2018	0.88
2019	0.88
2020	0.89
2021	0.89
2022	0.89
2023	0.89
2024	0.88
2025	0.87

2. Proposed Policy for CY 2026

Section 16002(b) of the 21st Century Cures Act (Pub. L. 114-255) amended section 1833(t)(18) of the Act by adding subparagraph (C), which requires that in applying § 419.43(i) (that is, the payment adjustment for certain cancer hospitals) for services furnished on or after January 1, 2018, the Secretary shall use a target PCR that is 1.0 percentage point less than the target PCR that would otherwise apply. Section 16002(b) of the 21st Century Cures Act also provides that, in addition to the percentage reduction, the Secretary may consider making an additional percentage point reduction to the target PCR that takes into account payment rates for

applicable items and services described under section 1833(t)(21)(C) of the Act for hospitals that are not cancer hospitals described under section 1886(d)(1)(B)(v) of the Act. Further, in making any budget neutrality adjustment under section 1833(t) of the Act, section 16002(b) of the 21st Century Cures Act provides that the Secretary shall not take into account the reduced expenditures that result from application of section 1833(t)(18)(C) of the Act.

We propose to provide additional payments to the 11 specified cancer hospitals so that each cancer hospital's proposed PCR is equal to the weighted average PCR (or "target PCR") for the other OPPS hospitals, generally using the most recent submitted or settled cost report data that are available, reduced by 1.0-percentage point, to comply with section 16002(b) of the 21st Century Cures Act. As discussed further below, we are not proposing an additional reduction beyond the 1.0-percentage point reduction required by section 16002(b) of the 21st Century Cures Act for CY 2026.

To calculate the proposed CY 2026 target PCR, we propose to use the same extract of cost report data from HCRIS used to estimate costs for the CY 2026 OPPS which, in most cases, would be the most recently available hospital cost reports. Using these cost report data, we included data from Worksheet E, Part B, for each hospital, using data from each hospital's most recent cost report, whether as submitted or settled.

We then limited the dataset to the hospitals with CY 2024 claims data that we used to model the impact of the proposed CY 2026 APC relative payment weights (3,388 hospitals) because it is appropriate to use the same set of hospitals that are being used to calibrate the modeled CY 2026 OPPS. The cost report data for the hospitals in this dataset were from cost report periods with fiscal year ends ranging from 2022 to 2024; however, the cost reporting periods were predominantly from fiscal years ending in 2023 and 2024. We then removed the cost report data of the 49 hospitals located in Puerto Rico from our dataset because we did not believe their cost structure reflected the costs of most hospitals paid under the OPPS, and, therefore, their inclusion may bias the calculation of hospital-weighted statistics. We also

removed the cost report data of 12 hospitals because these hospitals had cost report data that were not complete (missing aggregate OPPS payments, missing aggregate cost data, or missing both), so that all cost reports in the study would have both the payment and cost data necessary to calculate a PCR for each hospital, leading to a proposed analytic file of 3,327 hospitals with cost report data.

Using this smaller dataset of cost report data, we estimated that, on average, the OPPS payments to other hospitals furnishing services under the OPPS were approximately 88 percent of reasonable cost (weighted average PCR of 0.88). Therefore, after applying the 1.0-percentage point reduction, as required by section 16002(b) of the 21st Century Cures Act, using our standard process the payment amount associated with the cancer hospital payment adjustment to be determined at cost report settlement would be the additional payment needed to result in a target PCR equal to 0.87 for each cancer hospital.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81586 through 81589), we explained that we believe we should begin to take into consideration the PCR of non-cancer hospitals based on the most recently available data for calculating the target PCR. We noted that we do not know if the changes in the data that have yielded lower PCRs for non-cancer hospitals are likely to continue in future years or if, when data from after the PHE is available, we will see the target PCR increase toward its historical norm. Therefore, in the CY 2024 OPPS/ASC final rule with comment period, we finalized our proposal to transition from the target PCR of 0.89 we finalized for CYs 2020 through 2024 (which included the 1.0-percentage point reduction as required by section 16002(b) of the 21st Century Cures Act) and incrementally reduce the target PCR by an additional 1.0 percentage point for each calendar year, beginning with CY 2024, until the target PCR equals the PCR of non-cancer hospitals calculated using the most recent data minus 1.0-percentage point as required by section 16002(b) of the 21st Century Cures Act. Therefore, utilizing this methodology, we finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93977 through 93980) our policy to reduce

the CY 2024 target PCR of 0.88 by 1-percentage point and finalized a cancer hospital target PCR of 0.87 for CY 2025.

Since the target PCR based on the OPPS payments to other hospitals furnishing services under the OPPS would be 0.87 after applying the 1.0-percentage point reduction, as required by the section 16002(b) of the 21st Century Cures Act, and would equal the CY 2025 target PCR, it is no longer necessary to continue our transition policy of gradually reducing the pre-COVID-19 PHE target PCR by 1.0 percentage point in lieu of our target PCR calculation. For CY 2026 and subsequent years, we propose to calculate the target PCR based on our longstanding target PCR calculation methodology described in this proposed rule, and then apply the 1.0-percentage point reduction as required by section 16002(b) of the 21st Century Cures Act.

Table 7 shows the estimated percentage increase in OPPS payments to each cancer hospital for CY 2026, due to the cancer hospital payment adjustment policy. The actual, final amount of the CY 2026 cancer hospital payment adjustment for each cancer hospital will be determined at cost report settlement and will depend on each hospital's CY 2026 payments and costs from the settled CY 2026 cost report. We note that the requirements contained in section 1833(t)(18) of the Act do not affect the existing statutory provisions that provide for TOPs for cancer hospitals. The TOPs will be assessed, as usual, after all payments, including the cancer hospital payment adjustment, have been made for a cost reporting period.

TABLE 7: ESTIMATED CY 2026 HOSPITAL-SPECIFIC PAYMENT ADJUSTMENT FOR CANCER HOSPITALS TO BE PROVIDED AT COST REPORT SETTLEMENT

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2026 due to Payment Adjustment
050146	City of Hope Comprehensive Cancer Center	36.9%
050660	USC Norris Cancer Hospital	36.3%
100079	Sylvester Comprehensive Cancer Center	30.9%
100271	H. Lee Moffitt Cancer Center & Research Institute	16.6%
220162	Dana-Farber Cancer Institute	46.4%

Provider Number	Hospital Name	Estimated Percentage Increase in OPPS Payments for CY 2026 due to Payment Adjustment
330154	Memorial Sloan-Kettering Cancer Center	51.6%
330354	Roswell Park Cancer Institute	11.9%
360242	James Cancer Hospital & Solove Research Institute	20.9%
390196	Fox Chase Cancer Center	18.2%
450076	M.D. Anderson Cancer Center	48.5%
500138	Seattle Cancer Care Alliance	49.4%

G. Proposed Hospital Outpatient Outlier Payments

1. Background

The OPPS provides outlier payments to hospitals to help mitigate the financial risk associated with high-cost and complex procedures, where a very costly service could present a hospital with significant financial loss. As explained in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66832 through 66834), we set our projected target for aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS for the prospective year. Outlier payments are provided on a service-by-service basis when the cost of a service exceeds the APC payment amount multiplier threshold (the APC payment amount multiplied by a certain amount) as well as the APC payment amount plus a fixed-dollar amount threshold (the APC payment plus a certain dollar amount). In CY 2025, the outlier threshold was met when the hospital's cost of furnishing a service exceeded 1.75 times the APC payment amount (the multiplier threshold) and exceeded the APC payment amount plus $7,175 (the fixed-dollar amount threshold) (89 FR 93980 through 93982). If the hospital's cost of furnishing a service exceeds both the multiplier threshold and the fixed-dollar threshold, the outlier payment is calculated as 50 percent of the amount by which the hospital's cost of furnishing the service exceeds 1.75 times the APC payment amount. Beginning with CY 2009 payments, outlier payments are subject to a reconciliation process similar to the IPPS outlier reconciliation process

for cost reports, as discussed in the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599).

It has been our policy to report the actual amount of outlier payments as a percent of total spending in the claims being used to model the OPPS. Our estimate of total outlier payments as a percent of total CY 2024 OPPS payments, using CY 2024 claims available for this CY 2026 OPPS/ASC proposed rule, is approximately 0.82 percent. Therefore, for CY 2024, we estimate that we did not meet the outlier target by 0.18 percent of total aggregated OPPS payments.

For this CY 2026 OPPS/ASC proposed rule, using CY 2024 claims data and CY 2025 payment rates, we estimate that the aggregate outlier payments for CY 2025 would be approximately 0.92 percent of the total CY 2025 OPPS payments. We provide estimated CY 2026 outlier payments for hospitals and CMHCs with claims included in the claims data that we used to model impacts in the Hospital–Specific Impacts - Provider-Specific Data file on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

2. Proposed Outlier Calculation for CY 2026

For CY 2026, we propose to continue our policy of estimating outlier payments to be 1.0 percent of the estimated aggregate total payments under the OPPS. We propose that a portion of that 1.0 percent, an amount equal to less than 0.01 percent of outlier payments (or 0.0001 percent of total OPPS payments), would be allocated to CMHCs for partial hospitalization program (PHP) and intensive outpatient program (IOP) outlier payments. This is the amount of estimated outlier payments that would result from the proposed CMHC outlier threshold as a proportion of total estimated OPPS outlier payments. We propose to continue our outlier policy that if a CMHC's cost for PHP and IOP services exceeds 3.40 times the APC payment rate, the outlier

payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the proposed APC payment rate.

For further discussion of CMHC outlier payments, we refer readers to section VIII.C. of this proposed rule.

To ensure that the estimated CY 2026 aggregate outlier payments would equal 1.0 percent of estimated aggregate total payments under the OPPS, we propose that the hospital outlier threshold be set so that outlier payments would be triggered when a hospital's cost of furnishing a service exceeds 1.75 times the APC payment amount and exceeds the APC payment amount plus the fixed-dollar threshold.

We calculate the proposed fixed-dollar threshold using the standard methodology most recently used for CY 2025 (89 FR 93980 through 93982). For purposes of estimating outlier payments for CY 2026, we use the hospital-specific overall ancillary CCRs available in the April 2025 update to the Outpatient Provider-Specific File (OPSF). The OPSF contains provider-specific data, such as the most current CCRs, which are maintained by the MACs and used by the OPPS Pricer to pay claims. The claims that we generally use to model each OPPS update lag by 2 years.

In order to estimate the CY 2026 hospital outlier payments, we inflate the charges on the CY 2024 claims using the same proposed charge inflation factor of 1.1118 that we used to estimate the IPPS fixed-loss cost threshold for the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18434 through 18436). We used an inflation factor of 1.05440 to estimate CY 2025 charges from the CY 2024 charges reported on CY 2024 claims before applying CY 2025 CCRs to estimate the percent of outliers paid in CY 2025. The proposed methodology for determining these charge inflation factors is discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18434). As we stated in the CY 2005 OPPS final rule with comment period (69 FR 65844 through 65846), we believe that the use of the same charge inflation factors is appropriate for the OPPS because, with the exception of the inpatient routine service cost

centers, hospitals use the same ancillary and cost centers to capture costs and charges for inpatient and outpatient services.

As noted in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68011), we are concerned that we could systematically overestimate the OPPS hospital outlier threshold if we did not apply a CCR inflation adjustment factor. Therefore, we propose to apply the same CCR adjustment factor that we proposed to apply for the FY 2026 IPPS outlier calculation to the CCRs used to simulate the proposed CY 2026 OPPS outlier payments to determine the fixed-dollar threshold. Specifically, for CY 2026, we propose to apply an adjustment factor of 0.970113 to the CCRs that were in the April 2025 OPSF to trend them forward from CY 2025 to CY 2026. The methodology for calculating the proposed CCR adjustment factor is discussed in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18434 through 18435).

To model hospital outlier payments for the CY 2026 proposed rule, we applied the overall CCRs from the April 2025 OPSF after adjustment (using the proposed CCR inflation adjustment factor of 0.970113 to approximate CY 2026 CCRs) to charges on CY 2024 claims that were adjusted (using the proposed charge inflation factor of 1.1118 to approximate CY 2026 charges). We simulated aggregated CY 2024 hospital outlier payments using these costs for several different fixed-dollar thresholds, holding the 1.75 multiplier threshold constant and assuming that outlier payments would continue to be made at 50 percent of the amount by which the cost of furnishing the service would exceed 1.75 times the APC payment amount, until the total outlier payments equaled 1.0 percent of aggregated estimated total CY 2026 OPPS payments. We estimated that a proposed fixed-dollar threshold of $6,450 combined with the proposed multiplier threshold of 1.75 times the APC payment rate, would allocate 1.0 percent of aggregated total OPPS payments to outlier payments for CY 2026. For CMHCs, we propose that, if a CMHC's cost for partial hospitalization or intensive outpatient services exceeds 3.40 times the APC payment rate, the outlier payment would be calculated as 50 percent of the amount by which the cost exceeds 3.40 times the APC payment rate.

Section 1833(t)(17)(A) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to report data required for the quality measures selected by the Secretary, in the form and manner required by the Secretary under section 1833(t)(17)(B) of the Act, incur a 2.0-percentage point reduction to their OPD fee schedule increase factor; that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that would apply to certain outpatient items and services furnished by hospitals that are required to report outpatient quality data and that fail to meet the Hospital Outpatient Quality Reporting (OQR) Program requirements. For hospitals that fail to meet the Hospital OQR Program requirements, we propose to continue the policy that we implemented in CY 2010 that the hospitals' costs would be compared to the reduced payments for purposes of outlier eligibility and payment calculation. For more information on the Hospital OQR Program, we refer readers to section XV. of this proposed rule.

H. Proposed Calculation of an Adjusted Medicare Payment from the National Unadjusted Medicare Payment

The national unadjusted payment rate is the payment rate for most APCs before accounting for the wage index adjustment or any applicable adjustments. The basic methodology for determining prospective payment rates for HOPD services under the OPPS is set forth in existing regulations at 42 CFR part 419, subparts C and D. For this proposed rule, the payment rate for most services and procedures for which payment is made under the OPPS is the product of the conversion factor calculated in accordance with section II.B. of this proposed rule and the relative payment weight described in section II.A. of this proposed rule. The national unadjusted payment rate for most APCs contained in Addendum A to this proposed rule (which is available on the CMS website "*Hospital Outpatient Regulations and Notices*[7]") and for

[7] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient-pps/quarterly-addenda-updates.*

most HCPCS codes to which separate payment under the OPPS has been assigned in Addendum B to this proposed rule (which is available on the CMS website, see link above) is calculated by multiplying the proposed CY 2026 scaled weight for the APC by the CY 2026 conversion factor.

We note that section 1833(t)(17) of the Act, which applies to hospitals, as defined under section 1886(d)(1)(B) of the Act, requires that hospitals that fail to submit data required to be submitted on quality measures selected by the Secretary, in the form and manner and at a time specified by the Secretary, incur a reduction of 2.0 percentage points to their OPD fee schedule increase factor, that is, the annual payment update factor. The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data and that fail to meet the Hospital OQR Program requirements. For further discussion of the payment reduction for hospitals that fail to meet the requirements of the Hospital OQR Program, we refer readers to section XIV. of this proposed rule.

Below we demonstrate the steps used to determine the APC payments that will be made in a CY under the OPPS to a hospital that fulfills the Hospital OQR Program requirements and to a hospital that fails to meet the Hospital OQR Program requirements for a service that has any of the following status indicator assignments: "J1," "J2," "P," "Q1," "Q2," "Q3," "Q4," "R," "S," "T," "U," or "V" (as defined in Addendum D1 to this proposed rule, which is available via the Internet on the CMS website), in a circumstance in which the multiple procedure discount does not apply, the procedure is not bilateral, and conditionally packaged services (status indicator of "Q1" and "Q2") qualify for separate payment. We note that, although blood and blood products with status indicator "R" and brachytherapy sources with status indicator "U" are not subject to wage adjustment, they are subject to reduced payments when a hospital fails to meet the Hospital OQR Program requirements.

Individual providers interested in calculating the payment amount that they would receive for a specific service from the national unadjusted payment rates presented in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website) should follow the formulas presented in the following steps. For purposes of the payment calculations below, we refer to the national unadjusted payment rate for hospitals that meet the requirements of the Hospital OQR Program as the "full" national unadjusted payment rate. We refer to the national unadjusted payment rate for hospitals that fail to meet the requirements of the Hospital OQR Program as the "reduced" national unadjusted payment rate. The reduced national unadjusted payment rate is calculated by multiplying the reporting ratio of 0.9806 times the "full" national unadjusted payment rate. The national unadjusted payment rate used in the calculations below is either the full national unadjusted payment rate or the reduced national unadjusted payment rate, depending on whether the hospital met its Hospital OQR Program requirements to receive the full CY 2025 OPPS fee schedule increase factor.

Step 1. Calculate 60 percent (the labor-related portion) of the national unadjusted payment rate. Since the initial implementation of the OPPS, we have used 60 percent to represent our estimate of that portion of costs attributable, on average, to labor. We refer readers to the April 7, 2000 OPPS final rule with comment period (65 FR 18496 through 18497) for a detailed discussion of how we derived this percentage. During our regression analysis for the payment adjustment for rural hospitals in the CY 2006 OPPS final rule with comment period (70 FR 68553), we confirmed that this labor-related share for hospital outpatient services is appropriate.

The formula below is a mathematical representation of Step 1 and identifies the labor-related portion of a specific payment rate for a specific service.

X is the labor-related portion of the national unadjusted payment rate.

X = .60 * (national unadjusted payment rate).

Step 2. Determine the wage index area in which the hospital is located and identify the wage index level that applies to the specific hospital. The wage index values assigned to each area would reflect the geographic statistical areas (which are based upon OMB standards) to which hospitals are assigned for FY 2026 under the IPPS, reclassifications through the Medicare Geographic Classification Review Board (MGCRB), section 1886(d)(8)(B) "Lugar" hospitals, and reclassifications under section 1886(d)(8)(E) of the Act, as implemented in § 412.103 of the regulations. For CY 2026, we propose to apply for the CY 2026 OPPS wage index any adjustments for the FY 2026 IPPS post-reclassified wage index, including, but not limited to, the rural floor adjustment and a wage index floor of 1.00 in frontier states, in accordance with section 10324 of the Affordable Care Act of 2010. For further discussion of the wage index we are applying for the CY 2026 OPPS, including the low wage index hospital policy, we refer readers to section II.C. of this proposed rule.

Step 3. Adjust the wage index of hospitals located in certain qualifying counties that have a relatively high percentage of hospital employees who reside in the county, but who work in a different county with a higher wage index, in accordance with section 505 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173). Addendum L to this proposed rule (which is available via the Internet on the CMS website) contains the qualifying counties and the associated wage index increase developed for the proposed FY 2026 IPPS wage index, which are listed in Table 3 associated with the FY 2026 IPPS proposed rule and available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps*. (Click on the link on the left side of the screen titled "FY 2026 IPPS Proposed Rule Home Page" and select "FY 2026 Proposed Rule Tables.") This step is to be followed only if the hospital is not reclassified or redesignated under section 1886(d)(8) or section 1886(d)(10) of the Act.

Step 4. Multiply the applicable wage index determined under Steps 2 and 3 by the amount determined under Step 1 that represents the labor-related portion of the national unadjusted payment rate.

The formula below is a mathematical representation of Step 4 and adjusts the labor-related portion of the national unadjusted payment rate for the specific service by the wage index.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

X_a = labor-portion of the national unadjusted payment rate * applicable wage index.

Step 5. Calculate 40 percent (the nonlabor-related portion) of the national unadjusted payment rate and add that amount to the resulting product of Step 4. The result is the wage index adjusted payment rate for the relevant wage index area.

The formula below is a mathematical representation of Step 5 and calculates the remaining portion of the national payment rate, the amount not attributable to labor, and the adjusted payment for the specific service.

Y is the nonlabor-related portion of the national unadjusted payment rate.

Y = 0.40 * (national unadjusted payment rate).

Step 6. If a provider is an SCH, as set forth in the regulations at § 412.92, or an EACH, which is considered to be an SCH under section 1886(d)(5)(D)(iii)(III) of the Act, and located in a rural area, as defined in § 412.64(b), or is treated as being located in a rural area under § 412.103, multiply the wage index adjusted payment rate by 1.071 to calculate the total payment.

The formula below is a mathematical representation of Step 6 and applies the rural adjustment for rural SCHs.

Adjusted Medicare Payment (SCH or EACH) = Adjusted Medicare Payment * 1.071.

Step 7. The adjusted payment rate is the sum of the wage adjusted labor-related portion of the national unadjusted payment rate and the nonlabor-related portion of the national unadjusted payment rate.

X_a is the labor-related portion of the national unadjusted payment rate (wage adjusted).

Y is the nonlabor-related portion of the national unadjusted payment rate.

Adjusted Medicare Payment = $X_a + Y$

We are providing examples below of the calculation of both the full and reduced national unadjusted payment rates that would apply to certain outpatient items and services performed by hospitals that meet and that fail to meet the Hospital OQR Program requirements, using the steps outlined previously. For purposes of this example, we are using a provider that is located in Brooklyn, New York that is assigned to CBSA 35614. This provider bills one service that is assigned to APC 5071 (Level 1 Excision/Biopsy/Incision and Drainage). The proposed CY 2026 full national unadjusted payment rate for APC 5071 is $703.32. The proposed reduced national adjusted payment rate for APC 5071 for a hospital that fails to meet the Hospital OQR Program requirements is $716.08. This reduced rate is calculated by multiplying the reporting ratio of 0.9805 by the full unadjusted payment rate for APC 5071.

Step 1. The labor-related portion of the proposed full national unadjusted payment is approximately $438.19 (0.60 * $703.32). The labor-related portion of the proposed reduced national adjusted payment is approximately $429.65 (0.60 * $716.08).

Step 2 & 3. The FY 2026 wage index for a provider located in CBSA 35614 in New York, which includes the adoption of the proposed IPPS 2026 wage index policies, is 1.2589.

Step 4. The wage adjusted labor-related portion of the proposed full national unadjusted payment is approximately $551.64 ($438.19 * 1.2589). The wage adjusted labor-related portion of the proposed reduced national adjusted payment is approximately $540.89 ($429.65 * 1.2589).

Step 5. The nonlabor-related portion of the proposed full national unadjusted payment is approximately $292.13 (0.40 * $730.32). The nonlabor-related portion of the proposed reduced national adjusted payment is approximately $286.43(0.40 * $716.08).

Step 6. For this example of a provider located in Brooklyn, New York, the rural adjustment for rural SCHs does not apply.

Step 7. The sum of the labor-related and nonlabor-related portions of the proposed full national unadjusted payment is approximately $843.77 ($551.64 + $292.13). The sum of the portions of the proposed reduced national adjusted payment is approximately $827.32 ($540.89 + $286.43) as shown in Table 8.

TABLE 8: PROPOSED FULL NATIONAL UNADJUSTED PAYMENT RATE AND PROPOSED REDUCED NATIONAL ADJUSTED PAYMENT RATE

Proposed Full national unadjusted payment rate	Proposed Reduced national adjusted payment rate
$843.77	$827.32

I. Proposed Beneficiary Copayments

1. Background

Section 1833(t)(3)(B) of the Act requires the Secretary to set rules for determining the unadjusted copayment amounts to be paid by beneficiaries for covered OPD services. Section 1833(t)(8)(C)(ii) of the Act specifies that the Secretary must reduce the national unadjusted copayment amount for a covered OPD service (or group of such services) furnished in a year in a manner so that the effective copayment rate (determined on a national unadjusted basis) for that service in the year does not exceed a specified percentage. As specified in section 1833(t)(8)(C)(ii)(V) of the Act, the effective copayment rate for a covered OPD service paid under the OPPS in CY 2006, and in CYs thereafter, shall not exceed 40 percent of the APC payment rate.

Section 1833(t)(3)(B)(ii) of the Act provides that, for a covered OPD service (or group of such services) furnished in a year, the national unadjusted copayment amount cannot be less than

20 percent of the OPD fee schedule amount. However, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure (including items such as drugs and biologicals) performed in a year to the amount of the inpatient hospital deductible for that year.

Section 4104 of the Affordable Care Act eliminated the Medicare Part B coinsurance for preventive services furnished on and after January 1, 2011, that meet certain requirements, including flexible sigmoidoscopies and screening colonoscopies, and waived the Part B deductible for screening colonoscopies that become diagnostic during the procedure. For a discussion of the changes made by the Affordable Care Act with regard to copayments for preventive services furnished on and after January 1, 2011, we refer readers to section XII.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72013).

Section 122 of the Consolidated Appropriations Act (CAA), 2021 (Pub. L. 116-260), Waiving Medicare Coinsurance for Certain Colorectal Cancer Screening Tests, amended section 1833(a) of the Act to offer a special coinsurance rule for screening flexible sigmoidoscopies and screening colonoscopies, regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure, that is furnished in connection with, as a result of, and in the same clinical encounter as the colorectal cancer screening test. We refer readers to section X.B., "Changes to Beneficiary Coinsurance for Certain Colorectal Cancer Screening Tests," of the CY 2022 OPPS/ASC final rule with comment period for the full discussion of this policy (86 FR 63740 through 63743). Under the regulation at 42 CFR 410.152(l)(5)(i)(B), the Medicare Part B payment percentage for colorectal cancer screening tests described in the regulation at § 410.37(j) that are furnished in CY 2023 through CY 2026 is 85 percent, with beneficiary coinsurance equal to 15 percent.

On August 16, 2022, the Inflation Reduction Act of 2022 (IRA) (Pub. L. 117-169) was signed into law. Section 11101(a) of the IRA amended section 1847A of the Act by adding a new subsection (i), which requires the payment of rebates into the Supplementary Medical

Insurance Trust Fund for Part B rebatable drugs if the payment limit amount exceeds the inflation-adjusted payment amount, which is calculated as set forth in section 1847A(i)(3)(C) of the Act. The provisions of section 11101 of the IRA were initially implemented through program instruction, as permitted under section 1847A(c)(5)(C) of the Act. On February 9, 2023 and December 14, 2023, we issued initial[8] and revised[9] guidance, respectively, implementing the Medicare Part B Inflation Rebate Program, including the computation of inflation-adjusted beneficiary coinsurance under section 1847A(i)(5) of the Act and amounts paid under section 1833(a)(1)(EE) of the Act.[10] For additional information regarding implementation of section 11101 of the IRA, please see the inflation rebates resources page at *https://www.cms.gov/inflation-reduction-act-and-medicare/inflation-rebates-medicare*.

Section 11101(b) of the IRA amended sections 1833(i) and 1833(t)(8) of the Act by adding a new paragraph (9) and subparagraph (F), respectively. Section 1833(i)(9) requires under the ASC payment system that, in the case of a Part B rebatable drug for which payment is not packaged into a payment for a service, in lieu of calculation of coinsurance that would otherwise apply under the ASC payment system, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply for calculation of beneficiary coinsurance in the same manner as the provisions of section 1847A(i)(5) of the Act apply under that section. Similarly, section 1833(t)(8)(F) of the Act requires under the OPPS that in the case of a Part B rebatable drug (except for a drug that has no copayment applied under subparagraph (E) of such section or for which payment is packaged into the payment for a covered OPD service or group of services), in lieu of the calculation of the copayment amount that would otherwise apply under the OPPS, the provisions of section 1847A(i)(5) of the Act shall, as determined appropriate by the Secretary, apply in the same manner as the provisions of section

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[8] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf*.
[9] *https://www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-revised-guidance.pdf.*
[10] In addition, beginning with the April 2023 ASP Drug Pricing file, the file includes the coinsurance percentage for each drug and specifies "inflation-adjusted coinsurance" in the "Notes" column if the coinsurance for a drug is less than 20 percent of the Medicare Part B payment amount. Drug pricing files are available at *https://www.cms.gov/medicare/medicare-fee-for-service-part-b-drugs/mcrpartbdrugavgsalesprice*.

1847A(i)(5) of the Act apply under that section. Section 1847A(i)(5) of the Act requires that for Part B rebatable drugs, as defined in section 1847A(i)(2)(A) of the Act, furnished on or after April 1, 2023, in quarters in which the payment amount described in section 1847A(i)(3)(A)(ii)(I) of the Act (or, in the case of selected drugs described under section 1192(c) of the Act, the payment amount described in section 1847A(b)(1)(B) of the Act), exceeds the inflation-adjusted payment amount determined in accordance with section 1847A(i)(3)(C) of the Act, the coinsurance will be 20 percent of the inflation-adjusted payment amount for such quarter (hereafter, the inflation-adjusted coinsurance amount). This inflation-adjusted coinsurance amount is applied as a percent, as determined by the Secretary, to the payment amount that would otherwise apply for such calendar quarter in accordance with section 1847A(b)(1)(B) or (C) of the Act, as applicable, including in the case of a selected drug.

Paragraph (9) of section 1833(i) of the Act and subparagraph (F) of section 1833(t)(8) of the Act, as added by section 11101(b) of the IRA, also provide that in lieu of the amounts of payment otherwise applicable under the ASC payment system and the OPPS, the provisions of paragraph (1)(EE) of subsection (a) of section 1833 of the Act shall apply, as determined appropriate by the Secretary. Section 11101(b) of the IRA amended section 1833(a)(1) of the Act by adding a new subparagraph (EE), which requires that if the payment amount under section 1847A(i)(3)(A)(ii)(I) of the Act or, in the case of a selected drug, the payment amount described in section 1847A(b)(1)(B) of the Act, for that drug exceeds the inflation-adjusted payment amount for a Part B rebatable drug, the Part B payment amount would, subject to the Part B deductible and sequestration, equal the difference between such payment amount and the inflation-adjusted coinsurance amount. Consistent with the policy adopted in section 40 of the revised Medicare Part B Drug Inflation Rebate Guidance, the calculation to determine the applicable beneficiary coinsurance amount would not be adjusted for sequestration. CMS codified the Medicare payment for Part B rebatable drugs in the CY 2024 PFS final rule by adding new paragraph (m) to § 410.152 (88 FR 79043).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81594), we codified the OPPS program payment and cost as required by section 1833(t)(8)(F) of the Act by adding a new paragraph (e) to § 419.41, which cross-references the regulations adopted in the CY 2024 PFS final rule (§§410.152(m) and 489.30(b)(6)). We also amended the regulation text to reflect our longstanding policies for calculating the Medicare program payment and cost sharing amounts for separately payable drugs and biologicals by adding a new paragraph (d) to §419.41. Similarly, we codified the ASC cost sharing amounts for Part B rebatable drugs as required by section 1833(i)(9) of the Act by revising §416.172(d) to include a cross-reference to 42 CFR 489.30(b)(6), which codified the cost sharing amounts for Part B rebatable drugs with prices increasing at a rate faster than inflation.

In the CY 2025 PFS final rule (89 FR 98228 through 98275), CMS codified regulations implementing section 11101 of the IRA in newly added 42 CFR part 427, chapter IV, including new provisions at §§ 427.200 and 427.201 to codify the policies regarding the computation of the inflation-adjusted beneficiary coinsurance, defined in § 427.200, for Part B rebatable drugs as required by section 1847A(i)(5) of the Act. As finalized, § 427.201(a) establishes that CMS will use the methodology established in such section to calculate the inflation-adjusted beneficiary coinsurance and associated adjusted Medicare payment percentage and incorporates references to the existing provisions at §§ 410.152(m), 419.41(e), and 489.30(b)(6). Section 427.201(c) provides that any category of products that is excluded from the identification of Part B rebatable drugs at § 427.101(b) is not subject to the inflation-adjusted beneficiary coinsurance. Examples of these excluded products include separately payable radiopharmaceuticals, skin substitute products, and qualifying biosimilar biological products.

Section 427.201(b) sets forth the calculation of the inflation-adjusted beneficiary coinsurance. CMS will compare the payment amount in paragraph (b)(3) of such section to the inflation-adjusted payment amount for an applicable calendar quarter; if the payment amount exceeds the inflation-adjusted payment amount, the inflation-adjusted beneficiary coinsurance is

calculated by multiplying the inflation-adjusted payment amount by 0.20. Section 427.201(b)(3) specifies that CMS will use the published payment amount in quarterly pricing files[11,12,13] to determine if a Part B rebatable drug should have an adjusted beneficiary coinsurance. If so, such adjusted beneficiary coinsurance shall be equal to 20 percent of the inflation-adjusted payment amount as described in section 1847A(i)(3)(C) of the Act for a calendar quarter. This approach deviates from the rebate calculation approach set forth in § 427.302, which relies on the specified amount defined at § 427.20 even when the specified amount and the published payment amount in quarterly pricing files differ.

We note that the cost sharing amounts of rebatable drugs paid under the OPPS published in the quarterly Addendum A and B updates reflect the inflation-adjusted coinsurance applied as a percent of the payment amount that would otherwise apply in accordance with section 1847A(b)(1)(B) or (C) of the Act, as determined by the Secretary pursuant to 1847A(i)(5) of the Act using the methodology in § 427.201. As we explained in the CY 2025 PFS final rule (89 FR 98237), this policy is intended to hold beneficiaries harmless in situations where the payment amount is calculated differently from the specified amount, and we believe this approach is consistent with the statutory language and appropriately reflects the differences in the statutory text of section 1847A(i)(5) of the Act, which sets forth the payment amount that is used to determine whether coinsurance should be adjusted, and section 1847A(i)(3)(A) of the Act, which sets forth the "specified amount" used to determine rebate amounts. We refer readers to the full discussion at 89 FR 98237 and 98238 for additional details.

2. Proposed OPPS Copayment Policy

For CY 2026, we propose to determine copayment amounts for new and revised APCs using the same methodology that we implemented beginning in CY 2004. We refer readers to the

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[11] See: *https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files.*

[12] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/addendum-a-b-updates.*

[13] See: *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-payment-rates-addenda*.

November 7, 2003 OPPS final rule with comment period for a discussion of that methodology (68 FR 63458). In addition, we propose to use the same standard rounding principles that we have historically used in instances where the application of our standard copayment methodology would result in a copayment amount that is less than 20 percent and cannot be rounded, under standard rounding principles, to 20 percent. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66687) in which we discuss our rationale for applying these rounding principles. The proposed national unadjusted copayment amounts for services payable under the OPPS that would be effective January 1, 2026, are included in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website).

As discussed in section XIV.E. of this proposed rule, for CY 2026, the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies will equal the product of the reporting ratio and the national unadjusted copayment, or the product of the reporting ratio and the minimum unadjusted copayment, respectively, for the service.

We note that OPPS copayments may increase or decrease each year based on changes in the calculated APC payment rates, due to updated cost report and claims data, and any changes to the OPPS cost modeling process. However, as described in the CY 2004 OPPS final rule with comment period, the development of the copayment methodology generally moves beneficiary copayments closer to 20 percent of OPPS APC payments (68 FR 63458 through 63459).

In the CY 2004 OPPS final rule with comment period (68 FR 63459), we adopted a new methodology to calculate unadjusted copayment amounts in situations including reorganizing APCs, and we finalized the following rules to determine copayment amounts in CY 2004 and subsequent years.

- When an APC group consists solely of HCPCS codes that were not paid under the OPPS the prior year because they were packaged or excluded or are new codes, the unadjusted copayment amount would be 20 percent of the APC payment rate.

• If a new APC that did not exist during the prior year is created and consists of HCPCS codes previously assigned to other APCs, the copayment amount is calculated as the product of the APC payment rate and the lowest coinsurance percentage of the codes comprising the new APC.

• If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is equal to or *greater than* the prior year's rate, the copayment amount remains constant (unless the resulting coinsurance percentage is less than 20 percent).

• If no codes are added to or removed from an APC and, after recalibration of its relative payment weight, the new payment rate is *less than* the prior year's rate, the copayment amount is calculated as the product of the new payment rate and the prior year's coinsurance percentage.

• If HCPCS codes are added to or deleted from an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in a decrease in the coinsurance percentage for the reconfigured APC, the copayment amount would not change (unless retaining the copayment amount would result in a coinsurance rate less than 20 percent).

• If HCPCS codes are added to an APC and, after recalibrating its relative payment weight, holding its unadjusted copayment amount constant results in an increase in the coinsurance percentage for the reconfigured APC, the copayment amount would be calculated as the product of the payment rate of the reconfigured APC and the lowest coinsurance percentage of the codes being added to the reconfigured APC.

We noted in the CY 2004 OPPS final rule with comment period that we would seek to lower the copayment percentage for a service in an APC from the prior year if the copayment percentage was greater than 20 percent. We noted that this principle was consistent with section 1833(t)(8)(C)(ii) of the Act, which accelerates the reduction in the national unadjusted coinsurance rate so that beneficiary liability will eventually equal 20 percent of the OPPS

payment rate for all OPPS services to which a copayment applies, and with section 1833(t)(3)(B) of the Act, which achieves a 20 percent copayment percentage when fully phased in and gives the Secretary the authority to set rules for determining copayment amounts for new services. We further noted that the use of this methodology would, in general, reduce the beneficiary coinsurance rate and copayment amount for APCs for which the payment rate changes as the result of the reconfiguration of APCs and/or recalibration of relative payment weights (68 FR 63459).

3. Proposed Calculation of an Adjusted Copayment Amount for an APC Group

Individuals interested in calculating the national copayment liability for a Medicare beneficiary for a given service provided by a hospital that met or failed to meet its Hospital OQR Program requirements should follow the formulas presented in the following steps.

Step 1. Calculate the beneficiary payment percentage for the APC by dividing the APC's national unadjusted copayment by its proposed payment rate. For example, using APC 5071, $140.07 is 20 percent of the full national unadjusted payment rate of $730.32. For APCs with only a minimum unadjusted copayment in Addenda A and B to this proposed rule (which are available via the Internet on the CMS website), the beneficiary payment percentage is 20 percent.

The formula below is a mathematical representation of Step 1 and calculates the national copayment as a percentage of national payment for a given service.

B is the beneficiary payment percentage.

B = National unadjusted copayment for APC/national unadjusted payment rate for APC.

Step 2. Calculate the appropriate wage-adjusted payment rate for the APC for the provider in question, as indicated in Steps 2 through 4 under section II.H. of this proposed rule. Calculate the rural adjustment for eligible providers, as indicated in Step 6 under section II.H. of this proposed rule.

Step 3. Multiply the percentage calculated in Step 1 by the payment rate calculated in Step 2. The result is the wage-adjusted copayment amount for the APC.

The formula below is a mathematical representation of Step 3 and applies the beneficiary payment percentage to the adjusted payment rate for a service calculated under section II.H. of this proposed rule, with and without the rural adjustment, to calculate the adjusted beneficiary copayment for a given service.

Wage-adjusted copayment amount for the APC = Adjusted Medicare Payment * *B*.

Wage-adjusted copayment amount for the APC (SCH or EACH) = (Adjusted Medicare Payment * 1.071) * *B*.

Step 4. For a hospital that failed to meet its Hospital OQR Program requirements, multiply the copayment calculated in Step 3 by the reporting ratio of 0.9805.

The unadjusted copayments for services payable under the OPPS that would be effective January 1, 2026, are shown in Addenda A and B to this proposed rule (which are available via the CMS website). We note that the proposed national unadjusted payment rates and copayment rates shown in Addenda A and B to this proposed rule reflect the CY 2026 OPD fee schedule increase factor discussed in section II.B. of this proposed rule.

In addition, as noted earlier, section 1833(t)(8)(C)(i) of the Act limits the amount of beneficiary copayment that may be collected for a procedure performed in a year to the amount of the inpatient hospital deductible for that year.

III. Proposed OPPS Ambulatory Payment Classification (APC) Group Policies

A. Proposed OPPS Treatment of New and Revised HCPCS Codes

Payments for OPPS procedures, services, and items are generally based on medical billing codes, specifically, Healthcare Common Procedure Coding System (HCPCS) codes, that are reported on hospital outpatient department (HOPD) claims. HCPCS codes are used to report surgical procedures, medical services, items, and supplies under the hospital OPPS. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II of the HCPCS. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system that is established and maintained by the American Medical

Association (AMA), and consists of Category I, II, III, MAAA, and PLA CPT codes. Level II, which is established and maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are used to report procedures, services, items, and supplies under the OPPS payment system. Specifically, we recognize the following codes on OPPS claims:

- Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;
- Category III CPT codes, which describe new and emerging technologies, services, and procedures;
- MAAA CPT codes, which describe laboratory multianalyte assays with algorithmic analyses (MAA);
- PLA CPT codes, which describe proprietary laboratory analyses (PLA) services; and
- Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

The codes are updated and changed throughout the year. CPT and Level II HCPCS code changes that affect the OPPS are published through the annual rulemaking cycle and through the OPPS quarterly update Change Requests (CRs). Generally, these code changes are effective January 1, April 1, July 1, or October 1. CPT code changes are released by the AMA (via their website) while Level II HCPCS code changes are released to the public via the CMS HCPCS website. CMS recognizes the release of new CPT and Level II HCPCS codes outside of the formal rulemaking process via OPPS quarterly update CRs. Based on our review, we assign the new codes to interim status indicators (SIs) and APCs. These interim assignments are finalized in the OPPS/ASC final rules. This quarterly process offers hospitals access to codes that more accurately describe the items or services furnished and provides payment for these items or services in a timelier manner than if we waited for the annual rulemaking process. We solicit

public comments on the new CPT and Level II HCPCS codes, status indicators, and APC assignments through our annual rulemaking process.

We note that, under the OPPS, the APC assignment determines the payment rate for an item, procedure, or service. The items, procedures, or services not exclusively paid separately under the hospital OPPS are assigned to appropriate status indicators. Certain payment status indicators provide separate payment while other payment status indicators do not. In section XI. "Proposed CY 2026 Payment Status and Comment Indicators" of this proposed rule, we discuss the various status indicators and comment indicators used under the OPPS. We also provide a complete list of the status indicators and their definitions in Addendum D1 to this proposed rule.

1. April 2025 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2025 update, 104 new HCPCS codes were established and made effective on April 1, 2025. Through the April 2025 OPPS quarterly update CR (Transmittal 13135, Change Request 13993, dated March 20, 2025), we recognized several new HCPCS codes for payment under the OPPS. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 9 (New HCPCS Codes Effective April 1, 2025). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The new codes effective April 1, 2025, are assigned to comment indicator "NP" in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed status indicators and definitions used under the OPPS can be found in Addendum D1 to this proposed rule, while the complete list of proposed comment indicators and definitions can be found in Addendum D2. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS

Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the CMS website.

TABLE 9: NEW HCPCS CODES EFFECTIVE APRIL 1, 2025

CY 2025 HCPCS Code	CY 2025 Long Descriptor
A2030	Miro3d fibers, per milligram
A2031	Mirodry wound matrix, per square centimeter
A2032	Myriad matrix, per square centimeter
A2033	Myriad morcells, 4 milligrams
A2034	Foundation drs solo, per square centimeter
A2035	Corplex p or theracor p or allacor p, per milligram
A6515	Gradient compression wrap with adjustable straps, full leg, each, custom
A6516	Gradient compression wrap with adjustable straps, foot, each, custom
A6517	Gradient compression wrap with adjustable straps, below knee, each, custom
A6518	Gradient compression wrap with adjustable straps, arm, each, custom
A6519	Gradient compression garment, not otherwise specified, for nighttime use, each
A6611	Gradient compression wrap with adjustable straps, above knee, each, custom
A9154	Artificial saliva, 1 ml
A9611	Flurpiridaz f 18, diagnostic, 1 millicurie
C8004	Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors
C8005	Bronchoscopy, rigid or flexible, non-thermal transbronchial ablation of lesion(s) by pulsed electric field (PEF) energy, including fluoroscopic and/or ultrasound guidance, when performed, with computed tomography acquisition(s) and 3D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) of all mediastinal and/or hilar lymph node stations or structures, and therapeutic intervention(s)
C9300	Injection, indigotindisulfonate sodium, 1 mg
C9301	Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose
C9302	Injection, zanidatamab-hrii, 2 mg
C9303	Injection, zolbetuximab-clzb, 1mg
C9304	Injection, marstacimab-hncq, subcutaneous, 0.5 mg
E0201	Penile contracture device, manual, greater than 3 lbs traction force
E1022	Wheelchair transportation securement system, any type includes all components and accessories
E1023	Wheelchair transit securement system, includes all components and accessories
E1032	Wheelchair accessory, manual swingaway, retractable or removable mounting hardware used with joystick or other drive control interface
E1033	Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for headrest, cushioned, any type
E1034	Wheelchair accessory, manual swingaway, retractable or removable mounting hardware for lateral trunk or hip support, any type
E1832	Static progressive stretch finger device, extension and/or flexion, with or without range of motion adjustment, includes all components and accessories
G0183	Quantitative software measurements of cardiac volume, cardiac chambers volumes and left ventricular wall mass derived from CT scan(s) data of the chest/heart (with or without contrast)
G0566	3D radiodensity-value bone imaging, algorithm derived, from previous magnetic resonance examination of the same anatomy
G0567	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, screening, amplified probe technique
J0281	Injection, aminocaproic acid, 1 gram
J1072	Injection, testosterone cypionate (azmiro), 1 mg

CY 2025 HCPCS Code	CY 2025 Long Descriptor
J1271	Injection, doxycycline hyclate, 1 mg
J1299	Injection, eculizumab, 2 mg
J1308	Injection, famotidine, 0.25 mg
J1808	Injection, folic acid, 0.1 mg
J1938	Injection, furosemide, 1 mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
J2428	Injection, paliperidone palmitate extended release (erzofri), 1 mg
J2804	Injection, rifampin, 1 mg
J2865	Injection, sulfamethoxazole 5 mg and trimethoprim 1 mg
J7521	Tacrolimus, granules, oral suspension, 0.1 mg
J9024	Injection, atezolizumab, 5 mg and hyaluronidase-tqjs
J9038	Injection, axatilimab-csfr, 0.1 mg
J9054	Injection, bortezomib (boruzu), 0.1 mg
J9161	Injection, denileukin diftitox-cxdl, 1 mcg
L0720	Cervical-thoracic-lumbar-sacral-orthoses (ctlso), anterior-posterior-lateral control, prefabricated item that has been trimmed, bent, molded, assembled, or otherwise customized to fit a specific patient by an individual with expertise
L1933	Ankle foot orthosis, rigid anterior tibial section, total carbon fiber or equal material, prefabricated, off-the-shelf
L1952	Ankle foot orthosis, spiral, (institute of rehabilitative medicine type), plastic or other material, prefabricated, off-the-shelf
L5827	Endoskeletal knee-shin system, single axis, electromechanical swing and stance phase control, with or without shock absorption and stance extension damping
L6028	Partial hand including fingers, flexible or non-flexible interface, endoskeletal system, molded to patient model, for use without external power, not including inserts described by L6692
L6029	Upper extremity addition, test socket/interface, partial hand including fingers
L6030	Upper extremity addition, external frame, partial hand including fingers
L6031	Replacement socket/interface, partial hand including fingers, molded to patient model, for use with or without external power
L6032	Addition to upper extremity prosthesis, partial hand including fingers, ultralight material (titanium, carbon fiber or equal)
L6033	Addition to upper extremity prosthesis, partial hand including fingers, acrylic material
L6037	Immediate post-surgical or early fitting, application of initial rigid dressing, including fitting alignment and suspension of components, and one cast change, partial hand including fingers
L6700	Upper extremity addition, external powered feature, myoelectronic control module, additional emg inputs, pattern-recognition decoding intent movement
L7406	Addition to upper extremity, user adjustable, mechanical, residual limb volume management system
Q2057	Afamitresgene autoleucel, including leukapheresis and dose preparation procedures, per therapeutic dose
Q4354	Palingen dual-layer membrane, per square centimeter
Q4355	Abiomend xplus membrane and abiomend xplus hydromembrane, per square centimeter
Q4356	Abiomend membrane and abiomend hydromembrane, per square centimeter
Q4357	Xwrap plus, per square centimeter
Q4358	Xwrap dual, per square centimeter
Q4359	Choriply, per square centimeter
Q4360	Amchoplast fd, per square centimeter
Q4361	Epixpress, per square centimeter
Q4362	Cygnus disk, per square centimeter
Q4363	Amnio burgeon membrane and hydromembrane, per square centimeter
Q4364	Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter
Q4365	Amnio burgeon dual-layer membrane, per square centimeter
Q4366	Dual layer amnio burgeon x-membrane, per square centimeter
Q4367	Amniocore sl, per square centimeter
Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg
Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram
Q5149	Injection, aflibercept-abzv (enzeevu), biosimilar, 1 mg
Q5150	Injection, aflibercept-mrbb (ahzantive), biosimilar, 1 mg

CY 2025 HCPCS Code	CY 2025 Long Descriptor
Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg
Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
Q9999	Injection, ustekinumab-aauz (otulfi), biosimilar, 1 mg
S4024	Air polymer-type a intrauterine foam, per study dose
0531U	Infectious disease (acid-fast bacteria and invasive fungi), DNA (673 organisms), next-generation sequencing, plasma
0532U	Rare diseases (constitutional disease/hereditary disorders), rapid whole genome and mitochondrial DNA sequencing for single-nucleotide variants, insertions/deletions, copy number variations, peripheral blood, buffy coat, saliva, buccal or tissue sample, results reported as positive or negative
0533U	Drug metabolism (adverse drug reactions and drug response), genotyping of 16 genes (ie, ABCG2, CYP2B6, CYP2C9, CYP2C19, CYP2C, CYP2D6, CYP3A5, CYP4F2, DPYD, G6PD, GGCX, NUDT15, SLCO1B1, TPMT, UGT1A1, VKORC1), reported as metabolizer status and transporter function
0534U	Oncology (prostate), microRNA, single-nucleotide polymorphisms (SNPs) analysis by RT-PCR of 32 variants, using buccal swab, algorithm reported as a risk score
0535U	Perfluoroalkyl substances (PFAS) (eg, perfluorooctanoic acid, perfluorooctane sulfonic acid), by liquid chromatography with tandem mass spectrometry (LC-MS/MS), plasma or serum, quantitative
0536U	Red blood cell antigen (fetal RhD), PCR analysis of exon 4 of RHD gene and housekeeping control gene GAPDH from whole blood in pregnant individuals at 10+ weeks gestation known to be RhD negative, reported as fetal RhD status
0537U	Oncology (colorectal cancer), analysis of cell-free DNA for epigenomic patterns, next-generation sequencing, >2500 differentially methylated regions (DMRs), plasma, algorithm reported as positive or negative
0538U	Oncology (solid tumor), next-generation targeted sequencing analysis, formalin-fixed paraffin-embedded (FFPE) tumor tissue, DNA analysis of 600 genes, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, and copy number alterations, microsatellite instability, tumor mutation burden, reported as actionable variant
0539U	Oncology (solid tumor), cell-free circulating tumor DNA (ctDNA), 152 genes, next-generation sequencing, interrogation for single-nucleotide variants, insertions/deletions, gene rearrangements, copy number alterations, and microsatellite instability, using whole-blood samples, mutations with clinical actionability reported as actionable variant
0540U	Transplantation medicine, quantification of donor-derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor-derived cell-free DNA to determine probability of rejection
0541U	Cardiovascular disease (HDL reverse cholesterol transport), cholesterol efflux capacity, LC-MS/MS, quantitative measurement of 5 distinct HDL-bound apolipoproteins (apolipoproteins A1, C1, C2, C3, and C4), serum, algorithm reported as prediction of coronary artery disease (pCAD) score
0542U	Nephrology (renal transplant), urine, nuclear magnetic resonance (NMR) spectroscopy measurement of 84 urinary metabolites, combined with patient data, quantification of BK virus (human polyomavirus 1) using real-time PCR and serum creatinine, algorithm reported as a probability score for allograft injury status
0543U	Oncology (solid tumor), next-generation sequencing of DNA from formalin-fixed paraffin-embedded (FFPE) tissue of 517 genes, interrogation for single-nucleotide variants, multi-nucleotide variants, insertions and deletions from DNA, fusions in 24 genes and splice variants in 1 gene from RNA, and tumor mutation burden
0544U	Nephrology (transplant monitoring), 48 variants by digital PCR, using cell-free DNA from plasma, donor-derived cell-free DNA, percentage reported as risk for rejection
0545U	Acetylcholine receptor (AChR), antibody identification by immunofluorescence, using live cells, reported as positive or negative
0546U	Low-density lipoprotein receptor-related protein 4 (LRP4), antibody identification by immunofluorescence, using live cells, reported as positive or negative
0547U	Neurofilament light chain (NfL), chemiluminescent enzyme immunoassay, plasma, quantitative
0548U	Glial fibrillary acidic protein (GFAP), chemiluminescent enzyme immunoassay, using plasma

CY 2025 HCPCS Code	CY 2025 Long Descriptor
0549U	Oncology (urothelial), DNA, quantitative methylated real-time PCR of TRNA-Cys, SIM2, and NKX1-1, using urine, diagnostic algorithm reported as a probability index for bladder cancer and/or upper tract urothelial carcinoma (UTUC)
0550U	Oncology (prostate), enzyme-linked immunosorbent assays (ELISA) for total prostate-specific antigen (PSA) and free PSA, serum, combined with age, previous negative prostate biopsy status, digital rectal examination findings, prostate volume, and image and data reporting of the prostate, algorithm reported as a risk score for the presence of high-grade prostate cancer
0551U	Tau, phosphorylated, pTau217, by single-molecule array (ultrasensitive digital protein detection), using plasma

2. July 2025 HCPCS Codes Proposed Rule Comment Solicitation

For the July 2025 update, 110 new codes were established and made effective July 1, 2025. Through the July 2025 OPPS quarterly update CR (Transmittal13258, Change Request 14091, dated June 23, 2025) we recognized several new codes for payment and assigned them to appropriate interim OPPS status indicators and APCs. In this proposed rule, we solicit public comments on the proposed APC and status indicator assignments for the codes listed in Table 10 (New HCPCS Codes Effective July 1, 2025). The proposed status indicator, APC assignment, and payment rate for each HCPCS code can be found in Addendum B to this proposed rule. The complete list of proposed status indicators and corresponding definitions used under the OPPS can be found in Addendum D1 to this proposed rule. In addition, the new codes are assigned to comment indicator "NP" in Addendum B to this proposed rule to indicate that the codes are assigned to an interim APC assignment and comments will be accepted on their interim APC assignments. The complete list of proposed comment indicators and definitions used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

TABLE 10: NEW HCPCS CODES EFFECTIVE JULY 1, 2025

CY 2025 HCPCS Code	CY 2025 Long Descriptor
C9174	Injection, datopotamab deruxtecan-dlnk, 1 mg
C9175	Injection, treosulfan, 50 mg
J0165	Injection, epinephrine, not otherwise specified, 0.1 mg

CY 2025 HCPCS Code	CY 2025 Long Descriptor
J0166	Injection, epinephrine (bpi), not therapeutically equivalent to j0165, 0.1 mg
J0167	Injection, epinephrine (hospira), not therapeutically equivalent to j0165, 0.1 mg
J0168	Injection, epinephrine (international medication systems), not therapeutically equivalent to j0165, 0.1 mg
J0169	Injection, epinephrine (adrenalin), not therapeutically equivalent to j0165, 0.1 mg
J0616	Injection, metoprolol tartrate, 1 mg
J0618	Injection, calcium chloride, 2 mg
J1163	Injection, diltiazem hydrochloride, 0.5 mg
J1326	Injection, zolbetuximab-clzb, 2 mg
J2312	Injection, naloxone hydrochloride, not otherwise specified, 0.01 mg
J2313	Injection, naloxone hydrochloride (zimhi), 0.01 mg
J3373	Injection, vancomycin hydrochloride, 10 mg
J3374	Injection, vancomycin hydrochloride (mylan) not therapeutically equivalent to j3373, 10 mg
J3375	Injection, vancomycin hydrochloride (xellia), not therapeutically equivalent to j3373, 10 mg
J3391	Injection, atidarsagene autotemcel, per treatment
J7172	Injection, marstacimab-hncq, 0.5 mg
J7356	Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg
J9038	Injection, axatilimab-csfr, 0.1 mg
J9174	Injection, docetaxel (beizray), 1 mg
J9220	Injection, indigotindisulfonate sodium, 1 mg
J9275	Injection, cosibelimab-ipdl, 2 mg
J9276	Injection, zanidatamab-hrii, 2 mg
J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy
J9341	Injection, thiotepa (tepylute), 1 mg
J9342	Injection, thiotepa, not otherwise specified, 1 mg
J9382	Injection, zenocutuzumab-zbco, 1 mg
Q4368	Amchothick, per square centimeter
Q4369	Amnioplast 3, per square centimeter
Q4370	Aeroguard, per square centimeter
Q4371	Neoguard, per square centimeter
Q4372	Amchoplast excel, per square centimeter
Q4373	Membrane wrap lite, per square centimeter
Q4375	Duograft ac, per square centimeter
Q4376	Duograft aa, per square centimeter
Q4377	Trigraft ft, per square centimeter
Q4378	Renew ft matrix, per square centimeter
Q4379	Amniodefend ft matrix, per square centimeter
Q4380	Advograft one, per square centimeter
Q4381	Matrix hd allograft dermis, per square centimeter
Q4382	Advograft dual, per square centimeter
Q5098	Injection, ustekinumab-srlf (imuldosa), biosimilar, 1 mg
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg
Q5153	Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg
0948T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system with interim analysis, review and report(s) by a physician or other qualified health care professional
0949T	Interrogation device evaluation (remote), up to 90 days, cardiac contractility modulation system, remote data acquisition(s), receipt of transmissions, technician review, technical support, and distribution of results
0950T	Ablation of benign prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance
0951T	Totally implantable active middle ear hearing implant; initial placement, including mastoidectomy, placement of and attachment to sound processor
0952T	Totally implantable active middle ear hearing implant; revision or replacement, with mastoidectomy and replacement of sound processor

CY 2025 HCPCS Code	CY 2025 Long Descriptor
0953T	Totally implantable active middle ear hearing implant; revision or replacement, without mastoidectomy and replacement of sound processor
0954T	Totally implantable active middle ear hearing implant; replacement of sound processor only, with attachment to existing transducers
0955T	Totally implantable active middle ear hearing implant; removal, including removal of sound processor and all implant components
0956T	Partial craniectomy, channel creation, and tunneling of electrode for sub-scalp implantation of an electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
0957T	Revision of sub-scalp implanted electrode array, receiver, and telemetry unit for electrode, when required, including imaging guidance
0958T	Removal of sub-scalp implanted electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
0959T	Removal or replacement of magnet from coil assembly that is connected to continuous bilateral electroencephalography monitoring system, including imaging guidance
0960T	Replacement of sub-scalp implanted electrode array, receiver, and telemetry unit with tunneling of electrode for continuous bilateral electroencephalography monitoring system, including imaging guidance
0961T	Shortwave infrared radiation imaging, surgical pathology specimen, to assist gross examination for lymph node localization in fibroadipose tissue, per specimen (List separately in addition to code for primary procedure)
0962T	Assistive algorithmic analysis of acoustic and electrocardiogram recording for detection of cardiac dysfunction (eg, reduced ejection fraction, cardiac murmurs, atrial fibrillation), with review and interpretation by a physician or other qualified health care professional
0963T	Anoscopy with directed submucosal injection of bulking agent into anal canal
0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism
0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, non-fixed hinge mechanism
0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism
0967T	Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source and monitoring system
0968T	Insertion or replacement of epicranial neurostimulator system, including electrode array and pulse generator, with connection to electrode array
0969T	Removal of epicranial neurostimulator system
0970T	Ablation, benign breast tumor (eg, fibroadenoma), percutaneous, laser, including imaging guidance when performed, each tumor
0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral
0972T	Assistive algorithmic classification of burn healing (ie, healing or nonhealing) by noninvasive multispectral imaging, including system set-up and acquisition, selection, and transmission of images, with automated generation of report
0973T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs; first 100 sq cm
0974T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs;each additional 100 sq cm (List separately in addition to code for primary procedure)
0975T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck, hands, feet, and/or multiple digits; first 100 sq cm
0976T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck,

CY 2025 HCPCS Code	CY 2025 Long Descriptor
	hands, feet, and/or multiple digits;each additional 100 sq cm (List separately in addition to code for primary procedure)
0977T	Upper gastrointestinal blood detection, sensor capsule, with interpretation and report
0978T	Submucosal cryolysis therapy; soft palate, base of tongue, and lingual tonsil
0979T	Submucosal cryolysis therapy; soft palate only
0980T	Submucosal cryolysis therapy; base of tongue and lingual tonsil only
0981T	Transcatheter implantation of wireless inferior vena cava sensor for long-term hemodynamic monitoring, including deployment of the sensor, radiological supervision and interpretation, right heart catheterization, and inferior vena cava venography, when performed
0982T	Remote monitoring of implantable inferior vena cava pressure sensor, physiologic parameter(s) (eg, weight, blood pressure, pulse oximetry, respiratory flow rate), initial set-up and patient education on use of equipment
0983T	Remote monitoring of an implanted inferior vena cava sensor for up to 30 days, including at least weekly downloads of inferior vena cava area recordings, interpretation(s), trend analysis, and report(s) by a physician or other qualified health care professional
0984T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)
0985T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)
0986T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)
0987T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; each additional vessel (List separately in addition to code for primary procedure)
0552U	Reproductive medicine (preimplantation genetic assessment), analysis for known genetic disorders from trophectoderm biopsy, linkage analysis of diseasecausing locus, and when possible, targeted mutation analysis for known familial variant, reported as low-risk or high-risk for familial genetic disorder
0553U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, and a mitochondrial DNA score, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, or mosaic, per embryo tested
0554U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from trophectoderm biopsy for aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal (euploidy), monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
0555U	Reproductive medicine (preimplantation genetic assessment), analysis of 24 chromosomes using DNA genomic sequence analysis from embryonic trophectoderm for structural rearrangements, aneuploidy, ploidy, a mitochondrial DNA score, and embryo quality control, results reported as normal/balanced (euploidy/balanced), unbalanced structural rearrangement, monosomy, trisomy, segmental aneuploidy, triploid, haploid, or mosaic, with quality control results reported as contamination detected or inconsistent cohort when applicable, per embryo tested
0556U	Infectious disease (bacterial or viral respiratory tract infection), pathogen-specific DNA and RNA by real-time PCR, 12 targets, nasopharyngeal or oropharyngeal swab, including multiplex reverse transcription for RNA targets, each analyte reported as detected or not detected
0557U	Infectious disease (bacterial vaginosis and vaginitis), realtime amplification of DNA markers for Atopobium vaginae, Gardnerella vaginalis, Megasphaera types 1 and 2, bacterial vaginosis associated bacteria-2 and -3 (BVAB-2, BVAB-3), Mobiluncus species, Trichomonas vaginalis,

CY 2025 HCPCS Code	CY 2025 Long Descriptor
	Neisseria gonorrhoeae, Candida species (C. albicans, C. tropicalis, C. parapsilosis, C. glabrata, C. krusei), Herpes simplex viruses 1 and 2, vaginal fluid, reported as detected or not detected for each organism
0558U	Oncology (colorectal), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted colorectal cancer protein marker (BF7 antigen), using serum, result reported as indicative of response/no response to therapy or disease progression/regression
0559U	Oncology (breast), quantitative enzyme-linked immunosorbent assay (ELISA) for secreted breast cancer protein marker (BF9 antigen), serum, result reported as indicative of response/no response to therapy or disease progression/regression
0560U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood and tumor tissue, baseline assessment for design and construction of a personalized variant panel to evaluate current MRD and for comparison to subsequent MRD assessments
0561U	Oncology (minimal residual disease [MRD]), genomic sequence analysis, cell-free DNA, whole blood, subsequent assessment with comparison to initial assessment to evaluate for MRD
0562U	Oncology (solid tumor), targeted genomic sequence analysis, 33 genes, detection of single-nucleotide variants (SNVs), insertions and deletions, copy-number amplifications, and translocations in human genomic circulating cell-free DNA, plasma, reported as presence of actionable variants
0563U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 11 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen
0564U	Infectious disease (bacterial and/or viral respiratory tract infection), pathogen-specific nucleic acid (DNA or RNA), 10 viral targets and 4 bacterial targets, qualitative RT-PCR, upper respiratory specimen, each pathogen reported as positive or negative
0565U	Oncology (hepatocellular carcinoma), next-generation sequencing methylation pattern assay to detect 6626 epigenetic alterations, cellfree DNA, plasma, algorithm reported as cancer signal detected or not detected
0566U	Oncology (lung), qPCRbased analysis of 13 differentially methylated regions (CCDC181, HOXA7, LRRC8A, MARCHF11, MIR129-2, NCOR2, PANTR1, PRKCB, SLC9A3, TBR1_2, TRAP1, VWC2, ZNF781), pleural fluid, algorithm reported as a qualitative result
0567U	Rare diseases (constitutional/heritable disorders), whole-genome sequence analysis combination of short and long reads, for single-nucleotide variants, insertions/deletions and characterized intronic variants, copy-number variants, duplications/deletions, mobile element insertions, runs of homozygosity, aneuploidy, and inversions, mitochondrial DNA sequence and deletions, short tandem repeat genes, methylation status of selected regions, blood, saliva, amniocentesis, chorionic villus sample or tissue, identification and categorization of genetic variants
0568U	Neurology (dementia), beta amyloid (Aβ40, Aβ42, Aβ42/40 ratio), tau-protein phosphorylated at residue (eg, pTau217), neurofilament light chain (NfL), and glial fibrillary acidic protein (GFAP), by ultra-high sensitivity molecule array detection, plasma, algorithm reported as positive, intermediate, or negative for Alzheimer pathology
0569U	Oncology (solid tumor), nextgeneration sequencing analysis of tumor methylation markers (>20000 differentially methylated regions) present in cell-free circulating tumor DNA (ctDNA), whole blood, algorithm reported as presence or absence of ctDNA with tumor fraction, if appropriate
0570U	Neurology (traumatic brain injury), analysis of glial fibrillary acidic protein (GFAP) and ubiquitin carboxylterminal hydrolase L1 (UCHL1), immunoassay, whole blood or plasma, individual components reported with the overall result of elevated or non-elevated based on threshold comparison
0571U	Oncology (solid tumor), DNA (80 genes) and RNA (10 genes), by next-generation sequencing, plasma, including single-nucleotide variants, insertions/deletions, copy-number alterations, microsatellite instability, and fusions, reported as clinically actionable variants
0572U	Oncology (prostate), highthroughput telomere length quantification by FISH, whole blood, diagnostic algorithm reported as risk of prostate cancer
0573U	Oncology (pancreas), 3 biomarkers (glucose, carcinoembryonic antigen, and gastricsin), pancreatic cyst lesion fluid, algorithm reported as categorical mucinous or non-mucinous
0574U	Mycobacterium tuberculosis, culture filtrate protein–10-kDa (CFP-10), serum or plasma, liquid chromatography mass spectrometry (LC-MS)

3. October 2025 HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we will solicit comments on the new CPT and Level II HCPCS codes that will be effective October 1, 2025, in the CY 2026 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2026 OPPS/ASC final rule with comment period. The HCPCS codes will be released to the public through the October 2025 OPPS Update CR and the CMS HCPCS website while the CPT codes will be released to the public through the AMA website.

For CY 2026, we propose to continue our established policy of assigning comment indicator "N1" in Addendum B to this proposed rule for those new HCPCS codes that will be effective October 1, 2025, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2026 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2027 OPPS/ASC final rule with comment period.

4. January 2026 HCPCS Codes

a. New Level II HCPCS Codes Final Rule Comment Solicitation

Consistent with past practice, we will solicit comments on the new Level II HCPCS codes that will be effective January 1, 2026, in the CY 2026 OPPS/ASC final rule with comment period, thereby allowing us to finalize the status indicators and APC assignments for the codes in the CY 2027 OPPS/ASC final rule with comment period. Unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the proposed new C-codes and G-codes listed in Addendum O of this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Consequently, for CY 2026, we propose to include the new Level II HCPCS codes effective January 1, 2026, in Addendum B to the CY 2026 OPPS/ASC final rule with comment period, which would be incorporated in the January 2026 OPPS quarterly update CR. Specifically, for

CY 2026, we propose to continue our established policy of assigning comment indicator "N1" in Addendum B to the OPPS/ASC final rule with comment period to the new HCPCS codes that will be effective January 1, 2026, to indicate that we are assigning them an interim status indicator, which is subject to public comment. We will be inviting public comments in the CY 2026 OPPS/ASC final rule with comment period on the status indicator and APC assignments, which would then be finalized in the CY 2027 OPPS/ASC final rule with comment period.

b. New CPT Codes Proposed Rule Comment Solicitation

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66841 through 66844), we finalized a revised process of assigning APC and status indicators for new and revised Category I and III CPT codes that would be effective January 1. Specifically, for the new/revised CPT codes that we receive in a timely manner from the AMA's CPT Editorial Panel, we finalized our proposal to include the codes that would be effective January 1 in the OPPS/ASC proposed rules, along with proposed APC and status indicator assignments for them, and to finalize the APC and status indicator assignments in the OPPS/ASC final rules beginning with the CY 2016 OPPS update. For those new/revised CPT codes that were received too late for inclusion in the OPPS/ASC proposed rule, we finalized our proposal to establish and use HCPCS G-codes that mirror the predecessor CPT codes and retain the current APC and status indicator assignments for a year until we can propose APC and status indicator assignments in the following year's rulemaking cycle. We note that even if we find that we need to create HCPCS G-codes in place of certain CPT codes for the PFS proposed rule, we do not anticipate that these HCPCS G-codes will always be necessary for OPPS purposes. We will make every effort to include proposed APC and status indicator assignments for all new and revised CPT codes that the AMA makes publicly available in time for us to include them in the proposed rule, and to avoid resorting to use of HCPCS G-codes and the resulting delay in utilization of the most current CPT codes. Also, we finalized our proposal to make interim APC and status indicator

assignments for CPT codes that are not available in time for the proposed rule and that describe wholly new services (such as new technologies or new surgical procedures), to solicit public comments in the final rule, and to finalize the specific APC and status indicator assignments for those codes in the following year's rule.

For the CY 2026 OPPS update, we received the CPT codes that will be effective January 1, 2026, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in Addendum B to this proposed rule (which is available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator "NP" in Addendum B of this proposed rule to indicate that the code is new for the next calendar year or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed APC assignment, and that comments will be accepted on the proposed APC assignment and status indicator. Further, we note that the CPT code descriptors that appear in Addendum B are short descriptors and do not accurately describe the complete procedure, service, or item described by the CPT code. Therefore, we are including the 5-digit placeholder codes and the long descriptors for the new and revised CY 2026 CPT codes in Addendum O, specifically under the column labeled "CY 2026 OPPS/ASC Proposed Rule 5-Digit AMA/CMS Placeholder Code." The final HCPCS code numbers will be included in the CY 2026 OPPS/ASC final rule with comment period. In summary, we solicit public comments on the proposed CY 2026 status indicators and APC assignments for the new and revised CPT codes that will be effective January 1, 2026. The CPT codes listed in Addendum B appear with short descriptors only, therefore, we list them again in Addendum O to this proposed rule with long descriptors. In addition, we propose to finalize the status indicator and APC assignments for these codes (with their final CPT code numbers) in the CY 2026 OPPS/ASC final rule with comment period. The proposed status indicator and APC assignment for these codes can be found in Addendum B to this proposed rule. In addition, the complete list of proposed comment indicators and definitions

used under the OPPS can be found in Addendum D2 to this proposed rule. We note that OPPS Addendum B (OPPS payment file by HCPCS code), Addendum D1 (OPPS Status Indicators), and Addendum D2 (OPPS Comment Indicators) are available via the internet on the CMS website.

Finally, in Table 11 (Comment and Finalization Timeframes for New and Revised OPPS-Related HCPCS Codes) below, we summarize our current process for updating codes through our OPPS quarterly update CRs, seeking public comments, and finalizing the treatment of these codes under the OPPS.

TABLE 11: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED OPPS-RELATED HCPCS CODES

OPPS Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2025	HCPCS (CPT and Level II Codes)	April 1, 2025	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
July 2025	HCPCS (CPT and Level II Codes)	July 1, 2025	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
October 2025	HCPCS (CPT and Level II Codes)	October 1, 2025	CY 2026 OPPS/ASC final rule with comment period	CY 2027 OPPS/ASC final rule with comment period
January 2026	CPT codes	January 1, 2026	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2026	CY 2026 OPPS/ASC final rule with comment period	CY 2027 OPPS/ASC final rule with comment period

B. OPPS Changes—Variations Within APCs

1. Background

Section 1833(t)(2)(A) of the Act requires the Secretary to develop a classification system for covered hospital outpatient department services. In addition, section 1833(t)(2)(B) of the Act provides that the Secretary may establish groups of covered OPD services within this classification system, so that services classified within each group are comparable clinically and

with respect to the use of resources. In accordance with these provisions, we developed a grouping classification system, referred to as Ambulatory Payment Classifications (APCs), as set forth in regulations at 42 CFR 419.31. We use Level I (also known as CPT codes) and Level II HCPCS codes (also known as alphanumeric codes) to identify and group the services within each APC. The APCs are organized such that each group is homogeneous both clinically and in terms of resource use. Using this classification system, we have established distinct groups of similar services. We also have developed separate APC groups for certain medical devices, drugs, biologicals, therapeutic radiopharmaceuticals, and brachytherapy devices that are not packaged into the payment for the procedure.

We have packaged into the payment for each procedure or service within an APC group, the costs associated with those items and services that are typically ancillary and supportive to a primary diagnostic or therapeutic modality and, in those cases, are an integral part of the primary service they support. Therefore, we do not make separate payment for these packaged items or services. In general, packaged items and services include, but are not limited to, the items and services listed in regulations at 42 CFR 419.2(b). A further discussion of packaged services is included in section II.A.3. of this proposed rule.

Under the OPPS, we generally pay for covered hospital outpatient services on a rate-per-service basis, where the service may be reported with one or more HCPCS codes. Payment varies according to the APC group to which the independent service or combination of services is assigned. For CY 2026, we propose that each APC relative payment weight represents the hospital cost of the services included in that APC, relative to the hospital cost of the services included in APC 5012 (Clinic Visits and Related Services). The APC relative payment weights are scaled to APC 5012 because it is the hospital clinic visit APC and clinic visits are among the most frequently furnished services in the hospital outpatient setting.

1. Application of the 2 Times Rule

Section 1833(t)(9)(A) of the Act requires the Secretary to review, not less often than annually, and revise the APC groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act to consider changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors. Section 1833(t)(9)(A) of the Act also requires the Secretary to consult with an expert outside advisory panel composed of an appropriate selection of representatives of providers to review (and advise the Secretary concerning) the clinical integrity of the APC groups and the relative payment weights. We note that the Advisory Panel on Hospital Outpatient Payment (also known as the HOP Panel or the Panel) recommendations for specific services for the CY 2026 OPPS update will be discussed in the relevant specific sections throughout the CY 2026 OPPS/ ASC final rule with comment period. In addition, section 1833(t)(2) of the Act provides that, subject to certain exceptions, the items and services within an APC group cannot be considered comparable regarding the use of resources if the highest cost for an item or service in the group is more than 2 times greater than the lowest cost for an item or service within the same group (referred to as the ‘‘2 times rule’’). The statute authorizes the Secretary to make exceptions to the 2 times rule in unusual cases, such as for low-volume items and services (but the Secretary may not make such an exception in the case of a drug or biological that has been designated as an orphan drug under section 526 of the Federal Food, Drug, and Cosmetic Act). In determining the APCs with a 2 times rule violation, we consider only those HCPCS codes that are significant based on the number of claims. We note that, for purposes of identifying significant procedure codes for examination under the 2 times rule, we consider procedure codes that have more than 1,000 single major claims or procedure codes that both have more than 99 single major claims and contribute at least 2 percent of the single major claims used to establish the APC cost to be significant (75 FR 71832). This longstanding definition of when a procedure code is significant for purposes of the 2 times rule was selected because we believe that a subset of 1,000 or fewer claims is negligible within the set of

approximately 100 million single procedure or single session claims we use for establishing costs. Similarly, a procedure code for which there are fewer than 99 single claims and that comprises less than 2 percent of the single major claims within an APC will have a negligible impact on the APC cost (75 FR 71832). In this section of this proposed rule, for CY 2026, we propose to make exceptions to this limit on the variation of costs within each APC group in unusual cases, such as for certain low-volume items and services.

For the CY 2026 OPPS update, we identified the APCs with violations of the 2 times rule, and we propose changes to the procedure codes assigned to these APCs (with the exception of those APCs for which we propose a 2 times rule exception) in Addendum B to this proposed rule. We note that Addendum B does not appear in the printed version of the **Federal Register** as part of this proposed rule. Rather, it is published and made available via the internet on the CMS website at *https:// www.cms.gov/medicare/payment/ prospective-payment-systems/hospital-outpatient/regulations-notices*. To eliminate a violation of the 2 times rule and improve clinical and resource homogeneity in the APCs for which we are not proposing a 2 times rule exception, we propose to reassign these procedure codes to new APCs that contain services that are similar with regard to both their clinical and resource characteristics. In many cases, the proposed HCPCS code reassignments and associated APC reconfigurations for CY 2026 included in this proposed rule are related to changes in costs of services that were observed in the CY 2024 claims data available for CY 2026 ratesetting. Addendum B to this proposed rule identifies with a comment indicator ‘‘CH’’ those procedure codes for which we propose a change to the APC assignment or status indicator, or both, that were initially assigned in the July 1, 2025, OPPS Addendum B Update, which is available via the internet on the CMS website at *https:// www.cms.gov/medicare/payment/prospective-payment-systems/hospital- outpatient/addendum-a-b-update.*

2. Proposed APC Exceptions to the 2 Times Rule

While considering the APC changes that we propose for CY 2026, we reviewed all of the APCs for which we identified 2 times rule violations to determine whether any of the APCs would qualify for an exception. We used the following criteria to evaluate whether to propose exceptions to the 2 times rule for affected APCs:

- Resource homogeneity;
- Clinical homogeneity;
- Hospital outpatient setting utilization;
- Frequency of service (volume); and
- Opportunity for upcoding and code fragments.

For a detailed discussion of these criteria, we refer readers to the April 7, 2000 final rule (65 FR 18457 through 18458).

Based on the CY 2024 claims data available for this proposed rule, we found 26 APCs with violations of the 2 times rule. We applied the criteria as described above to identify the APCs for which we propose to make exceptions under the 2 times rule for CY 2026 and found that all of the 26 APCs we identified meet the criteria for an exception to the 2 times rule based on the CY 2024 claims data available for this proposed rule. We note that, on an annual basis, based on our analysis of the latest claims data, we identify violations to the 2 times rule and propose changes when appropriate. Those APCs that violate the 2 times rule are identified and appear in Table 12. In addition, we did not include in that determination those APCs where a 2 times rule violation was not a relevant concept, such as APC 5401 (Dialysis), which only has two HCPCS codes assigned to it that have similar geometric mean costs and do not create a 2 times rule violation. Therefore, we have only identified those APCs, including those with criteria-based costs, such as device-dependent CPT/ HCPCS codes, with violations of the 2 times rule, where a 2 times rule violation is a relevant concept.

Table 12 of this proposed rule lists the 26 APCs for which we propose to make an exception under the 2 times rule for CY 2026 based on the criteria cited above and claims data

submitted between January 1, 2024, and December 31, 2024, and processed on or before December 31, 2024, and CCRs, if available. The proposed geometric mean costs for covered hospital outpatient services for these and all other APCs that were used in the development of this proposed rule can be found on the CMS website at *https://www.cms.gov/ medicare/payment/prospective- payment-systems/hospital-outpatient/ regulations-notices.*

TABLE 12: PROPOSED CY 2026 APC EXCEPTIONS TO THE 2 TIMES RULE

APC	APC Group Title
5012	Clinic Visits and Related Services
5054	Level 4 Skin Procedures
5071	Level 1 Excision/Biopsy/Incision and Drainage
5301	Level 1 Upper GI Procedures
5502	Level 2 Extraocular, Repair, and Plastic Eye Procedures
5521	Level 1 Imaging without Contrast
5522	Level 2 Imaging without Contrast
5523	Level 3 Imaging without Contrast
5524	Level 4 Imaging without Contrast
5572	Level 2 Imaging with Contrast
5611	Level 1 Therapeutic Radiation Treatment Preparation
5612	Level 2 Therapeutic Radiation Treatment Preparation
5613	Level 3 Therapeutic Radiation Treatment Preparation
5627	Level 7 Radiation Therapy
5671	Level 1 Pathology
5674	Level 4 Pathology
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5724	Level 4 Diagnostic Tests and Related Services
5731	Level 1 Minor Procedures
5734	Level 4 Minor Procedures
5791	Pulmonary Treatment
5811	Manipulation Therapy
5821	Level 1 Health and Behavior Services
5822	Level 2 Health and Behavior Services
5823	Level 3 Health and Behavior Services

C. New Technology APCs

1. Background

In the CY 2002 OPPS final rule (66 FR 59903), we finalized changes to the time period in which a service can be eligible for payment under a New Technology APC. Beginning in CY 2002, we retain services within New Technology APC groups until we gather sufficient claims data to enable us to assign the service to an appropriate clinical APC. This policy allows us to move a service from a New Technology APC in less than 2 years if sufficient data are

available. It also allows us to retain a service in a New Technology APC for more than 2 years if sufficient data upon which to base a decision for reassignment have not been collected.

We also adopted in the CY 2002 OPPS final rule the following criteria for assigning a complete or comprehensive service to a New Technology APC: (1) the service must be truly new, meaning it cannot be appropriately reported by an existing HCPCS code assigned to a clinical APC and does not appropriately fit within an existing clinical APC; (2) the service is not eligible for transitional pass-through payment (however, a truly new, comprehensive service could qualify for assignment to a new technology APC even if it involves a device or drug that could, on its own, qualify for pass-through payment); and (3) the service falls within the scope of Medicare benefits under section 1832(a) of the Act and is reasonable and necessary in accordance with section 1862(a)(1)(A) of the Act (66 FR 59898 through 59903). For additional information about our New Technology APC policy, we refer readers to *https:// www.cms.gov/Medicare/Medicare-Fee- for-Service-Payment/HospitalOutpatientPPS/passthrough payment* on the CMS website and then follow the instructions to access the MEARIS™ system for OPPS New Technology APC applications.[14]

In the CY 2004 OPPS final rule with comment period (68 FR 63416), we restructured the New Technology APCs to make the cost intervals more consistent across payment levels and refined the cost bands for these APCs to retain two parallel sets of New Technology APCs: one set with a status indicator of ‘‘S’’ (Significant Procedures, Not Discounted when Multiple. Paid under OPPS; separate APC payment) and the other set with a status indicator of ‘‘T’’ (Significant Procedure, Multiple Reduction Applies. Paid under OPPS; separate APC payment). These current New Technology APC configurations allow us to price new technology services more appropriately and consistently.

For CY 2025, there were 52 New Technology APC levels, ranging from the lowest cost band assigned to APC 1491 (New Technology—Level 1A ($0– $10)) to the highest cost band

[14] Currently approved under OMB control number 0938-0860; expires October 31, 2027.

assigned to APC 1908 (New Technology—Level 52 ($145,001–$160,000)). We note that the cost bands for the New Technology APCs, specifically, APCs 1491 through 1599 and 1901 through 1908, vary with increments ranging from $10 to $14,999. These cost bands identify the APCs to which new technology procedures and services with estimated service costs that fall within those cost bands are assigned under the OPPS. Payment for each APC is made at the mid-point of the APC's assigned cost band. For example, payment for APC 1507 (New Technology—Level 7 ($501–$600)) is made at $550.50.

Under the OPPS, one of our goals is to make payments that are appropriate for the services that are necessary for the treatment of Medicare beneficiaries. The OPPS, like other Medicare payment systems, is budget neutral and increases are limited to the annual hospital market basket increase reduced by the productivity adjustment. We believe that our payment rates reflect the costs that are associated with providing care to Medicare beneficiaries and are adequate to ensure access to services (80 FR 70374). For many emerging technologies, there is a transitional period during which utilization may be low, often because providers are first learning about the technologies and their clinical utility. Quite often, parties request that Medicare make higher payments under the New Technology APCs for new procedures in that transitional phase. These requests, and their accompanying estimates for expected total patient utilization, often reflect very low rates of patient use of expensive equipment, resulting in high per-use costs for which requesters believe Medicare should make full payment. Medicare does not, and we believe should not, assume responsibility for more than its share of the costs of procedures based on projected utilization for Medicare beneficiaries and does not set its payment rates based on initial projections of low utilization for services that require expensive capital equipment. For the OPPS, we rely on hospitals to make informed business decisions regarding the acquisition of high-cost capital equipment, taking into consideration their knowledge about their entire patient base (Medicare beneficiaries included) and an understanding of Medicare's and other payers'

payment policies. We refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68314) for further discussion regarding this payment policy.

Some services assigned to New Technology APCs have low annual volume, which we consider to be fewer than 100 claims in the year of claims data used for ratesetting (86 FR 63528). Where utilization of services assigned to a New Technology APC is low, it can lead to wide variation in payment rates from year to year, resulting in even lower utilization and potential barriers to access of new technologies, which ultimately limits our ability to assign the service to the appropriate clinical APC. To mitigate these issues, we finalized a policy in the CY 2019 OPPS/ ASC final rule with comment period to utilize our equitable adjustment authority at section 1833(t)(2)(E) of the Act to adjust how we determine the costs for low-volume services assigned to New Technology APCs (83 FR 58892 through 58893). Specifically, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58893), we established that, in each of our annual rulemakings, we would calculate and present the result of each statistical methodology (arithmetic mean, geometric mean, and median) based on up to 4 years of claims data and solicit public comment on which methodology should be used to establish the payment rate for the low-volume new technology service. In the CY 2022 OPPS/ASC final rule (86 FR 63529), we replaced the New Technology APC low volume policy with the universal low volume APC policy. Unlike the New Technology APC low volume policy, the universal low volume APC policy applies to clinical APCs and brachytherapy APCs, in addition to procedures assigned to New Technology APCs, and uses the highest of the geometric mean, arithmetic mean, or median based on up to 4 years of claims data to set the payment rate for the APC. We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63529) for further discussion regarding this policy.

Despite the universal low volume APC policy, we continued to see payment instability for services with very low claims volume of fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. For CY 2025, we finalized a policy to exempt

services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period used for the universal low volume policy. Instead of assigning these services to a different New Technology APC based on the very few claims available, we maintained the New Technology APC assignment for each service from the prior year, CY 2024. We refer readers to the CY 2025 OPPS/ASC final rule with comment period for a discussion on the policy (89 FR 94016 through 94018).

Finally, we note that, in a budget-neutral system, payments may not fully cover hospitals' costs in a particular circumstance, including those for the purchase and maintenance of capital equipment. We rely on hospitals to make their decisions regarding the acquisition of high-cost equipment with the understanding that the Medicare program must be careful to establish its initial payment rates, including those made through New Technology APCs, for new services that lack hospital claims data based on realistic utilization projections for all such services delivered in cost-efficient hospital outpatient settings. As the OPPS acquires claims data regarding hospital costs associated with new procedures, we regularly examine the claims data and any available new information regarding the clinical aspects of new procedures to confirm that our OPPS payments remain appropriate for procedures as they transition into mainstream medical practice (77 FR 68314). For CY 2026, we included the proposed payment rates for New Technology APCs 1491 to 1599 and 1901 through 1908 in Addendum A to this proposed rule (which is available on the CMS website at *https:// www.cms.gov/Medicare/Medicare-Fee- for-Service-Payment/ HospitalOutpatientPPS/Hospital- Outpatient-Regulations-and-Notices*.

2. Proposal to Continue to Exempt Services with Under 10 Claims in the 4-year Lookback Period from APC Reassignment Based on the Universal Low Volume Policy

We continue to be concerned about payment stability for services assigned to New Technology APCs, specifically services with fewer than 10 claims in the 4-year lookback period used under the universal low volume APC policy. We also continue to believe that determining initial cost estimates for these services may be particularly challenging, given the lack of cost

information for new and innovative technologies, and that we generally utilize claims data from hospitals as soon as these data become available.

We propose to continue our policy moving forward to exempt services assigned to New Technology APCs with fewer than 10 claims over the 4-year lookback period from the universal low volume policy. Instead of assigning these services to a different clinical or New Technology APC based on the very few claims available, we propose to continue maintaining the New Technology APC assignment for each service from the prior year. For example, for CY 2026, services assigned to New Technology APCs with fewer than 10 claims in up to the previous four years will maintain their New Technology APC assignment from CY 2025. We propose to continue this policy in future years, until, or unless, an alternative policy is finalized. We maintain that it is appropriate to apply this policy to services assigned to New Technology APCs because these services represent new technologies for which it may be more challenging to determine an appropriate cost than for other, more established services. We continue to believe 10 claims is an appropriate ceiling for exempting services from reassignment based on the universal low volume APC policy because we believe that at 10 claims a rough standard distribution begins to appear. We also continue to believe that services with so few claims over the 4-year lookback period would be especially vulnerable to large changes in payment rates year-to-year as a result of one or two new claims being available or one or two claims from what was previously the fourth year of the lookback period no longer being included in that period.

Consistent with our overall policy regarding use of updated claims data in the final rule, we propose to perform a similar analysis for the final rule using updated claims data, including determining whether specific HCPCS codes continue to meet the criteria for our universal low volume APC policy or would be subject to our proposed policy to continue exempting services with fewer than 10 claims in the 4-year lookback period from the universal low volume APC policy and maintain the New Technology APC assignment from the previous year. We would update the APC placement as needed in the final rule.

3. Procedures Assigned to New Technology APC Groups for CY 2026

As we described in the CY 2002 OPPS final rule (66 FR 59902), we generally retain a procedure in the New Technology APC to which it is initially assigned until we have obtained sufficient claims data to justify reassignment of the procedure to a clinically appropriate APC. In addition, in cases where we find that our initial New Technology APC assignment was based on inaccurate or inadequate information (although it was the best information available at the time), where we obtain new information that was not available at the time of our initial New Technology APC assignment, or where the New Technology APCs are restructured, we may, based on more recent resource utilization information (including claims data) or the availability of refined New Technology APC cost bands, reassign the procedure or service to a different New Technology APC that more appropriately reflects its cost (66 FR 59903).

Consistent with our current policy, for CY 2026, we propose to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment of the service to an appropriate clinical APC. The flexibility associated with this policy allows us to reassign a service from a New Technology APC in less than 2 years if we have obtained sufficient claims data. It also allows us to retain a service in a New Technology APC for more than 2 years if we have not obtained sufficient claims data upon which to base a reassignment decision (66 FR 59902).

a. Administration of Subretinal Therapies Requiring Vitrectomy (APC 1563)

Effective January 1, 2021, CMS established HCPCS code C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) and assigned it to a New Technology APC based on the geometric mean cost of CPT code 67036 (Vitrectomy, mechanical, pars plana approach) due to similar resource utilization. For CY 2021, HCPCS code C9770 was assigned to APC 1561 (New Technology – Level 24 ($3001-$3500)). This code may be used to describe the administration of HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes). This procedure was previously discussed

in depth in the CY 2021 OPPS/ASC final rule with comment period (85 FR 85939 through 85940). For CY 2022, we maintained the APC assignment of APC 1561 (New Technology – Level 24 ($3001-$3500)) for HCPCS code C9770 (86 FR 63531 through 63532).

HCPCS code J3398 (Injection, voretigene neparvovec-rzyl, 1 billion vector genomes) is for a gene therapy product indicated for a rare mutation-associated retinal dystrophy. Voretigene neparvovec-rzyl (Luxturna®) was approved by FDA in December of 2017 and is an adeno-associated virus vector-based gene therapy indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy.[15] This therapy is administered through a subretinal injection, which interested parties describe as an extremely delicate and sensitive surgical procedure. The FDA-approved package insert describes one of the steps for administering Luxturna as, "after completing a vitrectomy, identify the intended site of administration. The subretinal injection can be introduced via pars plana."

Interested parties, including the manufacturer of Luxturna®, recommended CPT code 67036 (Vitrectomy, mechanical, pars plana approach) for the administration of the gene therapy.[16] However, the manufacturer previously contended the administration was not accurately described by any existing codes as CPT code 67036 (Vitrectomy, mechanical, pars plana approach) does not account for the administration itself. CMS recognized the need to accurately describe the unique procedure that is required to administer the therapy described by HCPCS code J3398. Therefore, in the CY 2021 OPPS/ASC final rule with comment period, we established a new HCPCS code, C9770 (Vitrectomy, mechanical, pars plana approach, with subretinal injection of pharmacologic/biologic agent) to describe this process. For CY 2021, we assigned HCPCS code C9770 to APC 1561 (New Technology –Level 24 ($3001-$3500)) using the geometric mean cost of CPT code 67036. For CY 2022, we continued to assign HCPCS

[15] Luxturna. FDA Package Insert. Available: https://www.fda.gov/media/109906/download.
[16] LUXTURNA REIMBURSEMENT GUIDE FOR TREATMENT CENTERS. *https://mysparkgeneration.com/uploads/2022/09/LUXTURNA-Reimbursement-Guide-for-Treatment-Centers-ISI-Update-April-2022-P-RPE65-US-320025.pdf*.

code C9770 to APC 1561 (New Technology – Level 24 ($3001-$3500)) using the geometric mean cost of CPT code 67036.

CY 2023 was the first year that claims data were available for HCPCS code C9770; therefore, we proposed and finalized a policy to base the payment rate of HCPCS code C9770 on claims data for that code rather than on the geometric mean cost of CPT code 67036. Given the low number of claims for this procedure, we designated HCPCS code C9770 as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data to calculate an appropriate payment rate for purposes of assigning HCPCS code C9770 to a New Technology APC.

Based on the claims data available for the CY 2023 OPPS/ASC final rule with comment period, we found the median was the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology fell within the cost band for APC 1562 (New Technology—Level 25 ($3501–$4000)). Therefore, we finalized our proposal to assign HCPCS code C9770 to APC 1562 for CY 2023.

For CY 2024, we proposed and finalized that we would delete HCPCS code C9770 effective December 31, 2023 and recognize CPT code 0810T (Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies) starting January 1, 2024 (88 FR 81617 through 81619). We determined the payment rate for CPT code 0810T using the claims data for HCPCS code C9770 and designated CPT code 0810T as a low volume procedure under our universal low volume APC policy and used the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data for HCPCS code C9770 to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC. For CY 2024, we finalized assignment of CPT code 0810T to APC 1563 (New Technology - Level 26 ($4001-$4500)) (88 FR 81617 through 81619). For 2025, claims data for CPT code 0810T was not yet available. Therefore, we continued to use claims data for

HCPCS code C9770 to determine the appropriate APC for CPT code 0810T and finalized to continue to assign CPT code 0810T to APC 1563 for CY 2025.

CY 2026 is the first year that we have claims data available for CPT code 0810T, and there are 6 claims available. Since the procedure described by CPT code 0810T was billed using HCPCS code C9770 prior to January 1, 2024, we propose to use the available combined 42 claims for both codes during this time period to allow for a more accurate picture of the costs associated with this procedure. For CY 2026, we propose to designate CPT code 0810T as a low volume procedure under our universal low volume APC policy, given that there are only 42 combined claims available. This is below the threshold of 100 claims for a service within a year required to designate a service as a low volume service and apply our universal low volume APC policy. Therefore, we propose to use the greater of the geometric mean, arithmetic mean, or median cost calculated based on the available claims data from a 4-year lookback period to calculate an appropriate payment rate for purposes of assigning CPT code 0810T to a New Technology APC.

Using all available claims for CPT code 0810T and HCPCS code C9770 from the 4-year lookback period, based on 42 claims, we determined the geometric mean cost to be approximately $4,040, the arithmetic mean cost to be $4,327, and the median cost to be $3,999. Because the arithmetic mean is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean of $4,327 falls within the cost band for APC 1563 (New Technology - Level 26 ($4001-$4500)). Therefore, we propose to continue to assign CPT code 0810T to APC 1563 for CY 2026. Additionally, we propose to perform a similar analysis using updated claims data, including determining if CPT code 0810T continues to meet the criteria for our universal low volume APC policy, in the CY 2026 OPPS/ASC final rule with comment period and update the APC assignment as needed.

Please refer to Table 13 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0810T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 13: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR CPT CODE 0810T

HCPCS Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0810T	Subretinal injection of a pharmacologic agent, including vitrectomy and 1 or more retinotomies	T	1563

b. BgRT (APC 1514 and 1525)

Biology Guided Radiation Therapy (BgRT) uses positron-emitting radiopharmaceuticals to control delivery of radiation therapy to treat primary and metastatic lung or bone tumors. During radiation treatment delivery, the same system applies these firing filters to the real-time positron emission tomography (PET) data collected by the radiation treatment delivery machine. Effective January 1, 2024, CMS created HCPCS codes C9794 (Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling) and C9795 (Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions) to describe the modeling and treatment delivery portions of the BgRT service. We assigned HCPCS code C9794 to APC 1521 (New Technology - Level 21 ($1901-$2000)) and HCPCS code C9795 to APC 1525 (New Technology - Level 25 ($3501-$4000)) for CY 2024.

For CY 2025, we continued to assign HCPCS code C9794 to APC 1521 (New Technology - Level 21 ($1901-$2000)) with a payment rate of $1,950.50 and HCPCS code C9795 to APC 1525 (New Technology - Level 25 ($3501-$4000)) with a payment rate of $3,750.50 because we did not have any claims data for the service.

Effective January 1, 2025, HCPCS codes C9794 and C9795 were replaced by HCPCS codes G0562 and G0563, respectively. For CY 2026, the proposed OPPS payment rates are based on available CY 2024 claims data. There are no CY 2024 claims for HCPCS codes G0562 and G0563 since they were not effective until CY 2025. However, as HCPCS codes C9794 and C9795 were still in use until December 31, 2024, we propose to determine the payment rate for HCPCS codes G0562 and G0563 using the available claims data for HCPCS codes C9794 and C9795, respectively. For CY 2026, we propose to designate HCPCS codes G0562 and G0563 as low volume procedures under our universal low volume APC policy, given that there are only 16 claims for C9794 and 28 claims for C9795 during the claims period. For HCPCS code G0562, using all available claims for C9794, we determined the arithmetic mean cost to be $1,241, the median cost to be $1,203, and the geometric mean cost to be $1,121. Because the arithmetic mean cost is the statistical methodology that estimated the highest cost for the service, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean cost of $1,241 falls within the cost band for APC 1514 (New Technology—Level 14 ($1201-$1300)). Therefore, we propose to assign HCPCS code G0562 to APC 1514 (New Technology - Level 14 ($1201-$1300) with a payment rate of $1,250.50 for CY 2026. For HCPCS code G0563, using all available claims for C9795, we determined the arithmetic mean cost to be $3,606; the median cost to be $2,915, and the geometric mean cost to be $3,348. The arithmetic mean cost is the statistical methodology that estimated the highest cost for the service; therefore, we propose to use this cost to determine the New Technology APC placement. The arithmetic mean cost of $3,606 falls within the cost band for APC 1525 (New Technology—Level 25 ($3501-$4000)). Therefore, we propose to assign HCPCS code G0563 to APC 1525 (New Technology—Level 25 ($3501-$4000) with a payment rate of $3750.50 for CY 2026.

Additionally, we propose to perform a similar analysis using updated claims data, including determining if HCPCS codes G0562 and G0563 continue to meet the criteria for our

universal low volume APC policy, in the CY 2026 OPPS/ASC final rule with comment period and update the APC assignments as needed.

Please refer to Table 14 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS codes G0562 and G0563 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 14: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR BIOLOGY GUIDED RADIATION THERAPY

HCPCS	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
G0562	Therapeutic radiology simulation-aided field setting; complex, including acquisition of PET and CT imaging data required for radiopharmaceutical-directed radiation therapy treatment planning (i.e., modeling)	S	1514
G0563	Stereotactic body radiation therapy, treatment delivery, per fraction to 1 or more lesions, including image guidance and real-time positron emissions-based delivery adjustments to 1 or more lesions, entire course not to exceed 5 fractions	S	1525

c. Blinded procedure for NYHA class III/IV heart failure

A randomized, double-blinded, controlled IDE study was conducted for the V-Wave interatrial shunt. The V-Wave interatrial shunt is for patients with severe symptomatic heart failure and is designed to regulate left atrial pressure in the heart. All participants who passed initial screening for the study receive a right heart catheterization procedure described by CPT code 93451 (Right heart catheterization including measurement(s) of oxygen saturation and cardiac output, when performed). Participants assigned to the experimental group also receive the V-Wave interatrial shunt procedure while participants assigned to the control group only receive right heart catheterization. The developer of V-Wave was concerned that the current coding of these services by Medicare would reveal to the study participants whether they had received the interatrial shunt because an additional procedure code, CPT code 93799 (Unlisted cardiovascular service or procedure), would be included on the claims for participants receiving the interatrial shunt. Therefore, for CY 2020, we created a temporary HCPCS code to describe

the V-Wave interatrial shunt procedure for both the experimental group and the control group in the study. Specifically, we established HCPCS code C9758 (Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study) to describe the service, and we assigned the service to APC 1589 (New Technology—Level 38 ($10,001–$15,000)) with a payment rate of $12,500.50.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 85946), we stated that we believe similar resources and device costs are involved with the V-Wave interatrial shunt procedure and the Corvia Medical interatrial shunt procedure (HCPCS code C9760), except that payment for HCPCS codes C9758 and C9760 differs based on how often the interatrial shunt is implanted when each code is billed. An interatrial shunt is implanted one-half of the time HCPCS code C9758 is billed, whereas an interatrial shunt is implanted every time HCPCS code C9760 is billed. Accordingly, for CY 2021, we reassigned HCPCS code C9758 to APC 1590 (New Technology—Level 39 ($15,001–$20,000)), which reflects the cost of furnishing the interatrial shunt one-half of the time the procedure is performed. Since CY 2021, HCPCS code C9758 has continued to be assigned to APC 1590.

For CY 2026, the developer of the V-Wave interatrial shunt informed us that the IDE study had concluded and HCPCS code C9758 was no longer being utilized. Therefore, we propose to delete HCPCS code C9758 for CY 2026.

Please refer to Table 15 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9758 for CY 2026.

TABLE 15: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AAND STATUS INDICATOR ASSIGNMENTS FOR BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC

C9758	Blinded procedure for NYHA class III/IV heart failure; transcatheter implantation of interatrial shunt or placebo control, including right heart catheterization, trans-esophageal echocardiography (TEE)/intracardiac echocardiography (ICE), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (IDE) study	D	N/A

d. Bronchoscopy with Transbronchial Ablation of Lesion(s) by Microwave Energy

Effective January 1, 2019, CMS established HCPCS code C9751 (Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)). This microwave ablation procedure utilizes a flexible catheter to access the lung tumor via a working channel and may be used as an alternative procedure to a percutaneous microwave approach. Based on our review of the New Technology APC application for this service and the service's clinical similarity to existing services paid under the OPPS, we estimated the likely cost of the procedure would be between $8,001 and $8,500. We assigned the procedure to APC 1571 (New Technology - Level 34 ($8001-$8500)) for CY 2019.

In claims data available from CY 2019 for the CY 2021 OPPS/ASC final rule with comment period, there were four claims reported for bronchoscopy with transbronchial ablation of lesions by microwave energy. Given the low volume of claims for the service, we proposed for CY 2021 to apply the universal low volume APC policy we adopted in CY 2019, under which we utilize our equitable adjustment authority under section 1833(t)(2)(E) of the Act to calculate the geometric mean, arithmetic mean, and median costs to determine an appropriate payment rate for purposes of assigning bronchoscopy with transbronchial ablation of lesions by microwave energy to a New Technology APC. Based on this analysis using claims from

CY 2019, we assigned HCPCS code C9751 to APC 1562 (New Technology – Level 25 ($3501-$4000)) with a $3750.50 payment rate for CY 2021.

There have been no separately payable claims reported for HCPCS code C9751 since 2019. Therefore, we have continued to use claims from CY 2019 to determine the payment rate for this service in CY 2023, CY 2024, and CY 2025 OPPS/ASC final rules with comment period. Based on the information available, we continue to assign HCPCS code C9751 to APC 1562 (New Technology—Level 25 ($3501–$4000)), with a payment rate of $3,750.50.

For CY 2026, we were informed that the Neuwave Flex program is no longer available for commercial use, and that HCPCS code C9751 is no longer being utilized. Therefore, we propose to delete HCPCS code C9751 for CY 2026.

Please refer to Table 16 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9751 for CY 2026.

TABLE 16: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODE C9751

HCPCS	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9751	Bronchoscopy, rigid or flexible, transbronchial ablation of lesion(s) by microwave energy, including fluoroscopic guidance, when performed, with computed tomography acquisition(s) and 3-D rendering, computer-assisted, image-guided navigation, and endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (e.g., aspiration[s]/biopsy[ies]) and all mediastinal and/or hilar lymph node stations or structures and therapeutic intervention(s)	D	N/A

e. Cardiac Positron Emission Tomography (PET)/Computed Tomography (CT) Studies (APCs 1519 and 1522)

For CY 2026, the OPPS payment rates for the service described by CPT codes 78431, 78432, and 78433 are proposed to be based on available CY 2024 claims data. CPT code 78431 had over 30,000 single frequency claims in CY 2024. The geometric mean cost for CPT code 78431 is approximately $2,200. The geometric mean falls within APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50, which is the current

APC assignment for this service. Therefore, we propose, for CY 2026, to continue to assign CPT code 78431 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50.

There were only 31 single frequency claims in CY 2024 for CPT code 78432. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 78432 to the appropriate New Technology APC. Using available claims data from CY 2021, CY 2022, and CY 2023, our analysis found the geometric mean cost of the service is approximately $1,591, the arithmetic mean cost of the service is approximately $1,737, and the median cost of the service is approximately $1,364. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. The arithmetic mean cost of $1,737, is an amount that is below the cost band for APC 1520 (New Technology—Level 20 ($1801–$1900)), where the procedure is currently assigned. Therefore, we propose, for CY 2026, to assign CPT code 78432 to APC 1519 (New Technology—Level 19 ($1701–$1800)) with a payment rate of $1,750.50.

There were over 1,400 single frequency claims for CPT code 78433 in CY 2024. The geometric mean for CPT code 78433 is approximately $2,037, which is an amount that is above the current New Technology APC cost band APC 1521 (New Technology - Level 21 ($1901-$2000)) to which it is assigned. Therefore, for CY 2026, we propose to reassign CPT code 78433 to APC 1522 (New Technology—Level 22 ($2001–$2500)) with a payment rate of $2,250.50.

We note that, over the past several years, the claims volumes for CPT codes 78431 and 78433 have increased significantly while the geometric mean costs of the codes have remained relatively stable. However, CPT code 78432, which is closely related to CPT codes 78431 and 78433, continues to have low claims frequency and fluctuating geometric mean costs. Due to our

concerns regarding CPT code 78432 and the lack of an appropriate clinical APC for CPT codes 78431 and 78433 at this time based on resource cost similarity, we propose to continue to assign CPT codes 78431 through 78433 to New Technology APCs for CY 2026.

Please refer to Table 17 for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 78431, 78432, and 78433 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to the CY 2026 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 17: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 78431, 78432, AND 78433

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
78431	Myocardial imaging, positron emission tomography (PET), perfusion study (including ventricular wall motion[s] and/or ejection fraction[s], when performed); multiple studies at rest and stress (exercise or pharmacologic), with concurrently acquired computed tomography transmission scan	S	1522
78432	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability);	S	1519
78433	Myocardial imaging, positron emission tomography (PET), combined perfusion with metabolic evaluation study (including ventricular wall motion[s] and/or ejection fraction[s], when performed), dual radiotracer (e.g., myocardial viability); with concurrently acquired computed tomography transmission scan	S	1522

f. CardiAMP (APC 1590)

The CardiAMP cell therapy IDE studies are two randomized, double-blinded, controlled IDE studies: the CardiAMP Cell Therapy Chronic Myocardial Ischemia Trial[17] and the

[17] ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Cells Using the CardiAMP Cell Therapy System in Patients With Refractory Angina Pectoris and Chronic Myocardial Ischemia." Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT03455725?term=NCT03455725&rank=1*.

CardiAMP Cell Therapy Heart Failure Trial.[18] The two trials are designed to investigate the safety and efficacy of autologous bone marrow mononuclear cell treatment for the following: (1) patients with medically refractory and symptomatic ischemic cardiomyopathy; and (2) patients with refractory angina pectoris and chronic myocardial ischemia. On April 1, 2022, we established HCPCS code C9782 to describe the CardiAMP cell therapy IDE studies and assigned HCPCS code C9782 to APC 1574 (New Technology - Level 37 ($9,501-$10,000)) with the status indicator "T." We subsequently revised the descriptor for HCPCS code C9782 to: (Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study) to clarify the inclusion of the Helix trans endocardial injection catheter device in the descriptor. Additionally, we determined that APC 1590 (New Technology - Level 39 ($15,001-$20,000)) most accurately accounted for the resources associated with furnishing the procedure described by HCPCS code C9782.

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. We identified three single frequency paid claims for C9782 for ratesetting for CY 2025. Because we finalized our proposal to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period, we continued to assign HCPCS code C9782 to APC 1590 with a payment rate of $17,500.50 for CY 2025.

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[18] ClinicalTrials.gov. "Randomized Controlled Pivotal Trial of Autologous Bone Marrow Mononuclear Cells Using the CardiAMP Cell Therapy System in Patients With Post Myocardial Infarction Heart Failure." Accessed May 10, 2022. *https://clinicaltrials.gov/ct2/show/NCT02438306*.

For CY 2026, there were no new claims reported for HCPCS code C9782. Therefore, there are still only three single frequency claims available for HCPCS code C9782 in the 4-year lookback period. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy moving forward, we propose to continue to assign HCPCS code C9782 to APC 1590 (New Technology - Level 39 ($15,001-$20,000)) with a payment rate of $17,500.50.

Please refer to Table 18 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code C9782 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 18: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE CARDIAMP CELL THERAPY IDE STUDIES

HCPCS Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9782	Blinded procedure for New York Heart Association (NYHA) Class II or III heart failure, or Canadian Cardiovascular Society (CCS) Class III or IV chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), all device(s), performed in an approved Investigational Device Exemption (IDE) study	T	1590

g. Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) (APC 1511)

Atherosclerosis Imaging-Quantitative Computer Tomography (AI-QCT) is a Software as a Service (SaaS) that assesses the extent of coronary artery disease severity. This procedure is performed to quantify the extent of coronary plaque and stenosis in patients who have undergone coronary computed tomography analysis (CCTA). The AMA CPT Editorial Panel established the following four codes associated with this service, effective January 1, 2021:

0623T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic

angiography; data preparation and transmission, computerized analysis of data, with review of computerized analysis output to reconcile discordant data, interpretation and report.

0624T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; data preparation and transmission.

0625T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography.

0626T: Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; review of computerized analysis output to reconcile discordant data, interpretation and report.

Of these four CPT codes, only CPT code 0625T was determined to be separately payable in the OPPS and was assigned to status indicator = "S" (Procedure or Service, Not Discounted When Multiple) starting October 1, 2022. We assigned CPT code 0625T to a separately payable status indicator based on the technology and its potential utilization in the HOPD setting, our evaluation of the service, as well as input from our medical advisors. The procedure was assigned to APC 1511 (New Technology - Level 11 ($900 - $1000)) with a payment rate of $950.50.

For CY 2024, the OPPS payment rates were based on available CY 2022 claims data. There were 37 claims for CPT code 0625T during this time period. As this was below the threshold of 100 claims for a service within a year, we explained that we could propose to designate CPT code 0625T as a low volume service under our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign code 0625T to the appropriate New Technology APC. We found the geometric mean cost for the service to be approximately $3.70,

the arithmetic mean cost to be approximately $4.10, and the median cost to be approximately $3.50. Under our universal low volume New Technology APC policy, we would use the greatest of the statistical methodologies, the arithmetic mean, to assign CPT code 0625T to New Technology 1491 (New Technology Level 1A – (0-$10)) with a payment rate of $5.00. However, we acknowledged that, because CPT code 0625T was only made separately payable as part of the OPPS in October 2022, and, therefore, the CY 2022 claims available only reflected two months of data, we were concerned that we did not have sufficient claims data to justify reassignment to another New Technology APC (66 FR 69902). Therefore, consistent with our current policy to retain services within New Technology APC groups until we obtain sufficient claims data to justify reassignment (66 FR 59902), for CY 2024, we finalized our proposal to maintain CPT code 0625T's assignment to APC 1511 (New Technology - Level 11 ($901 - $1000) with a payment rate of $950.50 rather than applying the universal low volume APC policy. For 2025, there were only 3 available claims for 0625T. We continued to have concerns that we did not have sufficient claims data to justify reassignment to another New Technology APC based on the CY 2023 geometric mean cost of $180. Therefore, we used our authority under section 1833(t)(2)(E) for CY 2025 to continue to assign CPT code 0625T to APC 1511 (New Technology - Level 11 ($901 - $1000) with a payment rate of $950.50.

Effective January 1, 2026, the AMA CPT Editorial Panel is creating a new Category I CPT code for AI-QCT, which is currently described by CPT placeholder code 75XX6 (Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified healthcare professional). CPT codes 0623T-0626T are being deleted and replaced with CPT placeholder code 75XX6. Since CPT placeholder code 75XX6 will not be effective until January 1, 2026, we will not have claims data available for ratesetting for this code until the CY 2028 rulemaking cycle. However, as CPT code 0625T will still be in use until December 31,

2025, we propose to determine the payment rate for CPT placeholder code 75XX6 using the available CY 2024 claims data for CPT code 0625T.

For CY 2026 ratesetting, there were 22 separately payable claims in the CY 2024 data reported for CPT code 0625T with a geometric mean cost of approximately $496. Given that there were fewer than 100 claims, CPT code 0625T would fall under our universal low volume New Technology APC policy where we would use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 0625T to the appropriate New Technology APC. Using a 4-year lookback of claims data, we determined the geometric mean cost to be $13.21, the arithmetic mean cost to be $243, and the median cost to be $3.51. However, this lookback includes the claims from CY 2021 and CY 2022 that indicate that the cost of the procedure is less than $5, which would not appear to cover the basic costs of this procedure including computing time, generating a report, and having medical personnel interpret the report. The claims were also significantly lower than the expected cost of this procedure based on evidence submitted by the manufacturer when this technology was initially evaluated for placement in a New Technology APC. For CY 2024, the geometric mean cost of around $496 based on 22 claims may better reflect the cost of the procedure described by CPT code 0625T, but there are not enough claims to be confident about the result. Due to these issues, we are not confident that the results of the 4-year lookback period accurately reflect the actual costs of CPT code 0625T. Additionally, we recognize that software-based technologies are unique and rapidly evolving and that a significant fluctuation in payment may hinder patient access to these new services. We are issuing a comment solicitation in section III.F. of this proposed rule to collect information on alternative and consistent payment methods that seek to reflect the underlying value of SaaS services under the OPPS to consider in future rulemaking. We hope to identify whether specific adjustments to our payment policies for SaaS services are needed to more accurately and appropriately pay for these products and services across settings of care. Therefore, we propose to use our authority under section 1833(t)(2)(E) to

assign CPT placeholder code 75XX6 to APC 1511 (New Technology - Level 11 ($901 - $1000) with a payment rate of $950.50 for CY 2026, which based on the information currently available to us, best reflects the cost of the service as described by the New Technology APC application.

Please refer to Table 19 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0625T and CPT placeholder code 75XX6 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to the CY 2026 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 19: PROPOSED CY 2026 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR ATHEROSCLEROSIS IMAGING-QUANTITATIVE COMPUTER TOMOGRAPHY (AI-QCT) HCPCS CODE 0625T

HCPCS Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0625T	Automated quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, using data from coronary computed tomographic angiography; computerized analysis of data from coronary computed tomographic angiography	D	N/A
75XX6	Quantification and characterization of coronary atherosclerotic plaque to assess severity of coronary disease, derived from augmentative software analysis of the data set from a coronary computed tomographic angiography, with interpretation and report by a physician or other qualified healthcare professional	S	1511

h. Corvia Medical Interatrial Shunt Procedure (APC 1592)

On July 1, 2020, we established HCPCS code C9760 (Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study) to facilitate payment for the implantation of the Corvia Medical interatrial shunt.

As we stated in the CY 2021 OPPS final rule with comment period (85 FR 85947), we believe that similar resources and device costs are involved with the Corvia Medical interatrial shunt procedure and the V-Wave interatrial shunt procedure. Unlike the V-Wave interatrial shunt, which is implanted half the time the associated interatrial shunt procedure described by HCPCS code C9758 is billed, the Corvia Medical interatrial shunt is implanted every time the associated interatrial shunt procedure (HCPCS code C9760) is billed. Therefore, for CY 2021, we assigned HCPCS code C9760 to APC 1592 (New Technology—Level 41 ($25,001–$30,000)) with a payment rate of $27,500.50. We also modified the code descriptor for HCPCS code C9760 to remove the phrase ‘‘or placebo control,’’ from the descriptor.

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. There were two claims for HCPCS code C9760 in CY 2023. We continued to assign HCPCS code C9760 to APC 1592 (New Technology—Level 41 ($25,001– $30,000)) based on our CY 2025 policy to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. There were no claims for HCPSC code C9760 in CY 2024. Therefore, for CY 2026, given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy moving forward, we propose to continue to assign HCPCS code C9760 to APC 1592 (New Technology—Level 41 ($25,001– $30,000)) with a payment rate of $27,500.50.

Please refer to Table 20 for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9760. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 20: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR NON-BLINDED INTRATRIAL SHUNT PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9760	(Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt or placebo control, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (for example, ultrasound, fluoroscopy)	T	1592

i. DARI Motion Procedure (APC 1505)

Effective January 1, 2022, CPT code 0693T (Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report) is associated with the DARI Motion Procedure, a service that provides human motion analysis to aid clinicians in pre- and post-operative surgical intervention and in making other treatment decisions, including selecting the best course of physical therapy and rehabilitation. The technology consists of eight cameras that surround a patient, which send live video to a computer workstation that analyzes the video to create a 3D reconstruction of the patient without the need for special clothing, markers, or devices attached to the patient's clothing or skin.

Since CPT code 0693T became effective January 1, 2022, we have had no claims for the DARI Motion Procedure and, therefore, have maintained its initial APC assignment to APC 1505 (New Technology—Level 5 ($301-$400)) with a payment of $350.50.

For CY 2026, the OPPS payment rates are proposed based on available CY 2024 claims data. Because we do not have any available claims data, we propose to continue to assign CPT code 0693T to APC 1505 (New Technology—Level 5 ($301-400)), with a payment rate of $350.50, for CY 2026.

Please refer to Table 21 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0693T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 21: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE DARI MOTION PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0693T	Comprehensive full body computer-based markerless 3D kinematic and kinetic motion analysis and report	S	1505

j. Instillation of Anti-Neoplastic Pharmacologic/Biologic Agent into Renal Pelvis (APC 1553)

Effective October 1, 2023, CMS established HCPCS code C9789 (Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed) and assigned it to APC 1559 (New Technology - Level 22 ($2001-$2500)), with a payment rate of $2,250.50 based on our review of the clinical and resource characteristics of this service.

This code may be used to describe the unique procedure associated with the administration of the drug described by HCPCS code J9281 (Mitomycin pyelocalyceal instillation, 1 mg) or similar products. HCPCS code J9281 may be used to describe the product, Jelmyto (mitomycin for pyelocalyceal solution). The FDA approved Jelmyto in 2020, and the FDA approved indication and usage for Jelmyto is as an alkylating drug indicated for the treatment of adult patients with low-grade Upper Tract Urothelial Cancer (LG-UTUS).19

For CY 2025, the OPPS payment rates were based on available CY 2023 claims data. Because we created HCPCS code C9789 effective October 1, 2023, we had limited claims data from CY 2023 available for CY 2025 rulemaking. Specifically, we only had 6 claims available for ratesetting, so we maintained the New Technology APC assignment of APC 1559 (New Technology – Level 22 ($2001-$2500)) with a payment of $2,250.50 for CY 2025, based on our CY 2025 policy to maintain the New Technology APC assignment for New Technology APC

[19] Jelymyto Package Insert, Revised: 01/2021. https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211728s002lbl.pdf

services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy.

For CY 2026, the OPPS payment rates are proposed based on available CY 2024 claims data. HCPCS code C9789 had 109 single frequency claims in CY 2024, which exceeds the 100 claims threshold generally used for the universal low volume APC policy. The geometric mean cost for HCPCS code C9789 is approximately$1,401. Therefore, for CY 2026, we propose to assign HCPCS code C9789 to APC 1553 (New Technology—Level 16 ($1401 - $1500)) with a payment rate of $1,450.50.

Please refer to Table 22 for the proposed OPPS New Technology APC and status indicator assignments for CPT code C9789 for CY 2026. The proposed CY 2026 payment rate for this HCPCS code can be found in Addendum B to the CY 2026 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 22: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR HCPCS CODE C9789

HCPCS Code	Long Descriptor	Proposed CY 2025 OPPS SI	Proposed CY 2025 OPPS APC
C9789	Instillation of anti-neoplastic pharmacologic/biologic agent into renal pelvis, any method, including all imaging guidance, including volumetric measurement if performed	T	1553

k. LimFlow TADV procedure CPT Code 0620T (APC 1579)

The LimFlow TADV procedure which is described by CPT code 0620T (Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed) is an endovascular procedure that is used to treat patients with chronic limb-threatening ischemia. According to the developer, these

patients are no longer eligible for conventional endovascular or open bypass surgery to treat their artery blockage, and without this procedure, they are likely to face limb amputation.

CPT code 0620T was established in January 2021 and was assigned to APC 5194 (Level 4 Endovascular Procedures) with a payment rate of approximately $17,400, which is the highest-paying APC for endovascular procedures. While we proposed to continue to assign CPT code 0620T to APC 5194 for CY 2024, we finalized a reassignment from a clinical APC to a New Technology APC with a higher payment rate based on comments received expressing concern that the low payment rate of the procedure would discourage providers from performing the procedure and deny access to the procedure. For CY 2024, the procedure was assigned to APC 1578 (New Technology - Level 41 ($25,001-$30,000)). For CY 2025 ratesetting, there were 11 single frequency claims for CPT code 0620T in the CY 2023 claims data. As this is below the threshold of 100 claims for a service within a year, we applied our universal low volume APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims and the application of the universal low volume APC policy, we assigned HCPCS code 0620T to APC 1579 (New Technology – Level 42 ($30,001-$40,000)) with a payment rate of $35,000.50 based on the median cost of approximately $36,400.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. There were 19 single frequency claims for 0620T in the CY 2024 claims data. As this is below the threshold of 100 claims for a service within a year, we propose to again apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on our review of the available claims, we have determined that the arithmetic mean is approximately $39,000; the median is approximately $38,000; and the geometric mean cost is approximately $35,000. Of these, the arithmetic mean is

the statistical methodology that estimated the highest cost for the service. The payment rate calculated using this methodology falls within the cost band for APC 1579 (New Technology—Level 42 ($30,001-$40,000)) with a payment rate of $35,000.50. Therefore, for CY 2026, we propose to designate this service as a low volume service under our universal low volume APC policy and to continue to assign HCPCS code 0620T to APC 1579 (New Technology—Level 42 ($30,001-$40,000)) with a payment rate of $35,000.50.

Please refer to Table 23 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0620T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 23: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIMFLOW TADV PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0620T	Endovascular venous arterialization, tibial or peroneal vein, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed	S	1579

l. Liver Histotripsy Service (APC 1579)

CPT code 0686T (Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance) was first effective July 1, 2021, and describes the histotripsy service associated with the use of the HistoSonics system. Histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy cancerous liver tumors and is currently in a non-randomized, prospective clinical trial to evaluate the efficacy and safety of the device for the treatment of primary or metastatic tumors

located in the liver.[20] When HCPCS code 0686T was first effective, the histotripsy procedure was designated as a Category A IDE clinical study (NCT04573881). Since devices in Category A IDE studies are excluded from Medicare payment, payment for CPT code 0686T only reflected the cost of the service that is performed (absent the cost of the device) each time it is reported on a claim. On March 2, 2023, the histotripsy IDE clinical study was re-designated as a Category B (Non-experimental/Investigational) IDE study. Due to this new designation, payment for CPT code 0686T in CY 2024 reflected payment for both the service that was performed and the device used each time it was reported on a claim. For CY 2024, we assigned CPT code 0686T to APC 1576 (New Technology – Level 39 ($15,001 - $20,000)) with a payment rate of $17,500.50. For CY 2025, we continued to assign CPT code 0686T to APC 1576 (New Technology – Level 39 ($15,001-$20,000) due to our CY 2025 policy to maintain current New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low volume APC policy, and based on the fact that there were only 3 claims for CPT code 0686T in the prior 4-year period.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. We have identified 94 claims for CPT code 0686T within this period. As this is below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT code 0686T to the appropriate New Technology APC. We identified $32,307.41 as the arithmetic mean, $20,577.77 as the median, and $21,264.91 as the geometric mean. The arithmetic mean was the statistical methodology that estimated the highest cost for CPT code 0686T. For CY 2026, we propose to

[20] ClinicalTrials.gov. "The HistoSonics System for Treatment of Primary and Metastatic Liver Tumors Using Histotripsy (#HOPE4LIVER) (#HOPE4LIVER)." Accessed May 10, 2022. https://clinicaltrials.gov/ct2/show/study/NCT04573881.

reassign CPT code 0686T to APC 1579 (New Technology - Level 42 ($30,001-$40,000)) with a payment rate of 35,000.50.

7For final rulemaking, when additional claims data are available, we update the values of the statistical methodologies with any additional CY 2024 claims that may have been processed between the time that the proposed rule is released, and the final rule is drafted. Therefore, if additional CY 2024 claims are processed after the proposed rule is released, the values of the statistical methodologies may change, impacting the final payment rate. We also note that if the total available CY 2024 single frequency claims for CPT 0686T surpass the 99-claim threshold for the universal low volume APC policy, we would anticipate using the geometric mean cost to set the payment rate for CPT 0686T for CY 2026 under our standard ratesetting methodology rather than the highest of the three statistical methodologies under the universal low volume APC policy.

Please refer to Table 24 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 0686T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 24: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0686T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant hepatocellular tissue, including image guidance	S	1579

m. LiverMultiScan Service (APC 1511)

CPT codes 0648T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; single organ) and

0649T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure); single organ (list separately in addition to code for primary procedure)) became effective July 1, 2021 and are associated with the LiverMultiScan service.

LiverMultiScan is a Software as a medical Service (SaaS) that is intended to aid the diagnosis and management of chronic liver disease, the most prevalent of which is Non-Alcoholic Fatty Liver Disease (NAFLD). It provides standardized, quantitative imaging biomarkers for the characterization and assessment of inflammation, hepatocyte ballooning, and fibrosis, as well as steatosis, and iron accumulation. LiverMultiScan receives MR images acquired from patients' providers and analyzes the images using their proprietary Artificial Intelligence (AI) algorithms. It then sends the providers a quantitative metric report of the patient's liver fibrosis and inflammation. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0649T, the add-on code for LiverMultiScan, is assigned to the identical APC and status indicator as CPT code 0648T, the standalone code for the same service.

For CY 2024 and CY 2025, we used our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0648T and 0649T to APC 1511 (New Technology – Level 11 ($901 - $1,000) with a payment rate of $950.50.

For CY 2026, the OPPS payment rates are proposed based on available CY 2024 claims data. We identified 107 single frequency claims for CPT code 0648T and 104 single frequency claims CPT code 0649T for CY 2024. The geometric mean cost for CPT code 0648T is $253.68 and the geometric mean cost for CPT code 0649T is $162.96. Based on the geometric mean cost for CPT code 0648T, we would assign CPT codes 0648T and 0649T to APC 1504 (New Technology – Level 4 ($201-$300)) with a payment rate of $250.50. However, assigning these

SaaS services based on the geometric costs would significantly impact the payment by decreasing the payment rate by around 75 percent. We recognize that software-based technologies, like those described by CPT codes 0648T and 0649T, continue to evolve and that the limited claims data that we have may not truly represent the cost of this service. We are issuing a comment solicitation in section III.F. of this proposed rule to collect information on alternative and consistent payment methods that seek to reflect the underlying value of SaaS services under the OPPS to consider in future rulemaking. We hope to identify whether specific adjustments to our payment policies for SaaS services are needed to more accurately and appropriately pay for these products and services across settings of care.

Therefore, we propose to use our authority under section 1833(t)(2)(E) for CY 2026 to continue to assign CPT codes 0648T and 0649T to APC 1511 (New Technology—Level 11 ($901-$1000)) with a payment rate of $950.50 which we believe best reflects the cost of the service at this time, based on information provided by the applicant.

The proposed New Technology APC and status indicator assignments for CPT codes 0648T and 0649T are shown in Table 25. The proposed CY 2026 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 25: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE LIVER MULTISCAN SERVICE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0648T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session; single organ	S	1511
0649T	Quantitative magnetic resonance for analysis of tissue composition (e.g., fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic MRI examination of the same anatomy (e.g., organ, gland, tissue, target structure) (List separately in addition to code for primary procedure)	S	1511

n. Optellum Lung Cancer Prediction (LCP) (APC 1508)

CPT codes 0721T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging) and 0722T (Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)) became effective July 1, 2022, and are associated with the Optellum LCP technology. The Optellum LCP applies an algorithm to a patient's CT scan to produce a raw risk score for a patient's pulmonary nodule. The physician uses the risk score to quantify the risk of lung cancer and to determine what the next management step should be for the patient (for example, CT surveillance versus invasive procedure). In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0722T, the add-on code for the Optellum LCP service, is assigned to the identical APC and status indicator as CPT code 0721T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0721T and 0722T to APC New Technology 1508 (New Technology - Level 8 ($601-$700)).

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. We identified only three claims for CPT codes 0721T and 0722T for ratesetting for CY 2025. We continued to assign CPT codes 0721T and 0722T to APC 1508 (New Technology - Level 8 ($601-$700)) with a payment rate of $650.50 based on our CY 2025 policy to maintain New Technology APC assignments for CY 2025 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. There were 496 combined claims for CPT codes 0721T and 0722T for CY 2024: 7 claims for CPT code 0721T and 489 claims for 0722T. The geometric mean cost of CPT code

0721T is $30.24 and the geometric mean cost for CPT code 0722T is $60.47. Based on the geometric mean cost for CPT code 0722T, which has a significantly greater number of claims than 0721T, we would assign CPT codes 0721T and 0722T to APC 1502 (New Technology – Level 2 ($51-$100) with a payment rate of $75.50. However, assigning these SaaS services based on the geometric costs would significantly impact the payment by decreasing the payment rate by close to 90 percent in 1 year. We recognize that software-based technologies, like those described by CPT codes 0721T and 0722T, continue to evolve and that the limited claims data that we have may not truly represent the cost of this service. We are issuing a comment solicitation in section III.F. of this proposed rule to collect information on alternative and consistent payment methods that seek to reflect the underlying value of SaaS services under the OPPS to consider in future rulemaking. We hope to identify whether specific adjustments to our payment policies for SaaS services are needed to more accurately and appropriately pay for these products and services across settings of care.

While we recognize that there are certain unknowns regarding the cost of technologies like the Optellum LCP service, we believe it would be unlikely for the cost to be 90 percent less than the initial estimated costs based on our review of the information provided in the New Technology APC application. Therefore, we propose to use our authority under section 1833(t)(2)(E) for CY 2026 to continue to assign CPT codes 0721T and 0722T to APC 1508 (New Technology - Level 8 ($601-$700)) with a payment rate of $650.50 based on the information provided to us by the manufacturer in their application, which we believe may better reflect the cost of the service at this time than the available claims data.

Please refer to Table 26 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS codes 0721T and 0722T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 26: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE OPTELLUM

LCP SERVICE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0721T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained without concurrent CT examination of any structure contained in previously acquired diagnostic imaging	S	1508
0722T	Quantitative computed tomography (CT) tissue characterization, including interpretation and report, obtained with concurrent CT examination of any structure contained in the concurrently acquired diagnostic imaging dataset (list separately in addition to code for primary procedure)	S	1508

o. Quantitative Magnetic Resonance (QMR) for Analysis of Tissue Composition (APC 1509)

Effective January 1, 2022, CPT codes 0697T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs) and 0698T (Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)) are associated with the CoverScan Software as a medical Service (SaaS). This service is a medical image management and processing software package that analyzes MR data and provides quantified metrics of multiple organs such as the heart, lungs, liver, spleen, pancreas, and kidney. For CY 2024, we assigned CPT codes 0697T and 0698T to APC 1511 (New Technology - Level 11 ($900-$1,000)).

For CY 2025, there were fewer than 100 claims for ratesetting and because we recognized that the number of claims used to apply our universal low volume policy (using the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years

of claims data) may not have represented the cost of this SaaS service, we used our equitable adjustment authority under section 1833(t)(2)(E) to continue to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($900-$1,000)) with a payment of $950.50. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Thus, CPT code 0698T, the add-on code for CoverScan was assigned to the identical APC and status indicator as CPT code 0697T, the standalone code for the same service.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. We identified 55 single frequency claims for CPT code 0698T and no claims for CPT code 0697T in CY 2024. Because the SaaS standalone and add-on services are identical, we believe it is important for purposes of ratesetting to use the data that is available, whether it is associated with the standalone code or the add-on code. As the 55 single frequency claims are below the threshold of 100 claims for a service within a year, we would propose applying our universal low volume APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign CPT codes 0697T and 0698T to the appropriate New Technology APC. Our analysis of the combined data, zero claims for CPT code 0697T and 137 claims for CPT code 0698T, yielded a geometric mean cost of approximately $422, an arithmetic mean cost of approximately $600, and a median cost of approximately $777. The median cost is the statistical methodology that estimates the highest cost for CPT codes 0697T and 0698T. Based on the median cost, we would propose to assign CPT codes 0697T and 0698T to APC 1509 (New Technology – Level 9 ($701 - $800)) with a payment of $750.50. As in CY 2025, for CY 2026, we recognize that the few claims available for CPT codes 0697T and 0698T may not truly represent the cost of this SaaS service. We recognize that software-based technologies, like those described by CPT codes 0697T and 0698T, are unique and rapidly evolving and that a significant fluctuation in payment may hinder patient access to these new services. We are issuing a comment solicitation in section III.F of this

proposed rule to collect information on alternative and consistent payment methods that seek to reflect the underlying value of SaaS services under the OPPS to consider in future rulemaking. We hope to identify whether specific adjustments to our payment policies for SaaS services are needed to more accurately and appropriately pay for these products and services across settings of care.

Because we continue to have the same concerns about payment variability and the possible effects the payment may have on patient access to these SaaS services, we propose to use our authority under section 1833(t)(2)(E) for CY 2026 to continue to assign CPT codes 0697T and 0698T to APC 1511 (New Technology—Level 11 ($900-$1,000)) with a payment of $950.50 which we believe best reflects the cost of the service at this time.

Please refer to Table 27 for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0697T and 0698T for CY 2026. The proposed CY 20265 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 27: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMR PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0697T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained without diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session; multiple organs	S	1511
0698T	Quantitative magnetic resonance for analysis of tissue composition (eg, fat, iron, water content), including multiparametric data acquisition, data preparation and transmission, interpretation and report, obtained with diagnostic mri examination of the same anatomy (eg, organ, gland, tissue, target structure); multiple organs (list separately in addition to code for primary procedure)	S	1511

p. Quantitative Magnetic Resonance Cholangiopancreatography (QMRCP) (APC 1511)

Effective July 1, 2022, CPT codes 0723T (Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) during the same session) and 0724T (Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (eg, organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)) are associated with the QMRCP Software as a medical Service (SaaS). The service performs quantitative assessment of the biliary tree and gallbladder. It uses a proprietary algorithm that produces a three-dimensional reconstruction of the biliary tree and pancreatic duct and also provides precise quantitative information of biliary tree volume and duct metrics. In accordance with our SaaS add-on codes policy (87 FR 72032 to 72033), SaaS CPT add-on codes are assigned to the same APCs and status indicators as their standalone codes. Consistent with our SaaS add-on codes policy, CPT code 0724T, the add-on code for QMRCP is assigned to the identical APC and status indicator as CPT code 0723T, the standalone code for the same service. For CY 2024, we assigned CPT codes 0723T and 0724T to APC 1511 (New Technology - Level 11 ($900-$1,000)). For CY 2025, we continued to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($900–$1,000)) based on there being fewer than 10 claims in the 4-year lookback period and the exception from the universal low- volume APC policy.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. There are only four new claims for HCPCS code 0724T and no claims for CPT code 0723T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period due to an exception from the universal low-volume APC policy, we propose, for CY 2026, to

continue to assign CPT codes 0723T and 0724T to APC 1511 (New Technology—Level 11 ($901 - $1000)), with a payment rate of $950.50.

Please refer to Table 28 for the proposed OPPS New Technology APC and status indicator assignments for CPT codes 0723T and 0724T for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 28: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE QMRCP PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0723T	Quantitative magnetic resonance cholangiopancreatography (QMRCP) including data preparation and transmission, interpretation and report, obtained without diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) during the same session	S	1511
0724T	Quantitative magnetic resonance cholangiopancreatography (QMRCP), including data preparation and transmission, interpretation and report, obtained with diagnostic magnetic resonance imaging (MRI) examination of the same anatomy (e.g., organ, gland, tissue, target structure) (list separately in addition to code for primary procedure)	S	1511

q. Scalp Cooling (APC 1515)

CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) became effective on July 1, 2021, to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. According to Medicare's National Coverage Determination (NCD) policy, specifically, NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss), the scalp cooling cap itself is classified as an incident to supply to a physician service, and would not be paid under the OPPS; however, interested parties have indicated that there are substantial resource costs of around $1,900 to $2,400 associated with calibrating and fitting the cap. CPT guidance states that CPT

code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves, for example, 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. We note that CPT code 0663T (Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)) describes an ancillary service, and is assigned to status indicator "N" to indicate that OPPS payment is packaged into the payment for the primary service.

For CY 2022, we assigned CPT code 0662T to APC New Technology 1520 (New Technology— Level 20 ($1,801–$1,900)) with a payment rate of $1,850.50. For CY 2023, we did not have any claims data, so we continued to assign CPT code 0662T to APC 1520. For CY 2024 we finalized reassignment of CPT code 0662T to APC 1514 (New Technology—Level 14 ($1,201–$1,300)) with a payment rate of $1,250.50 based on 11 single frequency claims.

For CY 2025, the OPPS payment rates were proposed to be based on available CY 2023 claims data. There were 50 single frequency paid claims for CPT code 0662T for CY 2023. As this is below the threshold of 100 claims for a service within a year, we designated CPT code 0662T as a low volume service under our universal low volume APC policy and used the highest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data to assign the service to the appropriate New Technology APC. Based on the median cost of the service, which we determined to be the highest statistical methodology for CY 2023 claims, we assigned CPT code 0662T to APC 1519 (New Technology—Level 19 ($1701-$1800)) with a payment rate of $1750.50 for CY 2025.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. CPT code 0662T had 112 single frequency claims in CY 2024. The geometric mean cost for CPT code 0662T is approximately $1,504, an amount that is lower than its current New Technology APC assignment. Therefore, we would propose to assign CPT code 0662T to APC 1517 (New Technology – Level 17 ($1501-$1600) with a $1,550.50 payment rate for CY 2026

based on its geometric mean cost. However, effective January 1, 2026, temporary CPT codes 0662T and 0663T will be replaced with three CPT Category I codes. Their current placeholder codes and descriptors are as follows:

● 9XX01 – Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education.

● 9XX02 – Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period).

● 9XX03 – Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure).

Based on our review of the procedure descriptions and input from our CMS medical officers, we believe that CPT placeholder code 9XX01 most closely describes the primary service currently described by CPT code 0662T, while CPT placeholder codes 9XX02 and 9XX03 describe ancillary services for which payment would be packaged in the primary service. Therefore, we are making two proposals. First, we propose to use the existing claims data for CPT code 0662T to set the New Technology APC assignment for CPT placeholder code 9XX01. Specifically, we propose to assign CPT placeholder code 9XX01 to APC 1517 (New Technology – Level 17 ($1501-$1600) with a $1,550.50 payment rate for CY 2026. Second, we propose to assign status indicator "N" to CPT placeholder codes 9XX02 and 9XX03 to align with our current packaging policies, generally, and specifically with regard to our current packaging of CPT code 0663T. Finally, we note that because CPT is deleting CPT codes 0662T and 0663T, they will similarly be deleted under the OPPS/ASC payment systems.

Please refer to Table 29 for the current and proposed OPPS New Technology APC and status indicator assignments for CPT codes 9XX01, 9XX02, and 9XX03. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 29: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR SCALP COOLING

CPT Codes	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
9XX01	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education	S	1517
9XX02	Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period)	N	N/A
9XX03	Mechanical scalp cooling; provided after discontinuation of chemotherapy, each 30 minutes (List separately in addition to code for primary procedure))	N	N/A

r. Supervised Visits for Esketamine Self-Administration (APCs 1512 and 1517)

On March 5, 2019, FDA approved Spravato™ (esketamine) nasal spray, used in conjunction with an oral antidepressant[21], for treatment of depression in adults who have tried other antidepressant medicines but have not benefited from them (treatment-resistant depression (TRD)). This is the first FDA approval of esketamine for any use.

Esketamine is a noncompetitive N-methyl D-aspartate (NMDA) receptor antagonist. It is a nasal spray supplied as an aqueous solution of esketamine hydrochloride in a vial with a nasal spray device. Each device delivers two sprays containing a total of 28 mg of esketamine. Patients would require either two (2) devices (for a 56 mg dose) or three (3) devices (for an 84 mg dose) per treatment.

Because of the risk of serious adverse outcomes resulting from sedation and dissociation caused by esketamine nasal spray administration, and the potential for misuse of the product, it is only available through a restricted distribution system under a Risk Evaluation and Mitigation Strategy (REMS). A REMS is a drug safety program that the FDA can require for certain medications with serious safety concerns to help ensure the benefits of the medication outweigh its risks. The Spravato™ REMS program requires the esketamine nasal spray to be dispensed

[21] The FDA Prior Approval supplemental new drug application (sNDA) provides for the following modification: expansion of the indication to include monotherapy of Spravato™ (esketamine) for treatment resistant depression (TRD). See *https://www.accessdata.fda.gov/drugsatfda_docs/appletter/2025/211243Orig1s016ltr.pdf*.

and administered to enrolled patients in health care settings that are certified in the REMS. See *www.fda.gov* for more information regarding the Spravato™ REMS program compliance requirements.

A treatment session of esketamine consists of instructed nasal self-administration by the patient followed by a period of at least 2 hours post-administration observation of the patient under direct supervision of a health care professional in the certified health care setting. Refer to the CY 2020 PFS final rule and interim final rule for more information about supervised visits for esketamine nasal spray self-administration (84 FR 63102 through 63105).

To facilitate prompt beneficiary access to the new, potentially life-saving treatment for TRD using esketamine, we created two new HCPCS G codes, G2082 and G2083, effective January 1, 2020. HCPCS code G2082 is for an outpatient visit for the evaluation and management of an established patient who requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine through nasal self-administration and includes two hours of post-administration observation. HCPCS code G2083 describes a similar service to HCPCS code G2082 but involves the administration of more than 56 mg of esketamine.

For CY 2025, HCPCS code G2082 was assigned to APC 1513 (New Technology—Level 13 ($1101-$1200)) with a payment rate of $1,150.50 and HCPCS code G2083 was assigned to APC 1516 (New Technology—Level 16 ($1401–$1,500)) with a payment rate of $1,450.50.

For CY 2026, the OPPS payment rates are proposed based on available CY 2024 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. Therefore, for CY 2026, we propose to assign HCPCS codes G2082 and G2083 to New Technology APCs based on each of the codes' geometric mean costs. Specifically, we propose to assign HCPCS code G2082 to APC 1512 (New Technology—Level 12 ($1001–$1100)) with a payment rate of $1,050.50 based on its geometric mean cost of $1,019, which was calculated using the available 558 single frequency claims from CY 2024

claims data. We also propose to assign HCPCS code G2083 to APC 1517 (New Technology—Level 17 ($1501–$1600)) with a payment rate of $1,550.50 based on its geometric mean cost of $1,549, which was calculated using the available 4,138single frequency claims from CY 2024 claims data. As we continue to gather adequate claims data on these codes, we invite public comment on the appropriate clinical APC assignments for HCPCS codes G2082 and G2083.

Please refer to Table 30 for the proposed OPPS New Technology APC and status indicator assignments for HCPCS code G2082 and G2083 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 30: PROPOSED CY 2026 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR HCPCS CODES G2082 AND G2083

HCPCS Codes	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
G2082	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of up to 56 mg of esketamine nasal self-administration, includes 2 hours post-administration observation	S	1512
G2083	Office or other outpatient visit for the evaluation and management of an established patient that requires the supervision of a physician or other qualified health care professional and provision of greater than 56 mg esketamine nasal self-administration, includes 2 hours post-administration observation	S	1517

s. Surfacer® Inside-Out® Access Catheter System (APC 1534)

HCPCS code C9780 (Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance) describes the procedure associated with the use of the Surfacer® Inside-Out® Access Catheter System that is designed to address central venous occlusion. HCPCS code C9780 was

established on October 1, 2021, and since its establishment the code has been assigned to APC 1534 (New Technology - Level 34 ($8001-$8500)).

For CY 2026, there are only three new claims for HCPCS code C9780. Therefore, there are only seven single frequency claims available for HCPCS code C9780 in the 2 years of data since the code has been available. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose for CY 2026 to continue to assign HCPCS code C9780 to APC 1534 (New Technology - Level 34 ($8001-$8500)) with a payment rate of $8,250.50.

Please refer to Table 31 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9780 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 31: PROPOSED CY 2026 NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SURFACER® INSIDE-OUT® ACCESS CATHETER SYSTEM PROCEDURE

HCPCS Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	S	1534

t. Transcatheter Atrial Shunt System (TASS) (APC 1537)

The Transcatheter Atrial Shunt System (TASS) is a nitinol self-expanding cardiovascular implant consisting of four arms including two left atrial (LA) arms and two coronary sinus (CS) arms placed between the left atrium and coronary sinus to create a 7mm flow diameter channel for blood to flow from the high pressure region of the left atrium to the lower pressure region of the right atrium via the coronary sinus.

TASS was designated as a Category A IDE clinical study (NCT03523416) on July 31, 2019. Effective October 1, 2023 CMS created HCPCS code C9792 (Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (IDE) study) to describe the TASS service and assigned it to APC 1537 (New Technology - Level 37 ($9501-$10000)) with a payment rate of $9750.50. Since devices in Category A IDE studies are not covered by Medicare during the study, the payment for HCPCS code C9792 reflects only the cost of the service that is performed each time it is reported on a claim.

For CY 2025, there were no claims available so we maintained the APC assignment for HCPCS code C9792 to APC 1537 (New Technology - Level 37 ($9501-$10000)).

For CY 2026, the proposed OPPS payment rates are based on available CY 2024 claims data. We do not have any claims data for HCPCS code C9792. Therefore, for CY 2026, we propose to continue to assign HCPCS code C9792 to APC 1537 (New Technology - Level 37 ($9501-$10000)) with a payment rate of $9,750.50.

Please refer to Table 32 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9792. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 32: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR TRANSCATHETER ATRIAL SHUNT SYSTEM

HCPCS	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9792	Blinded or nonblinded procedure for symptomatic New York Heart Association (NYHA) Class II, III, IVa heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., TEE or ICE ultrasound, fluoroscopy), performed	S	1537

	under general anesthesia in an approved investigational device exemption (IDE) study		

u. Magnetic Resonance Imaging with Inhaled Hyperpolarized Xenon-129 Contrast Agent (APC 1551)

HCPCS code C9791 (Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent) was established on October 1, 2023. For CY 2023, we assigned HCPCS code C9791 to APC 1551 (New Technology - Level 14 ($1201- $1300)). Due to the effective date of the service of October 1, 2023, there were no claims available for HCPCS code C9791 for rate setting in CY 2024. Therefore, in CY 2024, we continued to assign HCPCS code C9791 to APC 1551(New Technology - Level 14 ($1201- $1300)). There were no claims available for HCPCS code C9791 when we were setting rates for CY 2025, so we continued to assign HCPCS code C9791 to APC 1551 (New Technology - Level 14 ($1201- $1300)).

For CY 2026, the proposed OPPS payment rates are based on the available CY 2024 data. There are only four new claims for HCPCS code C9791. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose for CY 2026 to continue to assign HCPCS code C9791 to APC 1551 –New Technology - Level 14 ($1201- $1300)), with a payment rate of $1,250.50.

Please refer to Table 33 for the proposed OPPS New Technology APC and status indicator assignment for HCPCS code C9791 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 33: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR MAGNETIC RESONANCE IMAGING WITH INHALED HYPERPOLARIZED XENON-129 CONTRAST AGENT PROCEDURE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
C9791	Magnetic resonance imaging with inhaled hyperpolarized xenon-129 contrast agent, chest, including preparation and administration of agent	T	1551

v. SAINT Neuromodulation System (APCs 1511, 1521, 1522, and 1525)

The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex to treat major depressive disorder (MDD). The patient first receives structural MRI and functional MRI scans that are analyzed by the provider to identify and localize the personalized stimulation target in the patient's dorsolateral prefrontal cortex. Once the areas targeted for treatment are identified, the patient receives non-invasive magnetic stimulation in the targeted area. The patient has 10 treatment sessions per day with each treatment session lasting 10 minutes followed by 50 minutes of rest before another treatment session occurs. The treatment is administered over five days for a total of 50 sessions of non-invasive magnetic stimulation therapy. There are four CPT codes listed in Table 34 that describe the MRI scans that are used to target the treatment and describe the administration of the non-invasive magnetic stimulation therapy.

TABLE 34: SAINT NEUROMODULATION SYSTEM CPT CODES AND DESCRIPTORS

CPT Code	Long Descriptor
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day

For CY 2025, the OPPS payment rates were proposed based on available CY 2023 claims data. However, CPT codes 0889T, 0890T, 0891T, and 0892T did not become effective until July 1, 2024, which means there are no claims data for the procedures described these CPT codes. We assigned our proposed rates for these services based on our evaluation of the resources needed to perform these services.

For CY 2026, the OPPS payment rates are proposed based on available CY 2024 claims data. There are only five claims for CPT code 0889T and three claims for CPT code 0892T within this period. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology APC services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue to assign CPT code 0889T to APC 1511 (New Technology—Level 11 ($901-$1000)) with a payment of $950.50 and CPT code 0892T to APC 1525 (New Technology—Level 25 ($3501-$4000)) with a payment of $3750.50.

There were 12 single frequency claims for CPT 0890T and 39 single frequency claims for CPT 0891T. As this is above the threshold of 10 claims and below the threshold of 100 claims for a service within a year, we propose to apply our universal low volume New Technology APC policy and use the highest of the geometric mean cost, arithmetic mean cost, or median cost

based on up to 4 years of claims data to assign CPT codes 0890T and 0891T to the appropriate New Technology APCs.

Using available claims data from CY 2024, our analysis found the geometric mean cost of CPT 0890T is approximately $1,646, the median mean cost is approximately $1,009, and the arithmetic mean cost is approximately $1,950. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2026, to assign CPT code 0890T to APC 1521 (New Technology—Level 21 ($1901-$2000)) with a payment rate of $1,950.50.

For CPT 0891T, using the available claims data from CY 2024, our analysis found the geometric mean cost is approximately $1,692, the median cost is approximately $1,009, and the arithmetic mean cost is approximately $2,010. The arithmetic mean is the statistical methodology that estimates the highest cost for the service. Therefore, we propose, for CY 2026, to assign CPT code 0891T to APC 1522 (New Technology—Level 22 ($2001-$2500)) with a payment rate of $2,250.50.

Please refer to Table 35 for the CY 2026 proposed OPPS New Technology APC and status indicator assignments for CPT codes 0889T, 0890T, 0891T, and 0892T. The proposed CY 2026 payment rates can be found in Addendum B to the CY 2026 OPPS/ASC proposed rule via the internet on the CMS website.

TABLE 35: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR CPT CODES 0889T, 0890T, 0891T, AND 0892T

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0889T	Personalized target development for accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation derived from a structural and resting-state functional MRI, including data preparation and transmission, generation of the target, motor threshold-starting location, neuronavigation files and target report, review and interpretation	S	1511
0890T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including target assessment, initial motor threshold determination, neuronavigation, delivery and management, initial treatment day	S	1521
0891T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent treatment day	S	1522
0892T	Accelerated, repetitive high-dose functional connectivity MRI-guided theta-burst stimulation, including neuronavigation, delivery and management, subsequent motor threshold redetermination with delivery and management, per treatment day	S	1525

w. Implantable Glucose Monitoring System (APC 1561)

Effective January 1, 2017, the AMA CPT Editorial Panel established CPT codes 0446T (Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training) and 0448T (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation) to describe an implantable glucose sensor for patients with diabetes. These codes were used to describe sensors with a 90-day or 180-day battery life. Although these CPT codes were effective January 1, 2017, the implantable interstitial glucose sensor did not receive FDA approval for marketing until June 6, 2019. For CY 2021, we assigned CPT codes 0446T and 0448T to APC 5054 (Level 4 Skin Procedures) and

a status indicator of "T" (Procedure or Service, Multiple Procedure Reduction Applies; Paid under OPPS; separate APC payment.) and have maintained these APC assignments since then.

In the CY 2025 OPPS/ASC final rule, we created the following two HCPCS G codes effective January 1, 2025, to describe the implantable interstitial glucose sensor with a 365-day battery life.

- G0546 (Creation of subcutaneous pocket with insertion of 365 day implantable interstitial glucose sensor, including system activation and patient training); and
- G0565 (Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new 365 day implantable sensor, including system activation).

We assigned HCPCS codes G0564 and G0565 to APC 1561 (New Technology—Level 24 ($3001-$3500)) with a payment rate of $3,250.50.

For the April 1, 2025, quarterly update, we deleted HCPCS codes G0564 and G0565 and assigned 0446T and 0448T to APC 1561 (New Technology—Level 24 ($3001-$3500)) with a payment rate of $3,250.50 to describe the new implantable interstitial glucose sensor with a 365-day battery life. The 365-day glucose sensor replaced previous versions of the implantable interstitial glucose sensor with shorter battery lives. Therefore, the 365-day sensor is the only sensor on the market and can only be described by CPT codes 0446T and 0448T.

For CY 2026, the proposed OPPS payment rates are based on available CY 2024 claims data. As CPT codes 0446T and 0448T were assigned to New Technology APCs to describe this new sensor for the April 2025 quarterly update and the G codes describing this service were only effective for one quarter, we do not have any claims data for the service. Therefore, for CY 2026, we propose to continue to assign CPT codes 0446T and 0448T to APC 1561 (New Technology—Level 24 ($3001-$3500)) with a payment rate of $3,250.50.

Please refer to Table 36 for the proposed OPPS New Technology APC and status indicator assignment for CPT codes 0446T and 0448T for CY 2026. The proposed CY 2026

payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 36: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR IMPLANTABLE GLUCOSE MONITORING

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0446T	Creation of subcutaneous pocket with insertion of implantable interstitial glucose sensor, including system activation and patient training	T	1561
0448T	Removal of implantable interstitial glucose sensor with creation of subcutaneous pocket at different anatomic site and insertion of new implantable sensor, including system activation	T	1561

x. Skin Cell Suspension Autograft (SCSA) Procedures (CPT Code 15013 and HCPCS code C8002) (APC 1567)

Effective January 1, 2025, both CPT code 15013 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin) and HCPCS code C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)) describe the preparation step of a skin cell suspension autograft (SCSA) procedure to treat acute thermal burn injuries. Both codes describe the preparation step of a three-step SCSA procedure: harvesting, preparation, and application. The difference between the codes is that CPT code 15013 describes the manual preparation of the SCSA, and HCPCS code C8002 describes the automated preparation of the SCSA. Due to the similarities between the procedures, in the CY 2025 OPPS/ASC final rule with comment period, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1567 (New Technology—Level 30 ($6,001– $6,500)) with a payment rate of $6,250.50 and status indicator ‘‘T’’. In the CY 2025 OPPS/ASC final rule with comment period, we noted that we believed the sum of the payment rates for the three-step process should approximate $10,000. However, because of the effect of the multiple procedure reduction, the total payment for the skin cell suspension autograft furnished using the RECELL System would have been approximately

$8,000, contrary to the intended target of $10,000 as stated in the CY 2025 OPPS/ASC final rule with comment period. To correct this error, in the CY 2025 OPS/ASC Correction Notice, we assigned both CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001-$7,500)) with a payment rate of $7,250.50 and status indicator "S" (Procedure or service, not discounted when multiple, paid under OPPS; separate APC payment).

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. Since CPT code 15013 and HCPCS code C8002 were not effective until January 1, 2025, we do not have any claims for either code for CY 2024. Therefore, for CY 2026, we propose to continue to assign CPT code 15013 and HCPCS code C8002 to APC 1532 (New Technology—Level 32 ($7,001-$7,500)) with a payment rate of $7,250.50.

Please refer to Table 37 for the proposed OPPS New Technology APC and status indicator assignments for CPT code 15013 and HCPCS code C8002 for CY 2026. The proposed CY 2026 payment rates can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 37: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENT FOR SKIN CELL SUSPENSION PREPARATION PROCEDURES

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	S	1532
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	S	1532

y. Renal Histotripsy Service (APC 1576)

HCPCS code C9790 (Histotripsy (that is, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) was created October 1, 2023, and was used to describe the Medicare approved Category B IDE (investigational device exemption) clinical study involving the renal histotripsy procedure associated with the use of the HistoSonics

Edison System. CPT code 0888T (Histotripsy (ie, non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance) replaced HCPCS code C9790 effective July 1, 2024.

Renal histotripsy is a non-invasive, non-thermal, mechanical process that uses a focused beam of sonic energy to destroy solid renal tumors and is currently in a prospective, multi-center, single-arm pivotal trial designed to evaluate the effectiveness and safety of the device for the destruction of kidney tissue by treating primary solid renal tumors.[22] Because the renal histotripsy clinical study is designated as a Category B (non-experimental/investigational) IDE study, the Medicare payment for CPT code 0888T reflects payment for both the service that is performed, and the device used each time it is reported on a claim. For CY 2025 we assigned CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001– $20,000)) with a payment rate of $17,500.50 based on the previous APC and status indicator assignments for HCPCS code C9790.

For CY 2026, the OPPS payment rates are proposed to be based on available CY 2024 claims data. We identified one single frequency claim for HCPCS code C9790 and six single frequency claims for CPT code 0888T. Given our proposal to maintain current New Technology APC assignments for CY 2026 for New Technology services with fewer than 10 claims in the 4-year lookback period applicable for the universal low-volume APC policy, we propose to continue to assign CPT code 0888T to APC 1576 (New Technology—Level 39 ($15,001–$20,000)) with a payment rate of $17,500.50 based on the data currently available to us, which we believe best reflects the cost of the service.

The proposed New Technology APC and status indicator assignment for CPT code 0888T is shown in Table 38. The proposed CY 2026 payment rates for these CPT codes can be found in Addendum B to this proposed rule via the internet on the CMS website.

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[22] See "The HistoSonics System for Treatment of Primary Solid Renal Tumors Using Histotripsy (#HOPE4KIDNEY) at *https://clinicaltrials.gov/study/NCT05820087*.

TABLE 38: PROPOSED CY 2026 OPPS NEW TECHNOLOGY APC AND STATUS INDICATOR ASSIGNMENTS FOR THE RENAL HISTOTRIPSY SERVICE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
0888T	Histotripsy (i.e., non-thermal ablation via acoustic energy delivery) of malignant renal tissue, including image guidance	S	1576

D. Universal Low Volume APC Policy for Clinical and Brachytherapy APCs

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a policy to designate clinical and brachytherapy APCs as low volume APCs if they have fewer than 100 single claims that can be used for ratesetting purposes in the claims year used for ratesetting for the prospective year. For the CY 2026 OPPS/ASC proposed rule, CY 2024 claims are generally the claims used for ratesetting; and clinical and brachytherapy APCs with fewer than 100 single claims from CY 2024 that can be used for ratesetting would be low volume APCs subject to our universal low volume APC policy. As we stated in the CY 2022 OPPS/ASC final rule with comment period, we adopted this policy to reduce the volatility in the payment rate for those APCs with fewer than 100 single claims. Where a clinical or brachytherapy APC has fewer than 100 single claims that can be used for ratesetting, under our low volume APC payment adjustment policy, we determine the APC cost as the greatest of the geometric mean cost, arithmetic mean cost, or median cost based on up to 4 years of claims data. We excluded APC 5853 (Partial Hospitalization for CMHCs) and APC 5863 (Partial Hospitalization for Hospital-based PHPs) from our universal low volume APC policy given the different nature of policies that affect the partial hospitalization program. We also excluded APC 2698 (Brachytx, stranded, nos) and APC 2699 (Brachytx, non-stranded, nos) as our current methodology for determining payment rates for non-specified brachytherapy sources is appropriate.

Based on claims data available for this CY 2026 OPPS/ASC proposed rule, we propose to designate six brachytherapy APCs and five clinical APCs as low volume APCs under the OPPS. The six brachytherapy APCs and five clinical APCs meet our criteria of having fewer

than 100 single claims in the claims' year used for ratesetting (CY 2024 for this CY 2026 OPPS/ASC proposed rule). Ten of the 11 APCs were designated as low volume APCs in CY 2025. Based on data for this CY 2026 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) has 103 single claims and no longer meets our criteria to be designated as a low volume APC; however, APC 2643 (Brachytx, non-stranded, c-131) has only 88 single claims and does meet our criteria to be designated as a low volume APC. Table 39 includes the CY 2024 claims available for ratesetting for each of the APCs we propose to designate as a low volume APC for CY 2026. The proposed cost statistics for our CY 2026 low volume APCs, such as the median, arithmetic mean, and geometric mean cost are available for download with this proposed rule on the CMS website. We refer readers to our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*; click on the relevant regulation to download the low volume APC cost statistics under the comprehensive (OPPS) ratesetting methodology in the downloads section of the webpage.

TABLE 39: PROPOSED LOW VOLUME APCS USING COMPREHENSIVE (OPPS) RATESETTING METHODOLOGY FOR CY 2026

APC	APC Description	CY 2024 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	1
2635	Brachytx, non-str, HA, p-103	9
2636	Brachy linear, non-str, p-103	0
2642	Brachytx, stranded, c-131	49
2643	Brachytx, non-stranded, c-131	88
2647	Brachytx, NS, Non-HDRIr-192	3
5244	Level 4 Blood Product Exchanges and Related Services	46
5494	Level 4 Intraocular Procedures	72
5495	Level 5 Intraocular Procedures	41
5496	Level 6 Intraocular Procedures	15
5881	Ancillary Outpatient Services When Patient Dies	57

E. APC-Specific Policies

1. Neurostimulator and Related Procedures (APCs 5461 Through 5465)

In the CY 2021 OPPS/ASC final rule with comment period, we finalized a five-level APC structure for the Neurostimulator and Related Procedures series (85 FR 85968 through 85970). For a detailed discussion of the history of neurostimulators policy, we refer readers to the CY 2015, CY 2020, CY 2021, CY 2023, CY 2024, and CY 2025 OPPS/ASC final rules with comment period (79 FR 66807 through 66808; 84 FR 61162 through 6116, 8 FR 85968 through 85970; 87 FR 71869; 88 FR 81645 through 81658; 89 FR 94062 through 96045).

CPT code 61885

Effective January 1, 1982, CMS established the CPT code 61885 (Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array) which is currently assigned to APC 5464 (Level 4 Neurostimulator and Related Procedures). Based on the claims data available for CY 2026 OPPS ratesetting, there are approximately 2,839 single claims with an estimated geometric mean cost of $31,512.82. APC 5465 (Level 5 Neurostimulator and Related Procedures) has an estimated geometric mean cost around $32,246.05. Based on the estimated resource costs and clinical similarity of HCPCS code 61885 to other procedures assigned to APC 5465, we propose to assign HCPCS 61885 to APC 5465 in the CY 2026 OPPS.

2. APC Structure

In prior rulemaking, some interested parties have requested that we create a Level 6 Neurostimulator and Related Procedures APC, due to their concerns around clinical and resource cost similarity in the Level 5 Neurostimulator and Related Procedures APC. We most recently responded to this request in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94064). We believe that the current 5 level APC structure for the Neurostimulator and Related Procedures series provides for an appropriate distribution of clinical and cost similarity at the different APC levels. As discussed in the CY 2021 OPPS/ASC final rule with comment

period, we reiterate that the OPPS is a prospective payment system. We group procedures with similar clinical characteristics and resource costs into APCs and establish a payment rate that reflects the geometric mean of all services in the group even though the cost of any individual service within the APC may be higher or lower than the APC's geometric mean. As a result, in the OPPS, any individual procedure may potentially be overpaid or underpaid because the payment rate is based on the geometric mean of the entire group of services in the APC. However, the impact of these payment differences should be mitigated when distributed across a large number of APCs (85 FR 85968).

While we continue to believe that a five-level structure for the Neurostimulator and Related Procedures APC series remains appropriate, we solicit comment from interested parties on the need for a Level 6 APC, given the clinical and estimated cost characteristics of the services currently assigned to the Level 5 and New Technology APC 1580.

In summary, for the CY 2026 OPPS, we propose to assign HCPCS code 61885 to APC 5465 and maintain the current 5 level structure for the Neurostimulator and Related Procedure APC series. We are also soliciting comments on potentially creating an additional Level 6 APC in the series.

See Table 40 for proposed CY 2026 SI and APC assignments for specific HCPCS codes in the series and Table 41 for the proposed CY 2026 Neurostimulator and Related Procedures APCs.

TABLE 40: PROPOSED CY 2026 APC AND STATUS INDICATOR ASSIGNMENTS

HCPCS Code	HCPCS Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
61885	Insertion or replacement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array	J1	5465

TABLE 41: PROPOSED CY 2026 NEUROSTIMULATOR AND RELATED PROCEDURES APCS

APC	Group Title	SI	Proposed CY 2026 APC Geometric Mean Cost
5461	Level 1 Neurostimulator and Related Procedures	J1	$3,780.68
5462	Level 2 Neurostimulator and Related Procedures	J1	$6,662.66
5463	Level 3 Neurostimulator and Related Procedures	J1	$11,885.66
5464	Level 4 Neurostimulator and Related Procedures	J1	$20,440.08
5465	Level 5 Neurostimulator and Related Procedures	J1	$32,246.05

3. Musculoskeletal Procedures (APCs 5111 through 5117)

Prior to the CY 2016 OPPS, payment for musculoskeletal procedures was primarily divided according to anatomy and the type of musculoskeletal procedure. As part of the CY 2016 reorganization to better structure the OPPS payments to utilize prospective payment packages, we consolidated these individual APCs so that they became a general Musculoskeletal APC series (80 FR 70397 and 70398).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59300), we continued to apply a six-level structure for the Musculoskeletal APCs because doing so provided an appropriate distinction for resource costs at each level and provided clinical homogeneity. However, we indicated that we would continue to review the structure of these APCs to determine whether additional granularity would be necessary. In the CY 2019 OPPS proposed rule (83 FR 37096), we recognized that commenters had previously expressed concerns regarding the granularity of the current APC levels and, therefore, requested comment on the establishment of additional levels. Specifically, we solicited comments on the creation of a new APC level between the current Level 5 and Level 6 within the Musculoskeletal APC series. While some commenters suggested APC reconfigurations and requested changes to APC assignments, many commenters requested that we maintain the current six-level structure and continue to monitor the claims data as they become available. Therefore, in the CY 2019

OPPS/ASC final rule with comment period, we maintained the six-level APC structure for the Musculoskeletal Procedures APCs (83 FR 58920 and 58921).

Since that time, we have continued an ongoing dialogue with interested parties regarding the six level structure of the Musculoskeletal Procedures APC series and the codes assigned to these APCs. For a detailed discussion of the history of musculoskeletal APC series policy, we refer readers to the CY 2020, CY 2021, CY 2022, CY 2023, CY 2024 and CY 2025 OPPS/ASC final rules with comment period (84 FR 61252 through 61254; 85 FR 85966 through 85968; 86 FR 63559; 87 FR 71868 through 71870; 88 FR 81696 through 81697; 89 FR 94106 through 94107).

In reviewing the claims data available for CY 2026 OPPS ratesetting, we note that APC 5116 (Level 6 Musculoskeletal Procedures) has a bimodal distribution in geomean costs for significant codes, with clusters from approximately $17,000 to $18,000 and approximately $27,000 to $28,000. This meaningful distinction between service costs within the APC suggests the creation of an additional level could be appropriate. Based on the distinction between the different cost significant services within the APC and the volume of claims available to establish ratesetting for both the additional APC level, as well as the codes remaining in the current APC, we believe that creating an additional payment level at the higher range of procedure costs for the Musculoskeletal Procedures APC series would allow for a smoother distribution of the costs between the different levels, based on their resource costs and clinical characteristics.

In addition, for CY 2026, as part of the proposed phased elimination of the Inpatient Only (IPO) List, we propose to remove musculoskeletal codes on the IPO List and assign them to clinical APCs, as discussed in section IX.B. of this proposed rule. As many of these proposed codes are in the Musculoskeletal Procedures APC series, we anticipate there may be effects on the geometric means of these APCs as the limited claims data for those codes is included in OPPS ratesetting. Several HCPCS codes proposed to be removed from the IPO List that are currently assigned to the Level 6 Musculoskeletal Procedures APCs have significant CY 2024

claims volume, with several codes having greater than a thousand single claims from which to calculate their geometric mean costs. The significant claims volume associated with these procedures makes these codes relevant for two times rule evaluation purposes and provides a meaningful basis for establishing the additional APC level. We believe creating an additional level would allow for the appropriate placement of procedures newly removed from IPO List to an APC with an applicable range of estimated costs, due to the large volume of claims data available for procedures with similar clinical and resource characteristics.

Therefore, based on our evaluation of the claims data and proposed removal of musculoskeletal codes from the IPO list, we propose to establish a 7 level Musculoskeletal Procedures APC series for CY 2026

Table 42 displays the proposed CY 2026 Musculoskeletal Procedures APC series' structure and APC geometric mean costs.

TABLE 42: PROPOSED CY 2026 MUSCULOSKELETAL PROCEDURES APCS

APC	Group Title	CY 2025 Final APC Geometric Mean Cost	CY 2026 Proposed APC Geometric Mean Cost
5111	Level 1 Musculoskeletal Procedures	$242.80	$258.52
5112	Level 2 Musculoskeletal Procedures	$1,619.82	$1,685.79
5113	Level 3 Musculoskeletal Procedures	$3,283.97	$3,429.79
5114	Level 4 Musculoskeletal Procedures	$7,230.38	$7,651.18
5115	Level 5 Musculoskeletal Procedures	$13,022.88	$13,460.76
5116	Level 6 Musculoskeletal Procedures	$18,613.09	$18,337.97
5117	Level 7 Musculoskeletal Procedures	N/A	$28,285.22

4. Fractional Flow Reserve Derived From Computed Tomography (FFRct), CPT Code 75580 (APC 5724)

Fractional Flow Reserve Derived from Computed Tomography (FFRCT), also known by the trade name HeartFlow®, is a noninvasive diagnostic service that allows physicians to measure coronary artery disease in a patient through the use of coronary CT scans. The HeartFlow® service is indicated for clinically stable symptomatic patients with coronary artery

disease, and, in many cases, may avoid the need for an invasive coronary angiogram procedure. HeartFlow® uses a proprietary data analysis process performed at a central facility to develop a three-dimensional image of a patient's coronary arteries, which allows physicians to identify the fractional flow reserve to assess whether patients should undergo further invasive testing (that is, a coronary angiogram). HeartFlow® is currently described by CPT code 75580 (Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional).

On January 1, 2024, the Category III CPT code 0503T was replaced with the Category I CPT code 75580 (Noninvasive estimated coronary fractional flow reserve (ffr) derived from coronary computed tomography angiography data using computation fluid dynamics physiologic simulation software analysis of functional data to assess the severity of coronary artery disease; analysis of fluid dynamics and simulated maximal coronary hyperemia, and generation of estimated ffr model) and was assigned to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a payment rate of approximately $1,000. We maintained the same payment assignments for CY 2025.

For CY 2026, the proposed OPPS payment rates are based on available CY 2024 claims data as the available single frequency claims exceed the 100 claims threshold generally used for our universal low volume policy. While we have identified 17,813 single frequency claims that were used to calculate the geometric mean cost of $278.51 in CY 2024, we believe that the geometric mean cost may have been impacted by an outdated automated return-to-provider (RTP) Healthcare Common Procedure Coding System-to-revenue code edit that occurred when the Category I CPT code became effective. This issue was identified by a commenter in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94094). The edit prevented providers from reporting the cardiology revenue code (0480), which maps to the cardiology cost center (03140), when billing CPT code 75580. The cardiology cost center has a higher cost-to-

charge ratio (CCR) than the imaging cost centers, and the inability to report the cardiology revenue code may have resulted in a lower payment rate for the HeartFlow® service as was the case with the cardiac CT CPT codes 75572, 75573, and 75574. (See 89 FR 59276 through 59279.) Since the OPPS ratesetting process utilizes the applicable cost center's CCR to reduce the charges on the claim to estimated cost, utilizing cost centers with lower CCRs results in a lower OPPS payment compared to utilizing cost centers with higher CCRs.

Although the edit was removed, and providers were notified (Official CMS news from the Medicare Learning Network®, Weekly Edition dated September 26, 2024)[23] to resubmit any incorrectly returned claims, we believe that the outdated edit may have impacted the geometric mean for CPT code 75580. Therefore, we propose to use our authority under section 1833(t)(2)(E) to continue to assign CPT code 75580 to APC 5724 (Level 4 Diagnostic Tests and Related Services) with a payment amount of approximately $1,000 which we believe best reflects the cost of the service at this time.

The proposed APC and status indicator assignment for CPT code 75580 is shown in Table 43. The proposed CY 2026 payment rates for CPT code 75580 can be found in Addendum B to this proposed rule via the internet on the CMS website.

TABLE 43: PROPOSED CY 2026 OPPS APC AND STATUS INDICATOR ASSIGNMENT FOR THE HEARTFLOW® SERVICE

CPT Code	Long Descriptor	Proposed CY 2026 OPPS SI	Proposed CY 2026 OPPS APC
75580	Noninvasive estimate of coronary fractional flow reserve (FFR) derived from augmentative software analysis of the data set from a coronary computed tomography angiography, with interpretation and report by a physician or other qualified health care professional	S	5724

F. Comment Solicitation on Payment Policy for Software as a Service (SaaS)

In recent years, there have been rapid developments in the use of software-based technologies with new functionalities, including artificial intelligence, to support clinical

[23] *https://www.cms.gov/training-education/medicare-learning-network/newsletter/2024-09-26-mlnc#_Toc178152800.*

decision-making in the outpatient and physician office settings. Medicare refers to these software-based technologies as software as a service (SaaS). Prior to CY 2018, SaaS procedures were considered supportive or ancillary services, and therefore, payment for the SaaS was packaged into the payment for the underlying clinical service. For example, payment for image processing software that visually enhances an image in an existing MRI, would be packaged into the payment for the MRI service. In recent years, CMS has paid separately for SaaS procedures under the OPPS through New Technology APCs, which are cost bands that allow us to provide appropriate and consistent payment for designated new procedures that are not yet reflected in our claims data, and various clinical APCs based on clinical and resource similarity to existing services, including Imaging APCs and Diagnostic Tests and Related Services APCs. We currently do not have a payment methodology specifically for SaaS, and as these technologies have continued to evolve and diversify, some interested parties have stated that the lack of a consistent payment policy for SaaS can be an impediment to patient access when these services are otherwise approved by the FDA. Interested parties have requested that CMS consider development of a payment policy for these services that is stable and consistent across settings of care, payment systems, and types of SaaS.

We welcome public comment as we consider how to appropriately pay for these services, including any applicable lessons or best practices from risk-bearing payment arrangements, how we can determine that Medicare payments for SaaS truly reflect the value of the technologies to medical practice, and how to ensure that any payment policies on this topic demonstrate fiscal responsibility and good stewardship by promoting high-value, cost-effective care. For pricing new technologies where we do not have substantive supporting data, there are ambiguities regarding the service costs for purposes of setting a payment rate. For example, we have observed wide variations in the purported costs of clinically similar SaaS technologies. The various costs that manufacturers consider when pricing their technologies, including research and development as well as software maintenance, are often not publicly verifiable. It is also unclear

to what extent Medicare should pay for the research and development costs of SaaS that could be frequently used by non-Medicare beneficiaries in hospital outpatient departments and ambulatory surgical center settings. Additionally, due to the novel and evolving nature of these technologies, there are rarely existing medical items or services that can be utilized for comparison purposes to determine clinical and resource similarity. Finally, while there has been a rapid increase in the development and coding of these services in recent years, there is a very limited amount of Medicare claims data for these services.

Given these issues and our interest in developing payment policies that seek to reflect the underlying value of a service or technology to the practice of medicine, we are requesting public comment on future SaaS payment ideas, including:

- What factors could Medicare consider when setting payment rates for SaaS?
- What APCs, existing or new, should we use to pay for SaaS?
- How should we assess the costs of SaaS, and how can we account for hospital acquisition costs?
- What cost or claims data should be used to establish the payment rates for the services?
- Why are the geometric mean costs, as provided in our claims data, for SaaS currently assigned to APCs (both clinical and New Technology APCs) consistently lower than the manufacturers' purported costs of the technologies?
- Is there an alternative data source outside of the limited Medicare claims data currently available and hospital invoices provided by manufacturers, which may not fully depict total hospital acquisition costs, that can accurately reflect the costs of the SaaS?
- What kinds of efficiencies, if any, would SaaS provide for services performed in hospital outpatient departments and ambulatory surgical centers?
- In the context of setting Medicare payment rates, how can CMS best reflect the quality and efficacy of SaaS technologies ?

We welcome input from interested parties on these questions as well as any additional suggestions that would enhance our ability to provide accurate and consistent payment for SaaS procedures. Finally, we note that there is a similar comment solicitation on a payment policy for SaaS under the Physician Fee Schedule, and direct readers to the CY 2026 PFS proposed rule with comment period to provide comments.

G. Continuation of Payment Policy for Radiation Therapy Services Furnished at Nonexcepted Off-Campus Provider Based Departments (PBDs)

1. Background on Section 603 of the Bipartisan Budget Act of 2015 and the PFS Relativity Adjuster

Section 603 of the Bipartisan Budget Act of 2015 (Pub. L. 114-74) (BBA, 2015) (hereinafter referred to as "section 603") amended section 1833(t) of the Act by adding a new clause (v) to paragraph (1)(B) and adding a new paragraph (21). As a general matter, under sections 1833(t)(1)(B)(v) and (t)(21) of the Act, applicable items and services furnished by certain off-campus outpatient departments of a provider on or after January 1, 2017, are not considered covered OPD services as defined under section 1833(t)(1)(B) of the Act for purposes of payment under the OPPS. Instead such items are paid "under the applicable payment system" under Medicare Part B if the requirements for such payment are otherwise met. Section 603 amended section 1833(t)(1)(B) of the Act by adding a new clause (v), which excludes from the definition of "covered OPD services" applicable items and services (defined in paragraph (21)(A) of the section) that are furnished on or after January 1, 2017, by an off-campus PBD, as defined in paragraph (21)(B) of the section.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719), we adopted a number of policies to implement section 603. Broadly, we: (1) defined applicable items and services in accordance with section 1833(t)(21)(A) of the Act for purposes of determining whether such items and services are covered OPD services under section 1833(t)(1)(B)(v) of the Act or whether payment for such items and services will instead be made

under the applicable payment system designated under section 1833(t)(21)(C) of the Act;
(2) defined off-campus PBD for purposes of sections 1833(t)(1)(B)(v) and (t)(21) of the Act; and
(3) established policies for payment for applicable items and services furnished by an off-campus PBD (nonexcepted items and services) under section 1833(t)(21)(C) of the Act. To do so, we finalized policies that define whether certain items and services furnished by a given off-campus PBD may be considered excepted and, thus, continue to be paid under the OPPS; established the requirements for the off-campus PBDs to maintain excepted status (both for the excepted off-campus PBDs and for the items and services furnished by such excepted off-campus PBDs); and described the applicable payment system for nonexcepted items and services (generally, the PFS).

To effectuate payment for nonexcepted items and services, in the CY 2017 interim final rule with comment period (81 FR 79720 through 79729), we established a new set of payment rates under the PFS that reflected the relative resource costs of furnishing the technical component of a broad range of services to be paid under the PFS specific to the nonexcepted off-campus PBDs of a hospital. Specifically, we established a PFS Relativity Adjuster that is applied to the OPPS rate for the billed nonexcepted items and services furnished in a nonexcepted off-campus PBD in order to calculate payment rates under the PFS. The PFS Relativity Adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the nonexcepted items and services furnished in nonexcepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. Nonexcepted items and services furnished by nonexcepted off-campus PBDs are generally paid under the PFS at the applicable OPPS payment rate adjusted by the PFS Relativity Adjuster of 40 percent (that is, 60 percent less than the OPPS rate) (82 FR 53030).

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79719 and 79725), we created modifier "PN" to collect data for purposes of implementing section 603 but also to trigger payment under the newly adopted PFS-equivalent rates for nonexcepted items and services. Nonexcepted off-campus PBDs bill for nonexcepted items and services on the institutional claim utilizing modifier "PN" to indicate that an item or service is a nonexcepted item or service.

For a full discussion of our initial implementation of section 603, we refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79699 through 79719) and the interim final rule with comment period (79720 through 79729). For a detailed discussion of the current PFS Relativity Adjuster related to payments under section 603, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 52356 through 52637) and the CY 2019 PFS final rule with comment period (82 FR 59505 through 59513).

2. Payment for Radiation Therapy Services furnished at Nonexcepted Off-Campus PBDs

The PFS Relativity Adjuster is not applied to radiation therapy services (radiation treatment delivery and related imaging guidance services) furnished by nonexcepted off-campus PBDs. Due to section 1848(c)(2)(K) of the Act, which required maintenance of the CY 2016 coding and payment inputs for these services for CY 2017 and CY 2018 under the PFS, when the section 603 requirements were implemented in the CY 2017 final OPPS rule, we instructed nonexcepted off-campus PBDs to bill the PFS G-codes for these services. As we explained in that rule:

> "…[S]everal radiation treatment delivery and imaging guidance services also are reported using different codes under the MPFS and the OPPS. CMS established HCPCS Level II G-codes to describe radiation treatment delivery services when furnished in the physician office setting (79 FR 67666 through 67667). However, these HCPCS G-codes are not recognized under the OPPS; rather, CPT codes are used to describe these services when furnished in the HOPD. Both sets of codes were implemented for CY 2015 and were

maintained for CY 2016. Under the MPFS, there is a particular statutory provision under section 1848(c)(2)(K) of the Act that requires maintenance of the CY 2016 coding and payment inputs for these services for CY 2017 and CY 2018. Accordingly, the finalized CY 2017 MPFS rates for these services were calculated based on the maintenance of the CY 2016 coding payment inputs. On that basis, we are establishing payment amounts for nonexcepted items and services consistent with the payments that would be made to other facilities under the MPFS. That is, an off-campus PBDs submitting claims for nonexcepted items and services will bill the HCPCS G-codes established under the MPFS to describe radiation treatment delivery procedures. However, the off-campus PBD must append modifier ‘‘PN’’ to each applicable claim line for nonexcepted items and services. The payment amount for these services will be set to reflect the technical component rate for the code under the MPFS.” (81 FR 79726).

As discussed in the CY 2026 Physician Fee Schedule (PFS) proposed rule, , we propose to delete radiation therapy G-codes (G6001 – G6017) that describe imaging guidance for radiation treatment (G6001, G6002, G6017) and radiation treatment delivery (G6003-G6015) because CPT codes 77402, 77407, and 77412 have been revised and may be used to report these services instead. See Table 44 for the long descriptors of the G codes that will be deleted effective January 1, 2026 and Table 45 for the current and revised long descriptors for CPT codes 77402, 77407, and 77412. The proposed CY 2026 payment rates for the radiation treatment delivery codes can be found in Addendum B to this proposed rule via the internet on the CMS website.

If finalized as proposed, the G-codes that nonexcepted off-campus PBDs currently use to report radiation therapy services will no longer be available after December 31, 2025. To continue paying the PFS-equivalent rate for these services to these departments, we propose that, effective January 1, 2026, nonexcepted off-campus PBDs use the revised CPT codes described in the 2026 PFS proposed rule. In other words, because the G codes are being eliminated, we

propose that the revised CPT codes be used to preserve the existing policy of paying nonexcepted off-campus PBDs a specific radiation treatment rate, which is the technical component for the code under the MPFS. Crosswalk information between the G codes and the revised CPT codes is available under the Downloads section[24] of the PFS proposed rule, under "CY 2025 Analytic Crosswalk to CY 2026." Nonexcepted off-campus PBDs should continue to append the "PN" modifier to each applicable claim line for these services. We emphasize that this is not a new policy but rather a continuation of current policy adjusting for the newly revised CPT codes and the corresponding deletion of the G codes.

TABLE 44: HCPCS G CODES THAT WILL BE DELETED EFFECTIVE JANUARY 1, 2026

HCPCS Code	Long Descriptor
G6001	Ultrasonic guidance for placement of radiation therapy fields
G6002	Stereoscopic x-ray guidance for localization of target volume for the delivery of radiation therapy
G6003	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: up to 5 mev
G6004	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 6-10 mev
G6005	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 11-19 mev
G6006	Radiation treatment delivery, single treatment area, single port or parallel opposed ports, simple blocks or no blocks: 20 mev or greater
G6007	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: up to 5 mev
G6008	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 6-10 mev
G6009	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 11-19 mev
G6010	Radiation treatment delivery, 2 separate treatment areas, 3 or more ports on a single treatment area, use of multiple blocks: 20 mev or greater
G6011	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; up to 5 mev
G6012	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 6-10 mev
G6013	Radiation treatment delivery,3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 11-19 mev
G6014	Radiation treatment delivery, 3 or more separate treatment areas, custom blocking, tangential ports, wedges, rotational beam, compensators, electron beam; 20 mev or greater
G6015	Intensity modulated treatment delivery, single or multiple fields/arcs,via narrow spatially and temporally modulated beams, binary, dynamic mlc, per treatment session
G6016	Compensator-based beam modulation treatment delivery of inverse planned treatment using 3 or more high resolution (milled or cast) compensator, convergent beam modulated fields, per treatment session
G6017	Intra-fraction localization and tracking of target or patient motion during delivery of radiation therapy (eg, 3D positional tracking, gating, 3D surface tracking), each fraction of treatment.

[24] *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-notices*.

TABLE 45: RADIATION TREATMENT DELIVERY CPT CODES: COMPARISON OF CURRENT DESCRIPTORS AND REVISED DESCRIPTORS EFFECTIVE JANUARY 1, 2026

CPT Code	Current Long Descriptor	Revised Long Descriptor
77402	Radiation treatment delivery, >=1 MeV; simple	Radiation treatment delivery; Level 1 (eg, single electron field, multiple electron fields, or 2D photons), including imaging guidance, when performed
77407	Radiation treatment delivery, >=1 MeV; intermediate	Radiation treatment delivery; Level 2, single isocenter (eg, 3D or IMRT), photons, including imaging guidance, when performed
77412	Radiation treatment delivery, >=1 MeV; complex	Radiation treatment delivery; Level 3, multiple isocenters with photon therapy (eg, 2D, 3D, or IMRT) OR a single isocenter photon therapy (eg, 3D or IMRT) with active motion management, OR total skin electrons, OR mixed electron/photon field(s), including imaging guidance, when performed

IV. OPPS Payment for Devices

A. Pass-Through Payment for Devices

1. Beginning Eligibility Date for Device Pass-Through Status and Quarterly Expiration of Device Pass-Through Payments

a. Background

The intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Under section 1833(t)(6)(B)(iii) of the Act, the period for which a device category eligible for transitional pass-through payments under the OPPS can be in effect is at least 2 years but not more than 3 years.

In the CY 2017 OPPS/ASC final rule with comment period, in accordance with section 1833(t)(6)(B)(iii)(II) of the Act, we amended § 419.66(g) to provide that the pass-through eligibility period for a device category begins on the first date on which pass-through payment is made under the OPPS for any medical device described by such category (81 FR 79654). In addition, in the CY 2017 OPPS/ASC final rule with comment period, we finalized a policy to

allow for quarterly expiration of pass-through payment status for devices to afford a pass-through payment period that is as close to a full 3 years as possible for all pass-through payment devices (81 FR 79655). We also established a policy to package the costs of the devices that are no longer eligible for pass-through payments into the costs of the procedures with which the devices are reported in the claims data used to set the payment rates (67 FR 66763).

We refer readers to the CY 2017 OPPS/ASC final rule with comment period (81 FR 79648 through 79661) for a full discussion of the current device pass-through payment policy.[25]

In the CY 2023 OPPS/ASC final rule with comment period, we finalized our policy to publicly post online OPPS device pass-through applications received on or after March 1, 2023, beginning with the issuance of the CY 2025 proposed rule and for each OPPS rulemaking thereafter. We refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71934 through 71938) for a full discussion of the policy to publicly post OPPS device pass-through applications.

b. Expiration of Transitional Pass-Through Payments for Certain Devices

As stated earlier, section 1833(t)(6)(B)(iii) of the Act requires that, under the OPPS, a category of devices be eligible for transitional pass-through payments for at least 2 years, but not more than 3 years. Currently, there are 17 device categories eligible for pass-through payment. These devices are listed in Table 46 of this proposed rule where we detail the expiration dates of pass-through payment status for each of the 17 devices currently receiving device pass-through payment.

TABLE 46: DEVICES WITH PASS-THROUGH STATUS EXPIRING IN 2025, IN 2026, OR IN 2027

[25] To apply for OPPS transitional device pass-through status, applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 et seq.). This information collection (CMS-10052) is currently approved under OMB control number 0938-0857 and has an expiration date of November 30, 2025.

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C1826	Generator, neurostimulator (implantable), includes closed feedback loop leads and all implantable components, with rechargeable battery and charging system	01/1/2023	12/31/2025
C1827	Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller	01/01/2023	12/31/2025
C1747	Endoscope, single-use (*i.e.* disposable), urinary tract, imaging/illumination device (insertable)	01/01/2023	12/31/2025
C1600	Catheter, transluminal intravascular lesion preparation device, bladed, sheathed (insertable)	01/01/2024	12/31/2026
C1601	Endoscope, single-use (*i.e.* disposable), pulmonary, imaging/illumination device (insertable)	01/01/2024	12/31/2026
C1602	Orthopedic/device/drug matrix/absorbable bone void filler, antimicrobial-eluting (implantable)	01/01/2024	12/31/2026
C1603	Retrieval device, insertable, laser (used to retrieve intravascular inferior vena cava filter)	01/01/2024	12/31/2026
C1604	Graft, transmural transvenous arterial bypass (implantable), with all delivery system components	01/01/2024	12/31/2026
C1605	Pacemaker, leadless, dual chamber (right atrial and right ventricular implantable components), rate-responsive, including all necessary components for implantation	07/01/2024	06/30/2027
C1606	Adapter, single-use (*i.e.* disposable), for attaching ultrasound system to upper gastrointestinal endoscope	07/01/2024	06/30/2027
C8000	Support device, extravascular, for arteriovenous fistula (implantable)	10/01/2024	9/30/2027
C1735	Catheter(s), intravascular for renal denervation, radiofrequency, including all single use system components	01/01/2025	12/31/2027
C1736	Catheter(s), intravascular for renal denervation, ultrasound, including all single use system components	01/01/2025	12/31/2027
C1737	Joint fusion and fixation device(s), sacroiliac and pelvis, including all system components (implantable)	01/01/2025	12/31/2027
C1738	Powered, single-use (i.e. disposable) endoscopic ultrasound-guided biopsy device	01/01/2025	12/31/2027
C1739	Tissue marker, probe detectable any method (implantable), with delivery system	01/01/2025	12/31/2027

HCPCS Code	Long Descriptor	Effective Date	Pass-Through Expiration Date
C9610	Catheter, transluminal drug delivery with or without angioplasty, coronary, non-laser (insertable)	01/01/2025	12/31/2027

2. New Device Pass-Through Applications for CY 2026

a. Background

Section 1833(t)(6) of the Act provides for pass-through payments for devices, and section 1833(t)(6)(B) of the Act requires CMS to use categories in determining the eligibility of devices for pass-through payments. As part of implementing the statute through regulations, we have continued to believe that it is important for hospitals to receive pass-through payments for devices that offer substantial clinical improvement in the treatment of Medicare beneficiaries to facilitate access by beneficiaries to the advantages of the new technology. Conversely, we have noted that the need for additional payments for devices that offer little or no clinical improvement over previously existing devices is less apparent. In such cases, these devices can still be used by hospitals, and hospitals will be paid for them through appropriate APC payment. Moreover, a goal is to target pass-through payments for those devices where cost considerations are most likely to interfere with patient access (66 FR 55852; 67 FR 66782; and 70 FR 68629).

As specified in regulations at § 419.66(b)(1) through (3), to be eligible for transitional pass-through payment under the OPPS, a device must meet the following criteria:

- If required by FDA, the device must have received FDA approval or clearance and FDA marketing authorization (except for a device that has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA), or meet another appropriate FDA exemption; and the pass-through payment application must be submitted within 3 years from the date of the initial FDA marketing authorization, if required, unless there is a documented, verifiable delay in U.S. market availability after FDA marketing authorization is granted, in which case CMS will consider the pass-through payment application if it is submitted within 3 years from the date of market availability;

- The device is determined to be reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body part, as required by section 1862(a)(1)(A) of the Act; and

- The device is an integral part of the service furnished, is used for one patient only, comes in contact with human tissue, and is surgically implanted or inserted (either permanently or temporarily), or applied in or on a wound or other skin lesion.

In addition, according to § 419.66(b)(4), a device is not eligible to be considered for device pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker).

Separately, we use the following criteria, as set forth under § 419.66(c), to determine whether a new category of pass-through payment devices should be established. The device to be included in the new category must—

- Not be appropriately described by an existing category or by any category previously in effect established for transitional pass-through payments, and was not being paid for as an outpatient service as of December 31, 1996;

- Have an average cost that is not "insignificant" relative to the payment amount for the procedure or service with which the device is associated as determined under § 419.66(d) by demonstrating: (1) the estimated average reasonable cost of devices in the category exceeds 25 percent of the applicable APC payment amount for the service related to the category of devices; (2) the estimated average reasonable cost of the devices in the category exceeds the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent; and (3) the difference between the estimated average reasonable cost of the devices

in the category and the portion of the APC payment amount for the device exceeds 10 percent of the APC payment amount for the related service (with the exception of brachytherapy and temperature-monitored cryoablation, which are exempt from the cost requirements as specified at § 419.66(c)(3) and (e)); and

- Demonstrate a substantial clinical improvement, that is, substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment, or, for devices for which pass-through payment status will begin on or after January 1, 2020, as an alternative pathway to demonstrating substantial clinical improvement, a device is part of the FDA's Breakthrough Devices Program and has received marketing authorization for the indication covered by the Breakthrough Device designation.

In the CY 2016 OPPS/ASC final rule with comment period, we changed our device pass-through evaluation and determination process. Device pass-through applications are still submitted to CMS through the quarterly process, but the applications are subject to notice and comment rulemaking in the next applicable OPPS annual rulemaking cycle. Under this process, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle, while submitters of applications that are not approved upon quarterly review will have the option of being included in the next applicable OPPS annual rulemaking cycle or withdrawing their application from consideration. Under this notice-and-comment process, applicants may submit new evidence, such as clinical trial results published in a peer-reviewed journal or other materials, for consideration during the public comment process for the proposed rule. This process allows those applications that we are able to determine meet all of the criteria for device pass-through payment under the quarterly review process to receive timely pass-through payment status, while still allowing for a transparent, public review process for all applications (80 FR 70417 through 70418).

In the CY 2020 OPPS/ASC final rule with comment period, we finalized an alternative pathway for devices that are granted a Breakthrough Device designation (84 FR 61295) and receive FDA marketing authorization for the indication covered by the Breakthrough Device designation. Under this alternative pathway, devices that are granted an FDA Breakthrough Device designation are not evaluated in terms of the current substantial clinical improvement criterion at § 419.66(c)(2) for the purposes of determining device pass-through payment status, but do need to meet the other requirements for pass-through payment status in our regulation at § 419.66. Devices that are part of the Breakthrough Devices Program, have received FDA marketing authorization for the indication covered by the Breakthrough Devices designation, and meet the other criteria in the regulation can be approved through the quarterly process and announced through that process (81 FR 79655). Proposals regarding these devices and whether pass-through payment status should continue to apply are included in the next applicable OPPS rulemaking cycle. This process promotes timely pass-through payment status for innovative devices, while also recognizing that such devices may not have a sufficient evidence base to demonstrate substantial clinical improvement at the time of FDA marketing authorization.

More details on the requirements for device pass-through payment applications are included on the CMS website in the application form itself at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/passthrough_payment.html*, in the "Downloads" section. In addition, CMS is amenable to meeting with applicants or potential applicants to facilitate information sharing to support the evaluation of an OPPS device pass-through payment application or discuss general application criteria, including the substantial clinical improvement criterion.

In accordance with section V. of this proposed rule, skin substitutes with an approved Biologics License Application (BLA) would be considered under transitional drug pass-through

payment status and skin substitutes with FDA Premarket approval (PMA) or FDA 510(k) clearance would continue to be evaluated under transitional device pass-through payment status.

b. Applications Received for Device Pass-Through Status for CY 2026

We received eight complete applications by the March 3, 2025, quarterly deadline, which was the last quarterly deadline for applications to be received in time to be included in this proposed rule. Of the complete applications, we received one application in the second quarter of 2024, three applications in the third quarter of 2024, one application in the fourth quarter of 2024, and three applications in the first quarter of 2025. One application was withdrawn. Two of the applications were approved for device pass-through payment during the quarterly review process: VasQ, which was preliminarily approved upon quarterly review under the alternative pathway effective July 1, 2024, and the SCOUT MD™ Surgical Guidance System which was preliminarily approved upon quarterly review under the alternative pathway effective September 1, 2024. As previously stated, all applications that are preliminarily approved upon quarterly review will automatically be included in the next applicable OPPS annual rulemaking cycle. Therefore, VasQ and the SCOUT MD™ Surgical Guidance System are discussed in the following section IV.2.b.1. of this proposed rule.

Applications received for the later deadlines for the remaining 2025 quarters (the quarters beginning June 1, September 1, and December 1 of 2025), if any, will be discussed in the CY 2027 OPPS/ASC proposed rule. We note that the quarterly application process and requirements have not changed because of the addition of rulemaking review. Detailed instructions on submission of a quarterly device pass-through payment application are included on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/catapp.pdf*.

Discussions of the applications we received by the March 3, 2025, deadline are included below.

(1) Alternative Pathway Device Pass-Through Applications

We received four device pass-through applications by the March 2025 quarterly application deadline for devices that have received Breakthrough Device designation from FDA and FDA marketing authorization for the indication for which they have a Breakthrough Device designation, and therefore were eligible to apply under the alternative pathway.

(a) aprevo® Cervical ACDF system, aprevo® Cervical ACDF-X system, aprevo® Cervical ACDF-X NO CAM system

Carlsmed, Inc. submitted an application for a new device category for transitional pass-through payment status for the aprevo® Cervical ACDF system, aprevo® Cervical ACDF-X system, and aprevo® Cervical ACDF-X NO CAM system (herein after collectively referred to as the aprevo® Cervical ACDF System) for CY 2026. Per the applicant, the aprevo® Cervical ACDF System is designed to stabilize the cervical spinal column and facilitate fusion. The applicant further explained that the personalized aprevo® Cervical ACDF System devices incorporate patient-specific features to allow the clinician to tailor the deformity correction to the individual needs of the patient and include an aperture for the packing of bone graft. Per the applicant, the aprevo® Cervical ACDF System includes the following components: (1) aprevo® implant, which includes two implants with slightly different heights for each vertebral level, (2) aprevo® insertion instrument, and (3) for the aprevo® Cervical ACDF-X system only, integrated fixation screws. The applicant further stated that the aprevo® Cervical ACDF-X NO CAM system has a part that blocks screws from backing out.

Please refer to the online application posting for the aprevo® Cervical ACDF System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250303GJ8LW.*

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the aprevo® Cervical ACDF System received FDA Breakthrough Device designation effective September 15, 2023, under the name aprevo® C cervical interbody fusion device. The approved FDA indication for the aprevo® Cervical ACDF System is:

● 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. DDD[26] is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should 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®-C cervical interbody fusion devices can be used with supplemental fixation, such as an anterior plate, or as a standalone construct to be used [with the] integrated bone screw fixation.

FDA granted the applicant 510(k) clearance for the aprevo® Cervical ACDF System on November 15, 2024, with separate indications for the aprevo® Cervical ACDF system and the aprevo® Cervical ACDF-X system (with and without CAM)[27]. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA 510(k) clearance for the aprevo® Cervical ACDF System vary, per FDA, the FDA 510(k) clearance indication is covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the aprevo® Cervical ACDF System on March 3, 2025, which is within 3 years of the date of the initial FDA marketing authorization.

It is unclear to us whether the aprevo® Cervical ACDF system and the aprevo® Cervical ACDF-X system (with and without CAM) are different devices such that they should be evaluated separately for OPPS pass-through payment status. We note that the aprevo® Cervical ACDF-X system (with and without CAM) includes additional components, such as the integrated fixation screws, and has a different indicated use as stated in the November 15, 2024 FDA 510(k) clearance letter (K242260). Specifically, based on the FDA 510(k) clearance indication, we note that a key difference of the aprevo® Cervical ACDF-X system (with and

[26] The Medicare Coverage Database defines DDD as degenerative disc disease. In addition, we believe that DDD is commonly referred to as degenerative disk disease in the healthcare industry.

[27] For more information on the aprevo® Cervical ACDF System's indications, we refer readers to the November 15, 2024, FDA 510(k) clearance letter (K242260) *https://www.accessdata.fda.gov/cdrh_docs/pdf24/K242260.pdf*

without CAM)'s interbody implant is that it incorporates integrated screw fixation and may be used as a standalone system for certain indications. We also note that, for deformity procedures to correct coronal angulation or any use of hyperlordotic correction (≥20°), the aprevo® Cervical ACDF-X system (with and without CAM) must include supplemental fixation such as posterior cervical screw fixation or anterior plating.

We are inviting public comments on whether the aprevo® Cervical ACDF system and aprevo® Cervical ACDF-X system should be evaluated separately for OPPS pass-through payment status. Separately, we are inviting public comments on whether the aprevo® Cervical ACDF System meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the aprevo® Cervical ACDF System meets the requirements at § 419.66(b)(3).

With respect to the aprevo® Cervical ACDF System, we question whether the aprevo® insertion instrument, the integrated fixation screws, and/or the CAM components or parts are integral to the service furnished. We note that, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005), we stated that we have interpreted the term "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. Given our interpretation of integral, we question whether these components and parts of the aprevo® Cervical ACDF System are integral to the service furnished as it remains unclear which of these components and parts are utilized during the primary procedure and we question whether some of these components or parts may be purely additive in nature and not necessary to furnish the service. Specifically, we note that it is unclear whether other available insertion instruments may be used to implant the aprevo® implant, and, for the aprevo® Cervical ACDF-X system, whether any or all of the integrated fixation screws may be replaced with other commercially available

screws. In addition, it is unclear whether the CAM is part of the aprevo® implant, part of the integrated fixation screws, or is a separate part altogether. It is also unclear whether the CAM can be removed and replaced by other products, and whether there are any requirements for its utilization. We are interested in additional information about these components and parts of the aprevo® Cervical ACDF System, including how and when they are used, and whether they can be substituted with other products.

We are inviting public comments on whether the aprevo® Cervical ACDF System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, the aprevo® Cervical ACDF System is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and is (2) not a material or supply furnished incident to a service, and, therefore, is eligible to be considered for pass-through payment.

With respect to the aprevo® Cervical ACDF System, we question whether the aprevo® insertion instrument, the integrated fixation screws, and/or the CAM components or parts may be considered a material or supply furnished incident to the service. Specifically, as discussed previously with respect to criteria at § 419.66(b)(3), we note that it is unclear whether other available insertion instruments may be used to implant the aprevo® implant and, for the aprevo® Cervical ACDF-X system, whether any or all of the integrated fixation screws may be replaced with other commercially available screws. In addition, we are unclear about whether the CAM is part of the aprevo® implant, part of the integrated fixation screws, or is a separate part altogether,

and whether the CAM can be removed and replaced by other products. We are seeking clarification about each of these components and parts, including how and when they are used and whether they can be substituted with other commercially available products. We question whether these components or parts of the aprevo® Cervical ACDF System may be considered a supply or material furnished incident to a service and excluded from device pass-through payment eligibility under § 419.66(b)(4).

We are inviting public comments on whether the aprevo® Cervical ACDF System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the existing pass-through code C1831 (Interbody cage, anterior, lateral or posterior, personalized (implantable)) does not appropriately describe the aprevo® Cervical ACDF System because C1831 was created for the original (lumbar-specific) aprevo® product. According to the applicant, the aprevo® Cervical ACDF System device is different from C1831 because (1) the original (lumbar-specific) aprevo® and the nominated aprevo® Cervical ACDF System are separate and distinct products that have no overlap in anatomical indications for use or patient population; (2) the original (lumbar-specific) aprevo® and the aprevo® Cervical ACDF System are billed with different primary procedure CPT codes, are indicated for a different set of surgical approaches, are typically assigned to different places of service, and are mapped to different payment classifications; and (3) CMS transmittals state that C1831 is limited to lumbar procedures.

We note, based on the description provided by the applicant, that the aprevo® Cervical ACDF System is a personalized interbody cage that is implanted using an anterior surgical approach, and therefore, could be appropriately described by C1831. Specifically, C1831 may

appropriately describe the aprevo® Cervical ACDF System because it describes any device that is a personalized interbody cage, designed for anterior, lateral, or posterior procedures. We note that CMS does not establish pass-through device categories for the purposes of describing specific devices, but rather, device categories which are intended to encompass all devices that can be appropriately described by a category. In this context, we believe that the aprevo® Cervical ACDF System may be similar to devices described by C1831 and therefore, the aprevo® Cervical ACDF System may be appropriately described by C1831.

We are inviting public comment on whether the aprevo® Cervical ACDF System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (i) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (ii) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The aprevo® Cervical ACDF System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the aprevo® Cervical ACDF System meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires us to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated

that the aprevo® Cervical ACDF System would be reported with HCPCS codes as shown in Table 47.

TABLE 47: HCPCS CODES REPORTED WITH THE APREVO® CERVICAL ACDF SYSTEM

HCPCS Code	Long Descriptor	SI	APC
22551	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2	J1	5115
22552**	Arthrodesis, anterior interbody, including disc space preparation, discectomy, osteophytectomy and decompression of spinal cord and/or nerve roots; cervical below C2, each additional interspace (list separately in addition to code for primary procedure)	N	
22554	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); cervical below C2	J1	5115
22585**	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); each additional interspace (list separately in addition to code for primary procedure)	N	

**Denotes that the HCPCS code was not included in Addendum P to the CY 2025 OPPS/ASC final rule with comment period, and therefore, had no CY 2025 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. Since not all of the HCPCS/CPT codes provided by the applicant had a CY 2025 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2025 HCPCS/CPT code level device offset amount for the HCPCS codes included in Addendum P and listed in the Table 47 to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS/ASC final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5115, which had a CY 2025 payment rate of $12,866.82 at the time the application was received. HCPCS code 22554 in APC 5115 had a device offset amount of $5,190.48 at the time the application was received. Per the applicant, the average number of levels for cervical interbody fusions per procedure is expected to be 3.25, based on the projected mix of diagnoses between deformity and degenerative condition. The applicant stated that, per procedure, the first level costs $19,000.00, and each additional level

costs $6,000.00. Therefore, according to the applicant, the average cost per procedure for the aprevo® Cervical ACDF System is $32,500.00.

Regarding the cost of the aprevo® Cervical ACDF System, as discussed previously with respect to § 419.66(b)(3) and (b)(4), we remain unclear regarding how and when the aprevo® insertion instrument, the integrated fixation screws, and the CAM components and parts are used and whether they can be substituted with other commercially available products. Therefore, we question how these components and parts are accounted for in the estimated average cost of the aprevo® Cervical ACDF System and whether these components or parts are eligible for OPPS pass-through payment status. In addition, we remain unclear whether the aprevo® Cervical ACDF system and the aprevo® Cervical ACDF-X system (with and without CAM) are different devices with different associated costs and, as such, whether this may require separate cost significance test evaluations. For the purposes of this proposed rule, we use the average cost per procedure provided by the applicant for the aprevo® Cervical ACDF System ($32,500.00). We welcome additional information about the use and cost of the aprevo® insertion instrument, the integrated fixation screws, and the CAM at each level per procedure. We also welcome information on the costs of the various systems (the aprevo® Cervical ACDF system and the aprevo® Cervical ACDF-X system (with and without CAM)) should we determine they are different devices.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $32,500.00 for the aprevo® Cervical ACDF System is 252.59 percent of the applicable APC payment amount for the service related to the category of devices of $12,866.82 (($32,500.00/$12,866.82) x 100 = 252.59 percent). Therefore, when utilizing the average cost provided by the applicant, we believe that the aprevo® Cervical ACDF System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $32,500.00 for the aprevo® Cervical ACDF System is 626.15 percent of the cost of the device-related portion of the APC payment amount for the related service of $5,190.48 (($32,500.00/$5,190.48) x 100 = 626.15 percent). Therefore, when utilizing the average cost provided by the applicant, we believe that the aprevo® Cervical ACDF System meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $32,500.00 for the aprevo® Cervical ACDF System and the portion of the APC payment amount for the device of $5,190.48 is 212.25 percent of the APC payment amount for the related service of $12,866.82 ((($32,500.00 - $5,190.48)/$12,866.82) x 100 = 212.25 percent). Therefore, when utilizing the average cost provided by the applicant, we believe that the aprevo® Cervical ACDF System meets the third cost significance requirement.

We are inviting public comment on whether the aprevo® Cervical ACDF System meets the cost criterion at § 419.66(c)(3).

(b) FARAPULSE™ Pulsed Field Ablation (PFA) System

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for the FARAPULSE™ PFA System for CY 2026. Per the applicant, the FARAPULSE™ PFA System is intended for the isolation of the pulmonary veins in the treatment of paroxysmal atrial fibrillation (PAF) by rendering targeted cardiac tissue electrically non-conductive to prevent cardiac arrhythmia initiation or maintenance. According to

the applicant, the FARAPULSE™ PFA System is comprised of several components, including the FARAWAVE™ PFA Catheter, FARADRIVE™ Steerable Sheath, FARASTAR™ Recording System Module, FARASTAR™ Catheter Connection Cable, and the FARASTAR™ PFA Generator.

The applicant is only seeking a new device category for transitional pass-through payment status for the FARAWAVE™ PFA Catheter component of the FARAPULSE™ PFA System. The applicant stated that the FARAWAVE™ PFA Catheter is a percutaneous, pentaspline, 20-electrode, over-the-wire catheter used to perform irreversible electroporation to treat drug-resistant (Class I, II, III, or IV), recurrent, symptomatic PAF. Per the applicant, the FARAWAVE™ PFA Catheter's deployment mechanism enables two poses, a partially-deployed basket shape and a fully-deployed flower shape, to deliver brief, high voltage PFA pulses (when connected to the FARASTAR™ PFA Generator) within and at the antral area of the pulmonary veins as well as full circumferential coverage around the entire pulmonary vein.

Please refer to the online application posting for the FARAPULSE™ Pulsed Field Ablation (PFA) System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2405312MYT4*.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), FARAPULSE™ PFA System received FDA Breakthrough Device designation under the name FARAPULSE™ Endocardial Ablation System on March 14, 2019. The approved FDA indication for the FARAPULSE™ PFA System is:

● The FARAPULSE Endocardial Ablation System is indicated for cardiac tissue ablation for the treatment of drug refractory, recurrent, symptomatic paroxysmal atrial fibrillation.[28]

[28] The FDA granted Breakthrough Device designation for the FARAPULSE™ Endocardial Ablation System, which is the previous name for the FARAPULSE™ PFA System.

FDA approved the premarket approval (PMA) application for the FARAPULSE™ PFA System on January 30, 2024. We note that while the indication for the FDA Breakthrough Device designation and the indication for the FDA PMA vary slightly, we believe that the FDA PMA indication is covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the FARAPULSE™ PFA System on May 31, 2024, which is within 3 years of the initial FDA marketing authorization.

We are inviting public comments on whether the FARAPULSE™ Pulsed Field Ablation (PFA) System, inclusive of the FARAWAVE™ PFA Catheter meets the newness criterion at § 419.66(b)(1).

As previously noted, the applicant is only seeking a new device category for transitional pass-through payment status for the FARAWAVE™ PFA Catheter component of the FARAPULSE™ PFA System, as such, the eligibility and exclusion criteria will evaluate FARAWAVE™ PFA Catheter.

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the FARAWAVE™ PFA Catheter meets the requirements at § 419.66(b)(3).

We are inviting public comments on whether the FARAWAVE™ PFA Catheter meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site

marker). Per the applicant, the FARAWAVE™ PFA Catheter is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and is (2) not a material or supply furnished incident to a service, and, therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether the FARAWAVE™ PFA Catheter meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the existing pass-through codes C1730 (Catheter, electrophysiology, diagnostic, other than 3D mapping (19 or fewer electrodes)) and C1731 (Catheter, electrophysiology, diagnostic, other than 3D mapping (20 or more electrodes)) do not appropriately describe the FARAWAVE™ PFA Catheter because the FARAWAVE™ PFA Catheter is used for ablation and is not a diagnostic catheter. The applicant also stated that the existing pass-through code C1732 (Catheter, electrophysiology, diagnostic/ablation, 3D or vector mapping) does not appropriately describe the FARAWAVE™ PFA Catheter because the FARAWAVE™ PFA Catheter is not a 3D or vector mapping catheter. In addition, the applicant asserted that the existing pass-through codes C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip) and C2630 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip) do not appropriately describe the FARAWAVE™ PFA Catheter because these codes describe catheters that deliver thermal energy, whereas the FARAWAVE™ PFA Catheter utilizes pulsed field energy to perform irreversible electroporation and deliver tissue selective ablation. The applicant also noted that the FARAWAVE™ PFA Catheter does not have a cool tip, as described by pass-through device code C2630. Finally, the applicant stated that the

existing pass-through code C1889 (Implantable/insertable device, not otherwise classified) does not appropriately describe the FARAWAVE™ PFA Catheter. We note that C1889 is not a device pass-through category code, and therefore, would not describe the FARAWAVE™ PFA Catheter for the purposes of device pass-through.

We note that, based on the description provided by the applicant, the FARAWAVE™ PFA Catheter is used to achieve catheter ablation to treat PAF, and therefore, could be appropriately described by C1733 (Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip). Specifically, we believe that the pass-through payment category C1733 might appropriately describe the FARAWAVE™ PFA Catheter because it includes a catheter used for ablation of tissue without a cool-tip. Further, C1733 does not specify the ablation modality, such as thermal energy or electroporation. In this context, we believe that the FARAWAVE™ PFA Catheter might be appropriately described by C1733.

We are inviting public comment on whether the FARAWAVE™ PFA Catheter meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The FARAPULSE™ PFA System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail in the newness criterion), and therefore, is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the FARAWAVE™ PFA Catheter meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated that the FARAWAVE™ PFA Catheter would be reported with HCPCS code as shown in Table 48.

TABLE 48: HCPCS CODES REPORTED WITH THE FARAWAVE™ PFA CATHETER

HCPCS Code	Long Descriptor	SI	APC
93656	Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and his bundle recording, when performed	J1	5213

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note that the applicant utilized the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5213, which had a CY 2024 payment rate of $22,629.19 at the time the application was received. HCPCS code 93656 in APC 5213 had a device offset amount of $11,251.23 at the time the application was received. According to the applicant, the cost of the FARAWAVE™ PFA Catheter is $7,983.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $7,983.00 for the FARAWAVE™ PFA Catheter is 35.28 percent of the applicable APC payment amount for the service related to the category of devices of $22,629.19 (($7,983.00/$22,629.19) x 100 = 35.28 percent). Therefore, we believe that the FARAWAVE™ PFA Catheter meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $7,983.00 for the FARAWAVE™ PFA Catheter is 70.95 percent of the cost of the device-related portion of the APC payment amount for the related service of $11,251.23 (($7,983.00/$11,251.23) x 100 = 70.95 percent). Therefore, we do not believe that the FARAWAVE™ PFA Catheter meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $7,983.00 for the FARAWAVE™ PFA Catheter and the portion of the APC payment amount for the device of $11,251.23 is negative14.44 percent of the APC payment amount for the related service of $22,629.19 (($7,983.00 - $11,251.23)/$22,629.19) x 100 = -14.44 percent). Therefore, we do not believe that the FARAWAVE™ PFA Catheter meets the third cost significance requirement.

We are inviting public comment on whether the FARAWAVE™ PFA Catheter meets the cost criterion at § 419.66(c)(3).

(c) SCOUT MD™ Surgical Guidance System

Merit Medical Systems submitted an application for a new device category for transitional pass-through payment status for the SCOUT MD™ Surgical Guidance System for CY 2026. According to the applicant, the SCOUT MD™ Surgical Guidance System communicates the location of tumor tissue during a tumor excision procedure. Per the applicant, the SCOUT MD™ Surgical Guidance System consists of the SCOUT MD™ Delivery System, SCOUT MD™ Guide, SCOUT MD™ Handpiece, and SCOUT MD™ Console.

The applicant is only seeking a new device category for transitional pass-through payment status for the SCOUT MD™ Delivery System component of the SCOUT MD™ Surgical Guidance System. The SCOUT MD™ Delivery System, consists of the SCOUT MD™ Reflectors and the SCOUT MD™ Delivery Device, a plastic, molded handle attached to a 16 GA introducer needle with a SCOUT MD™ Reflector preloaded inside. According to the applicant, the SCOUT MD™ Delivery System is used to implant the SCOUT MD™ Reflectors, which identify the location of the tumor tissue to be excised and/or the boundaries of the region of tissue to be excised during a separately scheduled procedure. The applicant further explained that there are four unique configurations of the SCOUT MD™ Reflectors, which return a detectable signal within surrounding tissue when illuminated by the micro-impulse radar signal from the SCOUT MD™ Guide and Handpiece used during the tumor excision procedure. Per the applicant, each single-use SCOUT MD™ Delivery System contains one SCOUT MD™ Delivery Device with one preloaded SCOUT MD™ Reflector.

Please refer to the online application posting for the SCOUT MD™ Surgical Guidance System, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP240830W9M8U.*

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), the SCOUT MD™ Surgical Guidance System received FDA

Breakthrough Device designation effective February 1, 2023. The approved FDA indication for the SCOUT MD™ Surgical Guidance System is:

● The SCOUT MD Reflectors are intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SCOUT MD System), the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

FDA granted 510(k) clearance for the SCOUT MD™ Surgical Guidance System on February 12, 2024, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for the SCOUT MD™ Surgical Guidance System on August 30, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the SCOUT MD™ Surgical Guidance System, inclusive of the SCOUT MD™ Delivery System meets the newness criterion at § 419.66(b)(1).

As previously noted, the applicant is only seeking a new device category for transitional pass-through payment status for the SCOUT MD™ Delivery System component of the SCOUT MD™ Surgical Guidance System, as such, the eligibility and exclusion criteria will evaluate SCOUT MD™ Delivery System.

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the SCOUT MD™ Delivery System meets the requirements at § 419.66(b)(3).

We are inviting public comments on whether the SCOUT MD™ Delivery System meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, the SCOUT MD™ Delivery System is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and is (2) not a material or supply furnished incident to a service, and, therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether the SCOUT MD™ Delivery System meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the existing pass-through codes C1879[29] (Tissue marker (implantable)) and C1819 (Tissue localization excision device) do not appropriately describe the SCOUT MD™ Delivery System because the SCOUT MD™ Delivery System is different than other wire-free localization/fiducial devices used for breast conserving surgery and is the only device that: (1) incorporates application-specific integrated

[29] Effective July 1, 2013, CMS deleted HCPCS code C1879 (Tissue marker, implantable) because it is described by HCPCS code A4648 (Tissue marker, implantable, any type). Centers for Medicare & Medicaid Services (2013). Pub 100-04 Medicare Claims Processing (Transmittal 2718) in CMS Manual System. Accessed at *https://www.cms.gov/regulations-and-guidance/guidance/transmittals/2013-transmittals-items/r2718cp.*

circuit (ASIC) technology customized for use with the SCOUT MD™ Surgical Guidance System; (2) uses radar technology to detect, locate and identify the implanted reflector(s) within ±1 millimeter (mm) of accuracy; (3) utilizes up to 4 uniquely shaped reflectors for a more clearly defined radiographic image of the area of interest to be excised; (4) incorporates differentiated radar signatures and detection cadences specific to each reflector; (5) can detect up to 4 unique reflectors simultaneously or individually to more precisely identify pre-defined surgical margins; and (6) has no significant MRI artifact. The applicant further explained that the SCOUT MD™ Delivery system includes four distinct implant (SCOUT MD™ Reflector) shapes, each with a unique radar signature that enables clear detection and identification of the multiple localization devices previously placed to mark the desired surgical margins during the excision procedure. Upon review, we have not identified an existing pass-through payment category that describes the SCOUT MD™ Delivery System.

We are inviting public comment on whether the SCOUT MD™ Delivery System meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The SCOUT MD™ Surgical Guidance System has a Breakthrough Device designation and marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether the SCOUT MD™ Delivery System meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated that the SCOUT MD™ Delivery System would be reported with HCPCS codes as shown in Table 49.

TABLE 49: HCPCS CODES REPORTED WITH THE SCOUT MD™ DELIVERY SYSTEM

HCPCS Code	Long Descriptor	SI	APC
19281	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds) percutaneous, first lesion, including mammographic guidance.	Q1	5072
19283	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds) percutaneous, first lesion, including stereotactic guidance.	Q1	5071
19285	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds) percutaneous, first lesion, including ultrasound guidance.	Q1	5071
19287	Placement of breast localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds) percutaneous, first lesion, including magnetic resonance guidance.	Q1	5071
10035	Placement of soft tissue localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.	T	5071

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note that the applicant utilized the CY 2025 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5071, which had a CY 2025 payment rate of $703.59 at the time the application was received. HCPCS code 19287 in APC 5071 had a

device offset amount of $240.56 at the time the application was received.[30] Per the applicant, an average of 1.95 SCOUT MD™ Reflectors are placed per procedure with a selling price of $550.00 for each single-use SCOUT MD™ Delivery System containing a SCOUT MD™ Delivery Device with one preloaded SCOUT MD™ Reflector. Therefore, according to the applicant, the average cost per procedure for the SCOUT MD™ Delivery System is $1,072.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $1,072.00 for the SCOUT MD™ Delivery System is 152.36 percent of the applicable APC payment amount for the service related to the category of devices, of $703.59 (($1,072.00/$703.59 x 100 = 152.36 percent). Therefore, we believe that the SCOUT MD™ Delivery System meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $1,072.00 for the SCOUT MD™ Delivery System is 445.63 percent of the cost of the device-related portion of the APC payment amount for the related service, of $240.56 ($1,072.00/$240.56 x 100 = 445.63 percent). Therefore, we believe that the SCOUT MD™ Delivery System meets the second cost significance requirement.

[30] We note the applicant selected APC 5072 and an APC payment rate of $1,620.24 for the three tests of the cost criteria. However, for our calculation, we selected APC 5071, which we believe had the lowest applicable APC payment rate of $703.59 found in the CY 2025 OPPS/ASC final rule with comment period, among the APCs related to the HCPCS/CPT codes provided by the applicant. We selected the HCPCS/CPT code level device offset amount of $240.56 related to HCPCS 19287 in APC 5071. Based on our initial assessment for this proposed rule, using the APC payment rate of $703.59 and the device offset amount of $240.56 would result in the SCOUT MD™ Delivery System meeting the cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $1,072.00 for the SCOUT MD™ Delivery System and the portion of the APC payment amount for the device of $240.56 is 118.17 percent of the APC payment amount for the related service, of $703.59 (((($1,072.00 - $240.56)/$703.59) x 100 = 118.17 percent). Therefore, we believe that the SCOUT MD™ Delivery System meets the third cost significance requirement.

We are inviting public comment on whether the SCOUT MD™ Delivery System meets the cost criterion at § 419.66(c)(3).

(d) VasQ™

Laminate Medical submitted an application for a new device category for transitional pass-through payment status for VasQ™ for CY 2026. Per the applicant, VasQ™ is a nitinol implant which is surgically placed outside and/or around an artery and/or vein to provide external support to arteriovenous fistulas created for vascular access by means of vascular surgery. The applicant further explained that VasQ™ reinforces the juxta-anastomotic region against increased wall tension in the newly arterialized vein, guides a more laminate hemodynamic profile of flow with its tapered configuration, and maintains the structural integrity of the anastomotic configuration.

Please refer to the online application posting for VasQ™, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2405312T1JR*.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), VasQ™ received FDA Breakthrough Device designation effective June 5, 2020. The approved FDA indication for VasQ™ is:

● For use include use as an external support for upper extremity arteriovenous fistulas created for vascular access by means of vascular surgery.

FDA granted De Novo classification for VasQ™ on September 26, 2023, for the same indication as the one covered by the Breakthrough Device designation. We received the application for a new device category for transitional pass-through payment status for VasQ™ on May 31, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether VasQ™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, VasQ™ meets the requirements at § 419.66(b)(3).

We are inviting public comments on whether VasQ™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, VasQ™ is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and is (2) not a material or supply furnished incident to a service, and, therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether VasQ™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, no existing (current or previous) device categories for pass-through payment appropriately describe VasQ™. According to the applicant, pass-through code: C1877 (Stent, non-coated/non-covered, without delivery system) does not appropriately describe VasQ™ because VasQ™ is not a stent and does not come in contact with blood. The applicant also stated that pass-through code C1768 (Graft, vascular) does not appropriately describe VasQ™ because VasQ™ is not a dialysis graft, is not permitted to be cannulated, and does not have direct contact with blood. The applicant asserted that pass-through code C1881 (Dialysis access system (implantable)) does not appropriately describe VasQ™ because VasQ™ is not a dialysis access system, is not permitted to be cannulated, and does not have direct contact with blood. Upon review, we have not identified an existing pass-through payment category that describes VasQ™.

We are inviting public comment on whether VasQ™ meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. VasQ™ has a Breakthrough Device designation and

marketing authorization from FDA for the indication covered by the Breakthrough Device designation (as explained in more detail of the newness criterion) and therefore is not evaluated for substantial clinical improvement.

We are inviting public comment on whether VasQ™ meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated that VasQ™ would be reported with HCPCS codes as shown in Table 50.

TABLE 50: HCPCS CODES REPORTED WITH VASQ™

HCPCS Code	Long Descriptor	SI	APC
36818	Arteriovenous anastomosis, open; by upper arm cephalic vein transposition	J1	5184
36819	Arteriovenous anastomosis, open; by upper arm basilic vein transposition	J1	5184
36820	Arteriovenous anastomosis, open; by forearm vein transposition	J1	5184
36821	Arteriovenous anastomosis, open; direct, any site (eg, Cimino type) (separate procedure)	J1	5183
36832	Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	J1	5184
36833	Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)	J1	5184

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2024 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5183, which had a CY 2024 payment rate of $3,037.01 at the time the application was received. HCPCS code 36821 in APC 5183 had a

device offset amount of $49.81 at the time the application was received. According to the applicant, the cost of VasQ™ is $4,900.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $4,900.00 for VasQ™ is 161.34 percent of the applicable APC payment amount for the service related to the category of devices of $3,037.01 (($4,900.00/$3,037.01) x 100 = 161.34 percent). Therefore, we believe that VasQ™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $4,900.00 for VasQ™ is 9,837.38 percent of the cost of the device-related portion of the APC payment amount for the related service of $49.81 (($4,900.00 /$49.81) x 100 = 9,837.38 percent). Therefore, we believe that VasQ™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $4,900.00 for VasQ™ and the portion of the APC payment amount for the device of $49.81 is 159.70 percent of the APC payment amount for the related service of $3,037.01 (((($4,900.00 - $49.81)/$3,037.01) x 100 = 159.70 percent). Therefore, we believe that VasQ™ meets the third cost significance requirement.

We are inviting public comment on whether VasQ™ meets the cost criterion at § 419.66(c)(3).

(2) Traditional Device Pass-Through Applications

(a) Axoguard HA+ Nerve Protector™

Axogen Corporation submitted an application for a new device category for transitional pass-through payment status for the Axoguard HA+ Nerve Protector™ for CY 2026. Per the applicant, the Axoguard HA+ Nerve Protector™ is a porcine small intestinal submucosa (SIS) decellularized extracellular matrix (ECM), with a dry coating of sodium hyaluronate and sodium alginate applied to both sides of the device that forms a thin layer of lubricous hydrogel when hydrated. According to the applicant, the Axoguard HA+ Nerve Protector™ is designed to be a protective interface between the nerve and the surrounding tissue to minimize the potential for soft tissue attachments and tethering that restricts the nerve's ability to glide and move through the tissue structures during anatomic movement.

Please refer to the online application posting for the Axoguard HA+ Nerve Protector™, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP240830YUKGT*.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), FDA granted the applicant 510(k) clearance for the Axoguard HA+ Nerve Protector™ on April 7, 2023, and then granted a second 510(k) clearance for an expanded indication on October 12, 2023. The approved FDA indications for the Axoguard HA+ Nerve Protector™ are:

- For the management of peripheral nerve injuries where there is no gap;
- For the management and protection of peripheral nerve injuries where there is no gap or following closure of the gap.

We received the application for a new device category for transitional pass-through payment status for the Axoguard HA+ Nerve Protector™ on August 30, 2024, which is within 3 years of the date of the initial FDA marketing authorization.

Per the applicant, the OPPS pass-through application for the Axoguard HA+ Nerve Protector™ is only for the protection of peripheral nerve injuries where there is no nerve gap, specifically for protecting a nerve following a revision (secondary) carpal tunnel (CT) or cubital tunnel (CuT) nerve decompression procedure.

We are inviting public comments on whether the Axoguard HA+ Nerve Protector™ meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the Axoguard HA+ Nerve Protector™ meets the requirements at § 419.66(b)(3).

We are inviting public comments on whether the Axoguard HA+ Nerve Protector™ meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter one of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, the Axoguard HA+ Nerve Protector™ is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets and is (2) not a material or supply furnished incident to a service, and therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether the Axoguard HA+ Nerve Protector™ meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect and was not being paid for as an outpatient service as of December 31, 1996. According to the applicant, no existing device categories for pass-through payment appropriately describe the Axoguard HA+ Nerve Protector™ because the existing device categories C1763 (Connective tissue, non-human (includes synthetic)), C1765 (Adhesion barrier), and C1781 (Mesh (implantable)) describe similar, but distinct products. The applicant stated that the existing pass-through code C1763 does not appropriately describe the Axoguard HA+ Nerve Protector™ because the devices described by C1763 are used for treating urinary incontinence or for implantation to reinforce soft tissues where weakness exists in the urological or musculoskeletal anatomy, whereas the Axoguard HA+ Nerve Protector™ is indicated for the management of peripheral nerve injuries. In addition, the applicant asserted that the existing pass-through code C1765 does not appropriately describe the Axoguard HA+ Nerve Protector™ because the devices described by C1765 are bioresorable substances and principally used in spinal surgeries, while the Axoguard HA+ Nerve Protector™ is indicated for peripheral nerves. Moreover, the applicant stated that the existing pass-through code C1781 does not appropriately describe the Axoguard HA+ Nerve Protector™ because the nominated device is indicated specifically for management of peripheral nerve injuries, whereas devices described by C1781 are for use in hernia repair. The applicant further asserted that C1765 and C1781 do not describe the Axoguard HA+ Nerve Protector™ because the device's porcine SIS ECM is not simply resorbed, but is remodeled into a meso/epineurium-like tissue, while its sodium hyaluronate and sodium alginate coating reduces friction and promotes nerve gliding.

We note that based on the description the applicant provided, the Axoguard HA+ Nerve Protector™ is a porcine SIS ECM with hyaluronate-alginate coating used for the management

and protection of peripheral nerve injuries where there is no gap or following closure of a gap, and thus, could be encompassed by the descriptors C1763 and C1765. Specifically, we believe that the description the applicant provided for the C1763 category definition is incomplete. The applicant stated that C1763 is indicated for treating urinary incontinence resulting from hypermobility or Intrinsic Sphincter Deficiency (ISD), pelvic floor repair, [or implanation] to reinforce soft tissues where weakness exists in the urological or musculoskeletal anatomy. However, we note that, in reference to C1763, section 60.4.3, Chapter 4 of the Medicare Claims Processing Manual provides that, these tissues include a natural, acellular collagen matrix typically obtained from porcine or bovine small intestinal submucosa, or pericardium. This bio-material is intended to repair or support damaged or inadequate soft tissue. They are used to treat urinary incontinence resulting from hypermobility or Intrinsic Sphincter Deficiency (ISD), pelvic floor repair, or for implantation to reinforce soft tissues where weakness exists in the urological or musculoskeletal anatomy. [This excludes those items that are used to replace skin.] Thus, because the Axoguard HA+ Nerve Protector™ is an ECM obtained from porcine SIS and intended to support a damaged or inadequate soft tissue (nerve), we believe that the pass-through payment category C1763 may appropriately describe the Axoguard HA+ Nerve Protector™.

Additionally, we believe that the pass-through payment category C1765 may also appropriately describe the Axoguard HA+ Nerve Protector™ because the device, as described by the applicant, is designed to be placed on and around neural structures to be a protective interface between a nerve and the surrounding tissue, to minimize the potential for soft tissue attachments, and to ensure the nerve's ability to glide through tissue structures during anatomic movement, and therefore may be appropriately described as an adhesion barrier consistent with devices described by C1765.

We further note that the two neuroplasty procedure codes that could be used with the Axoguard HA+ Nerve Protector™ (CPT® codes 64718 and 64721) have previously been used with both categories C1763 and C1765 and that FDA has previously approved devices described

by C1763 and C1765 and billed using CPT® codes 64718 or 64721 for neuroplasty and/or transposition of the ulnar nerve at elbow or median nerve at carpal tunnel. We also note that the inclusion of these neuroplasty devices in categories C1763 and C1765 appears contradictory to the applicant's assertion that the categories are inapplicable for devices indicated for peripheral nerves. In this context, we believe the Axoguard HA+ Nerve Protector™ may be similar to the devices described by C1763 and C1765, and therefore, the Axoguard HA+ Nerve Protector™ may be appropriately described by C1763 and C1765.

We are inviting public comment on whether the Axoguard HA+ Nerve Protector™ meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant asserted that the Axoguard HA+ Nerve Protector™ represents a substantial clinical improvement over existing technologies in the management of peripheral nerve injuries where there is no nerve gap, specifically in protecting a nerve following a revision (secondary) CT or CuT nerve decompression procedure.

The applicant provided three redacted manufacturer internal reports to support these claims, as well as eight background articles/documents about the predicate device, the Axoguard Nerve Protector™. We note that the predicate device differs from the Axoguard HA+ Nerve Protector™ in that the nominated device has a dry coating of sodium hyaluronate and sodium alginate applied to both sides that forms a thin layer of lubricous hydrogel when hydrated. The

addition of the dry coating of sodium hyaluronate and sodium alginate to the Axoguard Nerve Protector™ appears to be the distinguishing feature of the device that is the subject of this application. In addition, the applicant submitted 32 supplemental background articles describing topics including general disease processes and disease prevalence. The applicant's assertions regarding the substantial clinical improvement criterion are shown in Table 51. Please see the online posting for the Axoguard HA+ Nerve Protector™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

TABLE 51: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
Nerve health in an injured tissue bed – Less adhesion, extraneural scar, and inflammatory markers	The quality, extent, tenacity, and overall impression of adhesions were not different from a sham surgery control group.	*Kokkalis, Z. T., Pu, C., Small, G. A., Weiser, R. W., Venouziou, A. I., & Sotereanos, D. G. (2011). Assessment of processed porcine extracellular matrix as a protective barrier in a rabbit nerve wrap model. *Journal of Reconstructive Microsurgery*, *27*(1), 19–28. *https://doi.org/10.1055/s-0030-1267379.*
	26 weeks following the surgical injury of a rat sciatic nerve tissue bed, Axoguard HA+ Nerve Protector as implanted into an injured nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve tissue bed. No statistical difference of adhesion scores was found between the Axoguard HA+ Nerve Protector group and the sham group. A statistically higher difference in adhesion scores was observed between the damaged tissue bed control and the sham control.	Axogen Corporation. (2024). *Preclinical study to evaluate the effect of protection in a tissue bed thermal injury model utilizing an Axoguard HA+ Nerve Protector: 26-week timepoint* [Redacted report].
	26 weeks following the surgical injury of a rat sciatic nerve tissue bed, Axoguard HA+ Nerve Protector was implanted into an injured nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve tissue bed. No statistical difference of extraneural collagen between the contralateral nerve was observed. Axoguard HA+ Nerve Protector group had significantly lower extraneural collogen versus the non-wrapped nerve control at 26 weeks.	Axogen Corporation, 2024, *op. cit.*
	26 weeks following the surgical injury of a rat sciatic nerve tissue bed, Axoguard HA+ Nerve Protector was implanted into an injured nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve	Axogen Corporation, 2024, *op. cit.*

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
	tissue bed. The Axoguard HA+ Nerve Protector group had significantly lower CD68 positive macrophages versus the non-wrapped nerve control at 26 weeks.	
	Axoguard HA+ Nerve Protector was implanted into an injured rat sciatic nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve tissue bed. At 6 weeks, adhesion scores of the untreated injury and Axoguard HA+ groups were significantly higher than the sham, $p<0.001$ and $p = 0.03$, respectively. At 26 weeks, the adhesion score trended higher in the untreated injury group than the Axoguard HA+ Nerve Protector.	Alsmadi, N. Z., Deister, C., Evans, P., Ghanem, T., Smetana, B. S., & Mercer, D. M. (2025). *Use of hyaluronate-alginate gel-coated small intestine submucosa for nerve protection in a preclinical adhesion model* [Conference presentation abstract]. 2025 American Association for Hand Surgery Annual Meeting, Waikoloa Village, HI, United States. *https://meeting.handsurgery.org/program/2025/HS64.cgi*.
	Axoguard HA+ Nerve Protector was implanted into an injured rat sciatic nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve tissue bed. At 6 and 26 weeks, extraneural collagen deposition was significantly higher in the untreated injury group than the sham and the Axoguard HA+ Nerve Protector, $p=0.02$ and $p<0.001$.	Alsmadi, 2025, *op. cit.*
	Axoguard HA+ Nerve Protector was implanted into an injured rat sciatic nerve tissue bed and compared to the contralateral nerve, a sham surgery control and a non-wrapped nerve placed into a damaged nerve tissue bed. CD68-positive macrophages were similar across groups at 6 weeks explant. At 26 weeks, CD68-positive macrophages in the untreated injury group were significantly higher than the Axoguard HA+ Nerve Protector group, $p = 0.01$	Alsmadi, 2025, *op. cit.*
Nerve health in an injured tissue bed – Tissue remodeling, vascularization	Significant increase in M2/M1 macrophage ratio indicating a pro-healing response ($p<0.001$) compared with bovine collagen. In addition, significantly greater vascularization ($p<0.001$) and fibroblast ingrowth ($p<0.01$) were observed. These are all markers of the remodeling process.	*Zhukauskas, R., Fischer, D. N., Deister, C., Alsmadi, N. Z., & Mercer, D. (2021). A Comparative Study of Porcine Small Intestine Submucosa and Cross-Linked Bovine Type I Collagen as a Nerve Conduit. *Journal of Hand Surgery Global Online*, *3*(5), 282–288. *https://doi.org/10.1016/j.jhsg.2021.06.006*.
	Histological examination of the material demonstrated revascularization of the material as early as 1 month. The nerve wrap gradually remodeled and incorporated into a connective tissue structure much like the nerve epineurium.	*Kokkalis, 2011, *op. cit.*
Low rate of recurrent symptoms	No evidence of recurrent symptoms following revision with Axoguard (n=12, mean follow-up of 41 months).	*Papatheodorou, L. K., Williams, B. G., & Sotereanos, D. G. (2015). Preliminary results of recurrent cubital tunnel syndrome treated with neurolysis and porcine extracellular matrix nerve wrap. *The Journal of Hand Surgery, 40*(5), 987–992.

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
		https://doi.org/10.1016/j.jhsa.2015.02.031.
	No evidence of recurrent symptoms following revision with Axoguard in 5 patients (up to 60 months).	*Kokkalis, S. T., Mavrogenis, A. F., Vottis, C., Papatheodorou, L., Papagelopoulos, P. J., Soucacos, P. N., & Sotereanos, D. G. (2016). Median nerve biodegradable wrapping: Clinical outcome of 10 patients. *Acta Orthopaedica Belgica, 82*(2), 351–357. *https://www.actaorthopaedica.be/assets/2407/28-mavrogenis-.pdf*.
	One of 35 patients underwent revision surgery for recurrent symptoms.	*Fones, L., DePascal, M., & Ilyas, A. M. (2024). Use of Nerve Wraps in the Upper Extremity. *Surgical Colectivel, 2*(1). *https://doi.org/10.58616/001c.90454*.
	One additional surgery among 34 decompression procedures. Patient was re-explored for an acute post-operative hematoma related to anti-coagulation.	*Jordaan, P. W., Uhiara, O., & Power, D. (2019). Management of the scarred nerve using porcine submucosa extracellular matrix nerve wraps. *Journal of Musculoskeletal Surgery and Research, 3*, 128-133. *https://doi.org/10.4103/jmsr.jmsr_69_18*.
	There were no re-revision procedures necessary at the latest follow-up (n=12).	*Imran, R., George, S., Jose, R., Shirley, C., & Power, D. M. (2022). Clinical outcomes following neurolysis and porcine collagen extracellular matrix wrapping of scarred nerves in revision carpal tunnel decompression. *Journal of Plastic, Reconstructive, & Aesthetic Surgery, 75*(8), 2802–2808. *https://doi.org/10.1016/j.bjps.2022.04.010*.
Sensory symptoms: Decreased post-operative pain and abnormal sensory sensations	A significant reduction in mean VAS pain score from 9 pre-operatively to 4.5 at post- operative ($p < 0.05$).	*Imran, 2022, *op. cit.*
	Average pain levels (VAS) were significantly reduced ($p<0.001$). Pre-operative range was 7-10; post-operative range was 1-2.	*Papatheodorou, 2015, *op. cit.*
	All patients showed improvement of VAS pain score at the final follow-up (mean 3 years). Pre-operative range was 6-10; post-operative range was 1-3.	*Kokkalis, 2016, *op. cit.*
	All patients showed improvement of hyperesthesia and numbness at the index and middle fingers at final follow-up. Tinel sign was absent and the static two-point discrimination test at the index and middle fingers was 5-9 mm. Mean follow-up was 3 years (range, 0.5 to 5 years).	*Kokkalis, 2016, *op. cit.*
Motor symptoms – Improved hand functionality and strength	Grip strength and pinch strength were both significantly improved ($p<0.001$) from preoperative levels at final follow-up (24-60 mo).	*Papatheodorou, 2015, *op. cit.*

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
	The Impact of Hand Nerve Disorders (I-HaND;Version 2) was used to measure symptom severity and functional limitations. There was a significant post-operative reduction in I-HaND score when compared with pre-operative scores ($p < 0.05$), demonstrating a significant reduction in hand disability.	*Imran, 2022, *op. cit.*
	All patients had delayed latencies and slowed conduction velocities pre-surgery, and all were improved at the final post-surgical follow-up. Mean follow-up was 3 years (range, 0.5 to 5 years).	*Kokkalis, 2016, *op. cit.*
Positive survey symptom severity, functional limitations, and patient satisfaction scores	Patient satisfaction rating for symptom resolution was 79% (range 20–100).	*Imran, 2022, *op. cit.*
Safety - No complications or infections	No foreign body reactions, post-operative infections, or wound complications.	*Papatheodorou, 2015, *op. cit.*
	Complications related to the nerve wrap materials were not observed. Mean follow up was 3 years.	*Kokkalis, 2011, *op. cit.*
	102 patients were analyzed, 35 had revision carpal or cubital tunnel decompression. There were no cases of wrap rejection, extrusion, or infection.	*Fones, 2024, *op. cit.*
	The median follow-up period was 23 months (range 6–36 months). There were no complications related to the use of the Axoguard Nerve Protector™.	*Imran, 2022, *op. cit.*
	No cases of infection, persistent inflammation, or recurrent symptomatic perineural fibrosis.	*Jordaan, 2019, *op. cit.*
Decreased friction between the nerve and surrounding tissue to allow for gliding and minimize potential for soft tissue attachment	Axoguard HA+ Nerve Protector was subjected to 6 months of real time aging, testing for the static CoF. The results found the mean static CoF was 95.01% lower compared to uncoated porcine SIS (t-stat of 11.1506)	Axogen Corporation. (n.d.). *Axoguard HA+ Nerve Protector (Next Generation Protection or NGP) static coefficient of friction (lubricity) test report: Performed following real-time age conditioning of 6 months* [Redacted report].
Device performance – sodium hyaluronate and sodium alginate gel layer and nerve gliding	Axoguard HA+ Nerve Protector features a lubricant layer that resorbs within 4-8 weeks.	Axogen Corporation. (2022, December 1). *Chronic GLP Evaluation of Local Biologic al Response of the Surrounding Muscle Tissue Post-Implantation of Next Generation Protection Device in a Rat Sciatic Nerve Model* [Redacted report].
Motor and Sensory Symptoms – Improved sensory and motor symptoms	After adjusting for baseline characteristics, patients in the wrapped group improved with a significant difference of 0.43 points more than the non-wrapped group (95% CI (0.01–0.86), $p = 0.049$) in terms of the McGowan scores. Wrapped patients scored higher on the Wilson Krout Grade with more excellent/good and less fair/poor outcomes versus the unwrapped group ($p = 0.04$).	*Burahee, A. S., Duraku, L. S., Bosman, R., Shirley, C., van der Oest, M. J. W., Zuidam, M. J., & Power, D. M. (2024). Porcine submucosal extracellular matrix wrapping of the ulnar nerve in revision cubital tunnel surgery. *Journal of Plastic, Reconstructive, & Aesthetic Surgery*, *98*, 176-183.

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Reference Title**
		https://doi.org/10.1016/j.bjps.2024.08.072.

* We note this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.
**The language included in the first two columns is the language the applicant provided to describe its claim and the evidence in support of its claim. The language does not reflect CMS's analysis of the information provided.

After review of the information provided by the applicant, we have the following concerns regarding whether the Axoguard HA+ Nerve Protector™ meets the substantial clinical improvement criterion.

The applicant asserted that the Axoguard HA+ Nerve Protector™ demonstrates clinical improvement in: (1) nerve health in an injured tissue bed through less adhesion, extraneural scarring, and inflammatory markers, (2) nerve health in an injured tissue bed through decreased friction between the nerve and surrounding tissue to allow for gliding and to minimize potential for soft tissue attachment, (3) device performance due to its sodium hyaluronate and sodium alginate gel layer that allows for nerve gliding, and (4) sensory and motor symptoms. We note that the applicant provided redacted internal studies of animal models (Axogen Corporation, 2024; Axogen Corporation, n.d.; Axogen Corporation, 2022) and an abstract (Alsmadi et al., 2025) on Axoguard HA+ Nerve Protector™ in rats. We note that the applicant did not submit studies assessing the Axoguard HA+ Nerve Protector™ in humans. Therefore, we question whether data from animal studies is sufficient to extrapolate to human populations for the purposes of demonstrating substantial clinical improvement.

For the other claims, the applicant provided only background evidence, specifically retrospective studies, which describe findings for a predicate device, the Axoguard Nerve Protector™, which received FDA 510(k) clearance on January 10, 2014, not the nominated device, the Axoguard HA+ Nerve Protector™. We note that the applicant stated that the nominated Axoguard HA+ Nerve Protector™ improved on the predicate device, but the

applicant did not provide any additional information or evidence to support this claim. We also note that the application does not include comparative outcome data between the Axoguard HA+ Nerve Protector™ and its predicate device. We would welcome additional information that compares outcome data from the Axoguard HA+ Nerve Protector™ and the predicate device, the Axoguard Nerve Protector™, to help inform our assessment of whether the Axoguard HA+ Nerve Protector™ demonstrates a substantial clinical improvement.

In addition, we are concerned that the provided evidence does not directly support the applicant's 10 claims that the Axoguard HA+ Nerve Protector™ demonstrates substantial clinical improvement over existing technologies. We note that no evidence was provided comparing the Axoguard HA+ Nerve Protector™ to other currently available treatments for the indicated condition including autologous flaps/fat pads and xenografts or off-the-shelf wraps that include materials sourced from human amniotic membrane, bovine, porcine, and plants. We welcome further evidence that compares the Axoguard HA+ Nerve Protector™ to currently available treatments in the clinical setting where it is most likely to be used. To demonstrate substantial clinical improvement over currently available treatments, we consider supporting evidence, preferably published peer-reviewed clinical trials, that show improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to the standard of care. Additional supporting evidence demonstrating these improved clinical outcomes would help inform our assessment of whether the Axoguard HA+ Nerve Protector™ demonstrates substantial clinical improvement over existing technologies.

We are inviting public comment on whether the Axoguard HA+ Nerve Protector™ meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated

that the Axoguard HA+ Nerve Protector™ would be reported with HCPCS codes as shown in Table 52.

TABLE 52: HCPCS CODES REPORTED WITH THE AXOGUARD HA+ NERVE PROTECTOR™

HCPCS Code	Long Descriptor	SI	APC
64718	Neuroplasty and/or transposition; ulnar nerve at elbow	J1	5431
64721	Neuroplasty and/or transposition; median nerve at carpal tunnel	J1	5431

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant utilized the CY 2025 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5431, which had a CY 2025 payment rate of $1,952.77 at the time the application was received. HCPCS code 64721 in APC 5431 had a device offset amount of $11.52 at the time the application was received. Per the applicant, the average selling price (ASP) of the Axoguard HA+ Nerve Protector™ will fluctuate slightly depending on the overall mix of units sold and contracted prices during a given time period. According to the applicant, the average cost of the Axoguard HA+ Nerve Protector™, which represents the ASP from August 2024 to February 2025, is $3,375.25.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $3,375.25 for the Axoguard HA+ Nerve Protector™ is 172.84 percent of the applicable APC payment amount for the service related to the category of devices of $1,952.77 (($3, 375.25/$1,952.77) x 100 = 172.84 percent). Therefore, we believe that the Axoguard HA+ Nerve Protector™ meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $3,375.25 for the Axoguard HA+ Nerve Protector™ is 29,299.05 percent of the cost of the device-related portion of the APC payment amount for the related service of $11.52 (($3,375.25/$11.52) x 100 = 29,299.05percent). Therefore, we believe that the Axoguard HA+ Nerve Protector™ meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $3,375.25 for the Axoguard HA+ Nerve Protector™ and the portion of the APC payment amount for the device of $11.52 is 172.25 percent of the APC payment amount for the related service of $1,952.77 (((($3,375.25 - $11.52)/$1,952.77) x 100 = 172.25 percent). Therefore, we believe that the Axoguard HA+ Nerve Protector™ meets the third cost significance requirement.

We are inviting public comment on whether the Axoguard HA+ Nerve Protector™ meets the cost criterion at § 419.66(c)(3).

(b) LithoVue™ Elite Digital Flexible Ureteroscope System with Pressure Monitoring

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for the LithoVue™ Elite Digital Flexible Ureteroscope System with Pressure Monitoring (the LithoVue™ Elite System) for CY 2026. Per the applicant, the LithoVue™ Elite System consists of a single-use, disposable flexible ureteroscope (the LithoVue™ Elite Ureteroscope) and a workstation (the StoneSmart Connect Console), that provide real-time intraluminal pressure monitoring in the kidney and ureter during ureteroscopy

and can be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract. The applicant stated that the distal tip of the LithoVue™ Elite Ureteroscope's shaft includes the working channel, the illumination optics, the digital imaging sensor, and a Micro-Electro-Mechanical Systems (MEMS) pressure sensor for monitoring the real-time intraluminal pressure during ureteroscopy.

The applicant is only seeking a new device category for transitional pass-through payment status for the LithoVue™ Elite Ureteroscope, a component of the LithoVue™ Elite System.

Please refer to the online application posting for the LithoVue™ Elite Digital Flexible Ureteroscope System with Pressure Monitoring, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP2503038TF22.*

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), FDA granted the applicant 510(k) clearance for the LithoVue™ Elite System on February 2, 2023. The approved FDA indication for the LithoVue™ Elite System is:

● To be used to visualize organs, cavities, and canals in the urinary tract (urethra, bladder, ureter, calyces and renal papillae) via transurethral or percutaneous access routes. It can also be used in conjunction with endoscopic accessories to perform various diagnostic and therapeutic procedures in the urinary tract.

On July 1, 2024, FDA granted the applicant Special 510(k) clearance for the LithoVue™ Elite Ureteroscope (with pressure monitoring) with a redesigned distal tip to improve its durability during a ureteroscopy for this same indication. We received the application for a new device category for transitional pass-through payment status for the LithoVue™ Elite System on March 3, 2025, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the LithoVue™ Elite System meets the newness criterion at § 419.66(b)(1).

As previously noted, the applicant is only seeking a new device category for transitional pass-through payment status for the LithoVue™ Elite Ureteroscope component of the LithoVue™ Elite System, and as such, the eligibility and exclusion criteria will evaluate LithoVue™ Elite Ureteroscope.

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the LithoVue™ Elite Ureteroscope meets the requirements at § 419.66(b)(3).

With respect to the LithoVue™ Elite Ureteroscope, we question whether the MEMS pressure sensor is integral to the service furnished. In the CY 2014 OPPS final rule with comment period (78 FR 75005), we stated that we have interpreted "integral" to mean that the device is necessary to furnish or deliver the primary procedure with which it is used. For example, a pacemaker is integral to the procedure of implantation of a pacemaker. Per the applicant, the LithoVue™ Elite Ureteroscope differs from other currently available ureteroscopes, because the device includes the MEMS pressure sensor which is located at the distal tip of the ureteroscope and enables continuous, real-time monitoring of intrarenal pressure (IRP) during ureteroscopy. We note that neither the FDA 510(k) indication nor the FDA Special 510(k) indication include the MEMS pressure sensor, and the cleared indications appear to be consistent with the indications for other FDA approved ureteroscopes. In addition, as discussed in more detail in the § 419.66(c)(2) discussion below, we question whether there is sufficient evidence to support the assertion that continuous pressure monitoring is necessary and/or required to furnish or deliver the primary procedure (ureteroscopy) with which it is used. While we do not question whether the ureteroscope itself is integral to the service furnished, we question whether the MEMS pressure sensor, the mechanism which the applicant asserts is the distinguishing feature of the LithoVue™ Elite Ureteroscope, is integral to the service furnished

in accordance with § 419.66(b)(3), because pressure monitoring during ureteroscopy procedures appears to be purely additive and not necessary to furnish the ureteroscopy.

We are inviting public comments on whether the LithoVue™ Elite Ureteroscope meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, the LithoVue™ Elite Ureteroscope, the component nominated in this application, is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and (2) not a material or supply furnished incident to a service, and therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether the LithoVue™ Elite Ureteroscope meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the existing pass-through code C1747 (Endoscope, single-use (i.e., disposable), urinary tract, imaging/illumination device (insertable)) does not appropriately describe the LithoVue™ Elite Ureteroscope because the category description does not include the LithoVue™ Elite Ureteroscope's pressure monitoring feature. The applicant also stated that the existing pass-through code C2624 (Implantable

wireless pulmonary artery pressure sensor with delivery catheter, including all system components) does not appropriately describe the LithoVue™ Elite Ureteroscope because the nominated device is an insertable ureteroscope that measures IRP, whereas C2624 is specific to sensors that measure pulmonary artery pressure.

We note that, based on the description the applicant provided, the LithoVue™ Elite Ureteroscope is a single use, disposable ureteroscope inserted into the urinary tract for imaging and illumination, and thus, could be appropriately described by C1747. Specifically, we believe that C1747 may appropriately describe the LithoVue™ Elite Ureteroscope because it describes any device that is a single-use (i.e., disposable) endoscope with imaging/illumination capabilities intended for use in the urinary tract to perform ureteroscopy procedures. We note that the descriptor for C1747 does not reference device features that would exclude the inclusion of a pressure monitoring feature. Further, we note that the HCPCS procedure codes with which the applicant has stated the LithoVue™ Elite Ureteroscope would be reported are consistent with the HCPCS codes approved for C1747. In this context, we believe that the LithoVue™ Elite Ureteroscope may be similar to the devices described by C1747, and therefore, the LithoVue™ Elite Ureteroscope may also be appropriately described by C1747.

We are inviting public comment on whether the LithoVue™ Elite Ureteroscope meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the

Breakthrough Device designation. The applicant asserted that the LithoVue™ Elite Ureteroscope represents a substantial clinical improvement over existing technologies because it addresses a critical unmet need by providing a novel feature to continuously measure real-time IRP during urological surgeries. According to the applicant, IRP management during ureteroscopy is a vitally important patient safety consideration. Per the applicant, irrigation of the renal collecting system during ureteroscopy is essential for maintaining a clear field of view, which is crucial for effective kidney stone treatment; however, the use of irrigation to enhance visibility typically increases IRP. The applicant stated that dangerous IRP elevations can occur without immediate warning signs, with symptoms often emerging only after significant physiological damage has taken place. The applicant further asserted that a prolonged increase in IRP can lead to complications both during and post procedure.

The applicant provided nine background documents to support these claims, which include six studies and three sets of clinical guidelines. The applicant's assertions regarding the substantial clinical improvement criterion are shown in Table 53. Please see the online posting for the LithoVue™ Elite System for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

TABLE 53: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support**	**Supporting evidence provided by the applicant****	**Reference Title**
Allows physicians to identify and address elevated IRP, which has been shown to be associated with post-surgical complications.	Several complications of retrograde intrarenal surgery (RIRS) are related to elevated IRPs, which cause pyelorenal backflow and forniceal rupture. Irrigation flow and pressure dynamics drive IRP changes during RIRS. Awareness of these factors will allow urologists to institute strategies to mitigate IRP during RIRS, thereby reducing complications and improving patient outcomes.	*John, J., Wisniewski, P., Fieggen, G., Kaestner, L., & Lazarus, J. (2024, January). Intrarenal pressure in retrograde intrarenal surgery: a narrative review. *Urology, 195*, 201-209. *https://doi.org/10.1016/j.urology.2024.09.026*.
Addresses unmet need to intraoperatively monitor IRP.	IRP increases during upper tract endourology remains a neglected predictor of complications, including pyelorenal backflow, sepsis, and renal damage, and intraoperative monitoring should be taken into consideration. The LithoVue™ System with pressure monitoring allows physicians to perform recommended monitoring.	*Tokas, T., Herrmann, T. R., Skolarikos, A., Nagele, U., & Training and Research in Urological Surgery and Technology (TRUST)-Group. (2019). Pressure matters: intrarenal pressures during normal and pathological conditions, and impact of increased values to renal physiology. *World Journal of Urology, 37*(1), 125-131. *https://doi.org/10.1007/s00345-018-2378-4*.
Enables surgeons to follow American Urological Association (AUA) guidelines recommending use of measure to minimize IRP.	The 2016 AUA guidelines identify risks associated with increased IRP and recommend maintaining low pressure. The LithoVue™ System with pressure monitoring enables a physician to monitor IRP, and therefore, be able to follow the guideline recommendations of taking measures to maintain low IRP.	*Assimos, D., Krambeck, A., Miller, N. L., Monga, M., Murad, M. H., Nelson, C. P., Pace, K. T., Pais, V. M., Pearle, M. S., Preminger, G. M., Razvi, H., Shah, O., & Matlaga, B. R. (2016, April). *Surgical management of stones: American Urological Association/Endourological Society Guideline.* American Urological Association. *https://www.auanet.org/documents/education/clinical-guidance/Surgical-Management-of-Stones.pdf.*
Enables surgeons to follow international guidelines for RIRS recommending use of measures to maintain low IRP.	The International Alliance of Urolithiasis recommends taking steps to minimize intraoperative IRP to reduce the risk of bleeding and infectious complications during	*Zeng, G., Traxer, O., Zhong, W., Osther, P., Pearle, M. S., Preminger, G. M., ... & Sarica, K. (2022a). International Alliance of Urolithiasis guideline on retrograde intrarenal surgery. *BJU International, 131*(2), 153-164. *https://doi.org/10.1111/bju.15836.*

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support**	**Supporting evidence provided by the applicant****	**Reference Title**
	RIRS. The LithoVue™ System with pressure monitoring is the only device that allows physicians to monitor IRP and follow the guidelines to limit IRP during RIRS.	
Enables surgeons to follow international guidelines for percutaneous nephrolithotomy (PCNL) recommending use of measures to maintain low IRP.	The European Association of Urology and International Alliance of Urolithiasis consensus guidelines for PCNL identifies maintenance of low intrarenal pressure is an important technical requirement to ensure the safety and efficiency of PCNL. The LithoVue™ Elite Ureteroscope with pressure monitoring is the only endoscope that allows the physician to monitor the IRP and follow the recommendation to maintain low intraoperative pressure.	*Zeng, G., Zhong, W., Pearle, M., Choong, S., Chew, B., Skolarikos, A., ... & Sarica, K. (2022b). European Association of Urology Section of Urolithiasis and International Alliance of Urolithiasis Joint Consensus on Percutaneous Nephrolithotomy. *European Urology Focus, 8*(2), 588-597. *https://doi.org/10.1016/j.euf.2021.03.008.*
Elevated IRP has been shown to be associated with complications following endourological procedures.	This systematic review assessed the relationship between IRP and complications during endourological procedures. Peak IRP above 30 mmHg or mean IRP above 20 mmHg for >10 minutes are associated with higher risks of infection, renal damage, and systemic inflammatory response. The findings highlight the importance of monitoring and optimizing IRP to minimize adverse outcomes during endourological procedures.	*Chew, B. H., Jung, H. U., Emiliani, E., Miller, L. E., Miller, A. L., & Bhojani, N. (2023, November). Complication risk of endourological procedures: the role of intrarenal pressure. *Urology, 181*, 45-47. *https://doi.org/10.1016/j.urology.2023.08.011.*
Almost all Medicare beneficiaries have at least one risk factor for adverse outcomes following ureteroscopy.	This 2025 real world database research using 290,610 Medicare patients, identified several risk factors associated with sepsis and intensive care unit admission within 30 days of ureteroscopy procedure: age over 70,	*Monga, M., Sato, R., White, J., Mehendale, S., Boulmani, M., Mashruwala, H., & Traxer, O. (2025). Risk Factors for Adverse Outcomes Following Ureteroscopy for Stone Management in US Medicare Patients [Article in press]. *Urology*. *https://doi.org/10.1016/j.urology.2025.02.021.*

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support**	**Supporting evidence provided by the applicant****	**Reference Title**
	preoperative stent, diabetes, urinary tract infection, and others. More than 94% of patients had at least one risk factor indicating targeted prevention and careful monitoring and management are warranted to minimize risk of sepsis.	
Sepsis after ureteroscopy increases the risk of 30-day inpatient mortality, intensive care unit (ICU) and hospital admission, and hospital readmission.	This large real world evidence research with 109,496 adults aged 18 to 64 years undergoing ureteroscopy showed 5.6% incidence of sepsis, which increased the risk of 30-day inpatient mortality, ICU and hospital admission, and hospital readmission. Moreover, the incidence of sepsis after ureteroscopy increased over time.	*Bhojani, N., Eisner, B., Monga, M., Paranjpe, R., Cutone, B., & Chew, B. H. (2023). Sepsis prevalence and associated hospital admission and mortality after ureteroscopy in employed adults. *BJU International, 132*(2), 210-216. *https://doi.org/10.1111/bju.16029.*
Age is a risk factor for postoperative urosepsis.	Evidence obtained in this research suggests that among patients undergoing ureteroscopy for treatment of stone disease, the risk of postoperative urosepsis was 5.0%. Older age, diabetes mellitus, ischemic heart disease, preoperative stent placement, a positive urine culture, and longer procedure time were associated with increased postoperative urosepsis risk.	*Bhojani, N., Miller, L. E., Bhattacharyya, S., Cutone, B., & Chew, B. H. (2021). Risk factors for urosepsis after ureteroscopy for stone disease: a systematic review with meta-analysis. *Journal of Endourology, 35*(7), 991-1000. *https://doi.org/10.1089/end.2020.1133.*

*We note this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.
**The language included in the first two columns is the language the applicant provided to describe its claim and the evidence in support of its claim. The language does not reflect CMS's analysis of the information provided.

After review of the information provided by the applicant, we have the following concerns regarding whether the LithoVue™ Elite Ureteroscope meets the substantial clinical improvement criterion.

First, we note that none of the studies provided by the applicant directly evaluate, assess, or review the LithoVue™ Elite Ureteroscope or any clinical outcomes associated with use of the nominated device. Rather, the applicant provided background documents that reference IRP monitoring in general and the potential risks associated with increased IRP during ureteroscopy procedures. While the background information provided is relevant to the assertion that IRP management during ureteroscopy is an important patient safety consideration, the evidence provided does not directly support the applicant's claim that utilization of the LithoVue™ Elite Ureteroscope during ureteroscopy procedures demonstrates a substantial clinical improvement over existing technologies because it addresses a critical unmet need of continuous IRP monitoring. Further, the applicant appears to rely on the assumption that use of the LithoVue™ Elite Ureteroscope's continuous real-time pressure monitoring correlates to a low IRP and reduced post-operative complications, but the submitted information does not support these assertions. Rather, the applicant provided evidence which seems to rely on indirect inferences from other sources of data that do not include the use of the nominated device. In addition, the evidence shows that adverse events and complications, including sepsis, may generally result from ureteroscopy and these risks may be higher in the Medicare population. We would welcome additional evidence that directly evaluates the clinical outcomes associated with the use of the LithoVue™ Elite Ureteroscope with continuous IRP monitoring during ureteroscopy procedures.

Second, while the applicant indicated that there are other single-use, disposable flexible ureteroscopes available on the market, such as the LithoVue™ Ureteroscope, Uretero1™ Ureteroscope System, and Ambu® aScope™ 5 Ureteroscope, the documents submitted lack direct comparison of the nominated device to other similar devices and do not directly show any clinical improvement that results from the use of the nominated device compared to the use of other devices. In order to demonstrate substantial clinical improvement over currently available ureteroscope options, we favor supporting evidence, preferably published peer-reviewed clinical

trials, that shows improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process comparing use of ureteroscopes with continuous pressure monitoring capability to use of ureteroscopes without continuous pressure monitoring capability. Further, we note that FDA determined that the LithoVue™ Elite Ureteroscope is substantially equivalent to the earlier, predicate device that the applicant had previously legally marketed. The FDA 510(k) summary indicated that both devices, the nominated and predicate, share similar technological characteristics, such as illumination source, a digital complementary metal oxide semiconductor imager, and raw image data. Furthermore, the 510(k) summary indicated that both devices have the same technical characteristics, including the working channel size, shaft working length, sterilization agent, imager type and location, mechanical specifications, and optical specifications. The only noted difference between the two devices is that the nominated LithoVue™ Elite Ureteroscope has continuous real-time IRP monitoring capability. Additional supporting evidence, preferably published peer-reviewed clinical trials, that shows these improved clinical outcomes would help inform our assessment of whether the LithoVue™ Elite Ureteroscope demonstrates substantial clinical improvement over existing technologies.

Third, the applicant provided three review articles highlighting that IRP monitoring during endourological procedures may potentially mitigate risks; three clinical guidelines that identify the risks associated with increased IRP and recommend maintaining low IRP for safety; and two retrospective studies and a meta-analysis presenting the common post-procedure risks of ureteroscopy, including sepsis. While the articles and studies affirm that increased IRP may be harmful, we note that the totality of the evidence provided does not establish that continuous real-time, routine IRP monitoring during ureteroscopy is mandatory or should be the standard of

care for ureteroscopies.[31,32,33] None of the three submitted clinical guidelines establish specific procedural IRP metrics, recommend continuous real-time IRP measurement during ureteroscopy, or suggest that continuous real-time IRP measurement should be adopted as the standard of care. Further, we note that the clinical relevance remains questionable and the utility of continuous real-time IRP monitoring is limited, as it is currently primarily used in clinical research as opposed to everyday clinical practice.[34] As such, it is not clear that use of continuous real-time interoperative IRP monitoring during ureteroscopy procedure represents a substantial clinical improvement.

Additionally, although the negative consequences of elevated IRP are accepted, the pressure levels at which these negative outcomes occur are not clearly defined. While not included in the evidence submitted by the applicant in support of the substantial clinical improvement claims for LithoVue™ Elite Ureteroscope, we note that three studies, Ho & Sivalingam (2023), Somani et al. (2025), and Bhojani et al. (2023), provide notable evidence directly related to IRP monitoring during ureteroscopy.[35,36,37] Ho & Sivalingam (2023) discusses AUA clinical guidelines that recommend maintaining low intrarenal irrigation pressure to avoid negative consequences of high IRP during endourological procedures. This article notes several ways to mitigate elevated IRP in addition to use of pressure sensing ureteroscopes, such as the

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[31] John, J., Wisniewski, P., Fieggen, G., Kaestner, L., & Lazarus, J. (2024, January). Intrarenal pressure in retrograde intrarenal surgery: a narrative review. *Urology, 195,* 201-209. *https://doi.org/10.1016/j.urology.2024.09.026*.

[32] Tokas, T., Herrmann, T. R., Skolarikos, A., Nagele, U., & Training and Research in Urological Surgery and Technology (TRUST)-Group. (2019). Pressure matters: intrarenal pressures during normal and pathological conditions, and impact of increased values to renal physiology. *World Journal of Urology, 37*(1), 125-131. *https://doi.org/10.1007/s00345-018-2378-4.*

[33] Chew, B. H., Jung, H. U., Emiliani, E., Miller, L. E., Miller, A. L., & Bhojani, N. (2023, November). Complication risk of endourological procedures: the role of intrarenal pressure. *Urology,* 181, 45-47. *https://doi.org/10.1016/j.urology.2023.08.011*.

[34] Ho, L., & Sivalingam, Sri. (2023, December 15). *What Is the True Value of Intrarenal Pressure Monitoring During Endourologic Procedures?* AUANews. *https://auanews.net/issues/articles/2023/december-extra-2023/what-is-the-true-value-of-intrarenal-pressure-monitoring-during-endourologic-procedures*.

[35] Ho, 2023, *op cit.*

[36] Somani, B., Davis, N., Emiliani, E., Göcke, M. I., Junge, H., Keller, E. X., Miernik, A., Proietti, S., Turney, B., Wiseman, O., Bosworth Smith, A., Caterino, M., Saunders, R., Boulmani, M., & Traxer, O. (2025). Intrarenal pressure monitoring during ureteroscopy: A Delphi panel consensus. European Urology Open Science, 73, 43–50. *https://doi.org/10.1016/j.euros.2025.01.005*.

[37] Bhojani, N., Koo, K. C., Bensaadi, K., Halawani, A., Wong, V. K., & Chew, B. H. (2023). Retrospective first-in-human use of the LithoVue™ Elite Ureteroscope to measure intrarenal pressure. *BJU International,* 132(6), 678-685. *https://doi.org/10.1111/bju.16173*.

LithoVue™ Elite Ureteroscope. Ho & Sivalingam (2023) further states that the clinical usefulness of IRP-monitoring technology is yet to be determined. Somani et al. (2025) details the findings of a Delphi panel assembled by the European Association of Urologists. The panel did not come to a consensus on a safe or acceptable IRP threshold during endourological procedures. Bhojani et al. (2023) established that a ureteroscope with pressure monitoring, such as the LithoVue™ Elite Ureteroscope, can be used to better understand the role of IRP during retrograde intrarenal surgery. Yet, these articles highlight that there is no consensus on the IRP levels or duration that may negatively impact patients, therefore questioning whether it is clinically relevant to continuously measure IRP in real-time. We again note that no evidence was presented on the current standard of care in regard to continuous monitoring of IRP levels during ureteroscopy. Without this information, it is unclear if the clinical outcomes of a patient population would improve as a result of the LithoVue™ Elite Ureteroscope's continuous IRP monitoring during ureteroscopy procedures.

Additionally, we note that, based on the language in the application, it is our understanding that continuous real-time pressure monitoring may only be relevant in kidney stone procedures. We would be interested in evidence and further information on other procedures where pressure is continuously monitored during ureteroscopy.

We question whether the evidence submitted by the applicant demonstrates that the use of continuous real-time intraoperative IRP monitoring by a ureteroscope offers a substantial clinical improvement over currently available treatments.

We are inviting public comment on whether the LithoVue™ Elite Ureteroscope meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section 419.66(d) includes three cost significance criteria that must each be met. The applicant stated

that the LithoVue™ Elite Ureteroscope would be reported with HCPCS codes in the codes as shown in Table 54.

TABLE 54: HCPCS CODES REPORTED WITH THE LITHOVUE™ ELITE URETEROSCOPE

HCPCS Code	Long Descriptor	SI	APC
50575	Renal endoscopy through nephrotomy or pyelotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with endopyelotomy (includes cystoscopy, ureteroscopy, dilation of ureter and ureteral pelvic junction, incision of ureteral pelvic junction and insertion of endopyelotomy stent)	J1	5375
50951	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service;	J1	5374
50953	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter	J1	5374
50955	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureter pyelography, exclusive of radiologic service; with biopsy	J1	5375
50961	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureter pyelography, exclusive of radiologic service; with removal of foreign body or calculus	J1	5375
50970	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service;	J1	5374
50972**	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with ureteral catheterization, with or without dilation of ureter	J1	5374
50974	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with biopsy	J1	5375
50976	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	J1	5375
50980	Ureteral endoscopy through ureterotomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus	J1	5375
52344	Cystourethroscopy with ureteroscopy; with treatment of ureteral stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52345	Cystourethroscopy with ureteroscopy; with treatment of ureteropelvic junction stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5374
52346	Cystourethroscopy with ureteroscopy; with treatment of intra-renal stricture (eg, balloon dilation, laser, electrocautery, and incision)	J1	5375
52351	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; diagnostic	J1	5374
52352	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	J1	5374
52353	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)	J1	5375
52354	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with biopsy and/or fulguration of ureteral or renal pelvic lesion	J1	5375
52355	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with resection of ureteral or renal pelvic tumor	J1	5375

HCPCS Code	Long Descriptor	SI	APC
52356	Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, Gibbons or double-J type)	J1	5375
C9761	Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with lithotripsy, and ureteral catheterization for steerable vacuum aspiration of the kidney, collecting system, ureter, bladder, and urethra if applicable (must use a steerable ureteral catheter)	J1	5376
50957[38]	Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureter pyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy	J1	5375
50080	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; simple (eg, stone[s] up to 2 cm in single location of kidney or renal pelvis, nonbranching stones)	J1	5376
50081	Percutaneous nephrolithotomy or pyelolithotomy, lithotripsy, stone extraction, antegrade ureteroscopy, antegrade stent placement and nephrostomy tube placement, when performed, including imaging guidance; complex (eg, stone[s] > 2 cm branching stones, stones in multiple locations, ureter stones, complicated anatomy)	J1	5376

** Denotes a HCPCS code that was not included in the Addendum P to the CY 2025 OPPS/ASC final rule with comment period, and therefore, had no CY 2025 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. Since not all of the HCPCS/CPT codes provided by the applicant had a CY 2025 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2025 HCPCS/CPT code level device offset amount for the HCPCS codes included in Addendum P and listed in Table 54 to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level (81 FR 79657). We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5374, which had a CY 2025 payment rate of $3,448.97 at the time the application was received. HCPCS code 50970 in APC 5374 had a

[38] We noted that the applicant stated the LithoVue™ Elite Ureteroscope would be reported with HCPCS code 50597, with the HCPCS code long descriptor being "Ureteral endoscopy through established ureterostomy, with or without irrigation, instillation, or ureter pyelography, exclusive of radiologic service; with fulguration and/or incision, with or without biopsy". We believe the HCPCS code the applicant provided was incorrect, and the correct HCPCS code that is associated with the HCPCS code long descriptor is HCPCS code 50957.

device offset amount of $192.45 at the time the application was received. According to the applicant, the cost of the LithoVue™ Elite Ureteroscope is $2,400.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $2,400.00 for the LithoVue™ Elite Ureteroscope is 69.59 percent of the applicable APC payment amount for the service related to the category of devices of $3,448.97 (($2,400.00/$3,448.97) x 100 = 69.59 percent). Therefore, we believe that the LithoVue™ Elite Ureteroscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $2,400.00 for the LithoVue™ Elite Ureteroscope is 1,247.08 percent of the cost of the device-related portion of the APC payment amount for the related service of $192.45 (($2,400.00/$192.45) x 100 = 1,247.08 percent). Therefore, we believe that the LithoVue™ Elite Ureteroscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $2,400.00 for the LithoVue™ Elite Ureteroscope and the portion of the APC payment amount for the device of $192.45 is 64.01 percent of the APC payment amount for the related service of $3,448.97 (((($2,400.00 - $192.45)/$3,448.97) x 100 = 64.01 percent). Therefore, we believe that the LithoVue™ Elite Ureteroscope meets the third cost significance requirement.

We are inviting public comment on whether the LithoVue™ Elite Ureteroscope meets the cost criterion at § 419.66(c)(3).

(c) VersaVue™ Single-Use Flexible Cystoscope

Boston Scientific Corporation submitted an application for a new device category for transitional pass-through payment status for the VersaVue™ Single-Use Flexible Cystoscope for CY 2026. Per the applicant, the VersaVue™ Single-Use Flexible Cystoscope is used in cystoscopy procedures to diagnose or treat diseases of the lower urinary tract. According to the applicant, the VersaVue™ Single-Use Flexible Cystoscope is a single-use, disposable flexible cystoscope intended to be operated with its compatible display system, the VersaVue™ Tablet (a tablet where the image is present directly on the tablet) or the VersaVue™ Video Box (a standalone imaging transfer system which can be connected to a computer to project live imaging), that provides live imaging of the lower urinary tract.

Please refer to the online application posting for the VersaVue™ Single-Use Flexible Cystoscope, available at *https://mearis.cms.gov/public/publications/device-ptp/DEP250211C4HRV*.

As stated previously, to be eligible for transitional pass-through payment under the OPPS, a device must meet the criteria at § 419.66(b)(1) through (4). With respect to the newness criterion at § 419.66(b)(1), FDA granted the applicant 510(k) clearance for the VersaVue™ Single-Use Flexible Cystoscope on October 6, 2023. The approved FDA indication for the VersaVue™ Single-Use Flexible Cystoscope is:

- The VersaVue™ Single-Use Flexible Cystoscope is a sterile, single-use, and flexible device intended to be operated with its compatible display system (VersaVue™ Tablet or VersaVue™ Video Box). The device provides endoscopic procedure and surgical treatment within the lower urinary tract. The Cystoscope is intended to provide visualization via [the] displaying unit. The Cystoscope is intended for use in a hospital environment or medical office environment. It is designed for use in adults.

We received the application for a new device category for transitional pass-through payment status for the VersaVue™ Single-Use Flexible Cystoscope on February 11, 2025, which is within 3 years of the date of the initial FDA marketing authorization.

We are inviting public comments on whether the VersaVue™ Single-Use Flexible Cystoscope meets the newness criterion at § 419.66(b)(1).

With respect to the eligibility criteria at § 419.66(b)(3), the device must be an integral part of the service furnished, be used for one patient only, come in contact with human tissue, and be surgically inserted or implanted, or applied in or on a wound or other skin lesion. Per the applicant, the VersaVue™ Single-Use Flexible Cystoscope meets the requirements at § 419.66(b)(3).

We are inviting public comments on whether the VersaVue™ Single-Use Flexible Cystoscope meets the eligibility criterion at § 419.66(b)(3).

With respect to the exclusion criteria at § 419.66(b)(4), a device is not eligible to be considered for pass-through payment if it is any of the following: (1) equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or (2) a material or supply furnished incident to a service (for example, a suture, customized surgical kit, or clip, other than a radiological site marker). Per the applicant, the VersaVue™ Single-Use Flexible Cystoscope is (1) not considered equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciation assets, and is (2) not a material or supply furnished incident to a service, and, therefore, is eligible to be considered for pass-through payment.

We are inviting public comments on whether the VersaVue™ Single-Use Flexible Cystoscope meets the exclusion criterion at § 419.66(b)(4).

In addition to the criteria at § 419.66(b)(1) through (4), the criteria for establishing new device categories are specified at § 419.66(c). The first criterion, at § 419.66(c)(1), provides that CMS determines that a device to be included in the category is not appropriately described by any of the existing categories or by any category previously in effect, and was not being paid for as an outpatient service as of December 31, 1996. Per the applicant, the existing pass-through code C1747 (Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)) does not appropriately describe the VersaVue™ Single-Use Flexible Cystoscope because cystourethroscopy procedures are not encompassed by this pass-through device category.[39] The applicant also stated that the existing code C1889 (Implantable/insertable device, not otherwise classified) does not appropriately describe the VersaVue™ Single-Use Flexible Cystoscope. We note that C1889 is not a device pass-through category code and therefore would not describe the VersaVue™ Single-Use Flexible Cystoscope for the purposes of device pass-through status. Upon review, we have not identified an existing pass-through payment category that describes the VersaVue™ Single-Use Flexible Cystoscope.

We are inviting public comment on whether the VersaVue™ Single-Use Flexible Cystoscope meets the device category criterion at § 419.66(c)(1).

The second criterion for establishing a device category, at § 419.66(c)(2), provides that CMS determines either of the following: (1) that a device to be included in the category has demonstrated that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device or devices in a previously established category or other available treatment; or (2) for devices for which pass-through status will begin on or after January 1, 2020, as an alternative to the

[39] As discussed in section IV.A.2 (New Device Pass-Through Applications for CY 2023) of the CY 2023 OPPS/ASC final rule with comment period, we approved HCPCS code C1747 (Endoscope, single-use (i.e. disposable), urinary tract, imaging/illumination device (insertable)), as a new device category for pass-through status under the OPPS, with an effective date of January 1, 2023. For the full discussion on the criteria used to evaluate device pass-through applications, refer to the CY 2023 OPPS/ASC final rule with comment period, which was published in the **Federal Register** on November 23, 2022 (87 FR 71929 through 71934). We note that HCPCS code C1747 was established for a ureteroscope that can only be used for a single procedure and cannot be reprocessed. As such, HCPCS code C1747 only describes devices that cannot be reprocessed.

substantial clinical improvement criterion, the device is part of the FDA's Breakthrough Devices Program and has received FDA marketing authorization for the indication covered by the Breakthrough Device designation. The applicant asserted that single-use, disposable cystoscopes, including the VersaVue™ Single-Use Flexible Cystoscope, represent a substantial clinical improvement of over reusable cystoscopes.

The applicant provided five documents to support these claims, which include three studies and two FDA communications concerning reusable, reprocessed urological endoscopes. The applicant's assertions regarding the substantial clinical improvement criterion are shown in Table 55. Please see the online posting for the VersaVue™ Single-Use Flexible Cystoscope for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

TABLE 55: SUBSTANTIAL CLINICAL IMPROVEMENT ASSERTIONS

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support**	**Supporting evidence provided by the applicant****	**Reference Title**
Use of disposable cystoscopes decreases post-procedure encounters and infections compared to reusable cystoscopes.	A urology practice evaluated the impact of converting cystoscopy procedures over to disposable cystoscopes by comparing post-procedure encounter and infection rates using disposable cystoscopes with those using reusable cystoscopes. The authors reviewed 1,000 cases (494 with a reusable scope, 506 with a disposable scope) and found substantial and statistically significant reductions in both outcomes for cases using disposable scopes.	*Geldmaker, L. E., Baird, B. A., Lyon, T. D., Regele, E. J., Wajswol, E. J., Pathak, R. A., Petrou, S. P., Haehn, D. A., Gajarawala, N. M., Ball, C. T., Broderick, G. A., & Thiel, D. D. (2023). Conversion to disposable cystoscopes decreased post-procedure encounters and infections compared to reusable cystoscopes. *Urology Practice, 12*(1), 58-64. *https://doi.org/10.1097/UPJ.0000000000000410.*
Single-use cystoscopes avoid post-cystoscopy infections and device malfunctions documented with use of reprocessed cystoscopes.	The authors reviewed 335 adverse events reported to the MAUDE database related to reusable flexible cystoscopes. Infection (n=124) was the leading cause of adverse events associated with patient harm, followed by mechanical malfunction (n=6), and allergic reaction (n=1). Of the patients with infections, 19 developed sepsis, one was admitted to the ICU and one died. Of the patients experiencing mechanical malfunction, four experienced device entrapment requiring surgery.	*Lee, J., Kaplan-Marans, E., Jivanji, D., Tennenbaum, D., & Schulman, A. (2022). Post-cystoscopy infections and device malfunctions in reprocessed flexible cystoscopes in a national database. *Canadian Journal of Urology, 29*(6), 11361-11365. *https://pubmed.ncbi.nlm.nih.gov/36495577.*
Use of disposable scopes would avoid contamination	Muscarella reviewed MAUDE reports for endoscopes from 2014 through 2021. He found that the number of adverse event	*Muscarella, L. F. (2022, January 28). Contamination of flexible endoscopes and associated

Substantial Clinical Improvement Assertion: The device demonstrates that it will substantially improve the diagnosis or treatment of an illness or injury or improve the functioning of a malformed body part compared to the benefits of a device(s) in a category or other available treatment		
Applicant statements in support**	**Supporting evidence provided by the applicant****	**Reference Title**
problems associated with reusable devices.	reports for urological endoscopes, including cystoscopes, increased by more than 2000% over the seven year period. Several bacterial outbreaks were linked to urological endoscopes. The study concludes that findings suggest healthcare providers should consider "the use of a single-use urological endoscope (if and/or when available and as warranted).	infections: A comprehensive review and analysis of FDA adverse event reports. *Discussions in Infection Control. https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/.*
Use of disposable cystoscope eliminates need for reprocessing as recommended by FDA.	FDA announcement of numerous reports of patient infections and possible contamination issues with reprocessing urological endoscopes, including cystoscopes. The reports include a patient death involving a cystoscope that did not pass a leak test, indicating damage to the device, that could have been an underlying factor in the infection. Use of single use, disposable devices eliminates the need for reprocessing. FDA has encouraged manufacturers to transition to such devices.	*U.S. Food and Drug Administration. (2021, April 1). *FDA is investigating reports of infections associated with reprocessed urological endoscopes: Agency is taking action to remind health care providers about the proper way to clean certain devices for reuse.* [FDA News Release]. *https://www.fda.gov/news-events/press-announcements/fda-investigating-reports-infections-associated-reprocessed-urological-endoscopes*.
Use of disposable cystoscopes avoids risk of infection associated with improper reprocessing.	FDA notified the public about a recall related to the risk of infection from improper reprocessing of the MAJ-891 Forceps/Irrigation Plug. The manufacturer of the device reported 120 injuries and 1 death due to infection following procedures in which the MAJ-891 was used with a cystoscope. Use of a disposable cystoscope, which requires no reprocessing, avoids the risk of this type of infection.	*U.S. Food and Drug Administration. (2025, January 31). *Update on alert: Endoscope accessories forceps/irrigation plug issue from Olympus*. *https://www.fda.gov/medical-devices/medical-device-recalls/update-alert-endoscope-accessories-forcepsirrigation-plug-issue-olympus*.

*We note this source does not assess, evaluate, or review the nominated device and only provides background information in support of the applicant's claims of substantial clinical improvement.
**The language included in the first two columns is the language the applicant provided to describe its claim and the evidence in support of its claim. The language does not reflect CMS's analysis of the information provided.

After review of the information provided by the applicant, we have the following concerns regarding whether the VersaVue™ Single-Use Flexible Cystoscope meets the substantial clinical improvement criterion.

Overall, we note that the applicant indicated that the technology does not offer a treatment option for patients unresponsive to or ineligible for currently available treatments, stating that the same patient population could be treated using a reusable, reprocessed cystoscope. Further, the applicant did not claim that the nominated device, the VersaVue™ Single-Use Flexible Cystoscope, offers a substantial clinical improvement over other single-use,

disposable cystoscopes available on the market. Specifically, the applicant stated that no claim is being made that a specific disposable device offers a substantial clinical improvement over other disposable devices in the same category. Rather, the applicant stated that it presented evidence to support its claim that single-use, disposable cystoscopes (as a group) demonstrate substantial clinical improvement over reusable cystoscopes. We note that for the purposes of the device pass-through evaluation process, CMS evaluates the nominated device that is the subject of an application to determine if the device meets the eligibility criteria described in § 419.66.

Further, for the purposes of our substantial clinical improvement evaluation, we consider both reusable, reprocessed cystoscopes and single-use, disposable cystoscopes as available treatment options for this patient population and note that single-use, disposable cystoscopes appear to be widely accessible and well utilized in the outpatient setting. According to the applicant, of the 2.2 million flexible cystoscopy procedures furnished annually across all payers, 23 percent are performed with single-use, disposable cystoscopes. As discussed in more detail below, we are interested in additional evidence that demonstrates substantial clinical improvement with the use of the VersaVue™ Single-Use Flexible Cystoscope over other available treatment options (both single-use, disposable cystoscopes and reusable, reprocessed cystoscopes). In order to evaluate substantial clinical improvement over currently available treatments to meet the transitional pass-through payment criterion at § 419.66(c)(2), we consider supporting evidence, preferably published peer-reviewed clinical trials, that demonstrates improved clinical outcomes, such as reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process comparing the nominated device to the standard of care (88 FR 81733).

First, the evidence provided did not include data demonstrating that the use of the VersaVue™ Single-Use Flexible Cystoscope compared to other available single-use, disposable cystoscopes for this patient population results in substantial clinical improvement. The applicant identified other devices it believes are closely related or similar to the VersaVue™ Single-Use

Flexible Cystoscope, including the following: (1) Ambu® aScope 4™ Cysto manufactured by AMBU A/S, (2) Ambu® aScope 5™ Cysto manufactured by AMBU A/S, (3) WiScope® Single-Use Digital Flexible Cystoscope manufactured by OTU Medical AnQing, (4) Medical Single Use Flexible Cystoscope manufactured by Shanghai AnQing Medical Instrument Company, and (5) Pusen Single Use Flexible Video Cystoscope System manufactured by Zhuhai Pusen Medical Technology Company. We note that the VersaVue™ Single-Use Flexible Cystoscope was determined to be substantially equivalent to a legally marketed device, the Ambu® aScope 4™ Cysto (K193095), which received 510(k) clearance on April 2, 2020.[40] The FDA 510(k) summary for the VersaVue™ Single-Use Flexible Cystoscope stated that both devices have the same intended use and similar specifications, and that there are no significant differences. According to the applicant, these five similar devices would also become eligible for transitional pass-through payment under the additional category proposed by the applicant. We reiterate that we consider other single-use, disposable cystoscopes as available treatment options for this patient population and that the devices appear to share similar technological and/or procedural characteristics. We note that none of the studies the applicant included reference another single-use, disposable device as a comparator against which to evaluate and assess the VersaVue™ Single-Use Flexible Cystoscope. While we find that the source articles provide background information about multiple risks associated with reprocessing reusable devices, we would welcome additional evidence demonstrating a comparison of the VersaVue™ Single-Use Flexible Cystoscope's performance against other similar single-use, disposable devices. We question whether the VersaVue™ Single-Use Flexible Cystoscope offers a substantial clinical improvement over other single-use, disposable cystoscopes currently on the market. We welcome evidence that demonstrates substantial clinical improvement with the use of the VersaVue™ Single-Use Flexible Cystoscope over other single-use, disposable cystoscopes.

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[40] U.S. Food and Drug Administration. (2020, April 2). *Decision Summary for K193095* [Ambu® aScope™ 4 Cysto]. U.S. Department of Health and Human Services. *https://www.accessdata.fda.gov/cdrh_docs/pdf19/K193095.pdf*.

Second, we question whether the supporting evidence submitted by the applicant demonstrates substantial clinical improvement of the VersaVue™ Single-Use Flexible Cystoscope over reusable, reprocessed cystoscopes for this patient population. In the first claim, the applicant asserted that the use of single-use, disposable cystoscopes decreases post-procedure encounters and infections compared to reusable cystoscope devices. However, while Geldmaker et al. (2023) reported some improved clinical outcomes with the use of a specific single-use, disposable cystoscope when compared to the use of a specific reusable cystoscope,[41] we note that the study does not assess, evaluate, or review clinical outcomes associated with the use of the VersaVue™ Single-Use Flexible Cystoscope or compare clinical outcomes associated with the use of the VersaVue™ Single-Use Flexible Cystoscope to reusable cystoscopes. Rather, the evidence provided compared clinical outcomes associated with another device, the single-use, disposable Ambu aS4C cystoscope [Ambu® aScope 4™ Cysto] to the reuseable Olympus® CYF-5 V2 Flexible cystoscope. Therefore, we question whether the use of the VersaVue™ Single-Use Flexible Cystoscope results in substantial clinical improvement as compared to reusable, reprocessed cystoscopes.

In addition, we note that, as a retrospective study, Geldmaker et al. (2023) fails to establish that the differences in the observed clinical outcomes are caused by using reusable, reprocessed cystoscopes versus single-use, disposable cystoscopes. We note that retrospective studies can only suggest associations between variables and cannot establish cause and effect relationships. While the propensity score matching did an adequate job of balancing the two groups (reusable, reprocessed cystoscope procedures versus single-use, disposable cystoscope procedures) and yielded statistically significant results, we question whether the propensity score matching variables used in the study adequately account for patient factors that may impact the

[41] Geldmaker, L. E., Baird, B. A., Lyon, T. D., Regele, E. J., Wajswol, E. J., Pathak, R. A., Petrou, S. P., Haehn, D. A., Gajarawala, N. M., Ball, C. T., Broderick, G. A., & Thiel, D. D. (2023). Conversion to disposable cystoscopes decreased post-procedure encounters and infections compared to reusable cystoscopes. *Urology Practice, 12*(1), 58-64. *https://doi.org/10.1097/UPJ.0000000000000410*

outcomes, such as the reason for the cystoscopy, positive preoperative UTI, and other comorbid conditions. We note that data were collected during different time periods (reusable, reprocessed cystoscope data were collected in 2020, and single-use, disposable cystoscope data were collected in 2021), which may introduce systematic errors in the measurement due to retrospective data collection or confounders not accounted for, such as changes in clinical practice between the 2 study years. Further, per the study authors, we note that urine cultures were ordered more frequently in the reusable cystoscope group, potentially increasing the likelihood of a UTI diagnosis in the reusable cystoscope group. We would be interested in whether equivalent pre- and post-procedure urine cultures from patients in both groups would have yielded different results. We note that the evidence is not conclusive to support whether the use of single-use, disposable cystoscopes results in improved clinical outcomes compared to reuseable, reprocessed cystoscopes.

Moreover, while not included in the evidence submitted by the applicant in support of the substantial clinical improvement claims for the VersaVue™ Single-Use Flexible Cystoscope, we note that two studies, Anderson et al. (2024) and Johnson et al. (2023), provide notable evidence directly related to the use of single-use, disposable cystoscopes versus reusable cystoscopes.[42,43] Anderson et al. (2024), a systematic review (using meta-analyses techniques) comparing the clinical outcomes of all single-use, disposable endoscopes used in urology with those of reusable endoscopes across a range of urological procedures, found that of the seven studies that reported the rate of postoperative infections, none found a statistically significant difference in postoperative infection rate between single-use, disposable endoscopes and reusable endoscopes.[44] Further, we note that the Anderson et al. (2024) sub-group analysis of cystoscopes

[42] Anderson, S., Patterson, K., Skolarikos, A., Somani, B., Bolton, D. M., & Davis, N. F. (2024). Perspectives on technology: To use or to reuse, that is the endoscopic question-a systematic review of single-use endoscopes. *BJU International, 133*(1), 14–24. *https://doi.org/10.1111/bju.16206*

[43] Johnson, B. A., Raman, J. D., Best, S. L., & Lotan, Y. (2023). Prospective randomized trial of single-use vs reusable cystoscope for ureteral stent removal. *Journal of Endourology, 37*(10). *https://doi.org/10.1089/end.2023.0134*

[44] Anderson, 2024, *op. cit.*

found no difference in overall complication rates or postoperative infection rates between the single-use, disposable cystoscopes and the reusable cystoscope subgroups. Similarly, Johnson et al. (2023) found no statistically significant difference in adverse events in a multicenter, randomized trial comparing single-use, disposable cystoscopes (Ambu® aScope 4™ Cysto) with reusable cystoscopes for ureteral stent removal in 102 patients.[45] Given the evidence in these additional studies, we question whether the totality of available evidence establishes that the use of a single-use, disposable cystoscope results in substantial clinical improvement when compared to reuseable, reprocessed cystoscopes, and furthermore, whether the use of the VersaVue™ Single-Use Flexible Cystoscope compared to reusable, reprocessed cystoscopes results in decreased adverse events, including post-procedure encounters and infections. We welcome studies that evaluate whether the use of the VersaVue™ Single-Use Flexible Cystoscope results in substantial clinical improvement over reusable, reprocessed cystoscopes, such as a reduction in mortality, complications, subsequent interventions, future hospitalizations, recovery time, pain, or a more rapid beneficial resolution of the disease process compared to reuseable, reprocessed cystoscopes.

Third, in the second, third, fourth and fifth claims, the applicant asserted that the use of single-use, disposable cystoscopes avoids post-cystoscopy infections, device malfunctions, and contamination problems associated with reusable devices, and eliminates the need for reprocessing and avoids the risk of infection associated with improper reprocessing. In support of these claims, the applicant provided two retrospective reviews (Lee et al., 2022 and Muscarella, 2022) of medical device reports (MDRs) from the FDA Manufacturer and User Facility Device Experience (MAUDE) database, an FDA News Release (2021, April 1) concerning infection and contamination risks associated with reusable urological endoscopes, and an FDA Update (2025, January 31) communicating the recall of endoscope accessories from Olympus® reusable

[45] Johnson, 2023, *op. cit.*

urological endoscopes as supporting evidence.[46,47] [48,49] First, we question whether, per the applicant, the avoidance of device malfunctions, contamination problems, and the elimination of the need for reprocessing demonstrates substantial clinical improvement, as these are not clinical outcome metrics. Second, while we concur that avoiding post-cystoscopy infections is important, we note that none of the studies the applicant submitted as evidence evaluated or assessed the VersaVue™ Single-Use Flexible Cystoscope and that none of the studies compared clinical outcomes, such as adverse events (including post-cystoscopy infection) associated with the use of the VersaVue™ Single-Use Flexible Cystoscope to clinical outcomes associated with reusable cystoscopes. Third, while these studies discuss potential adverse events from reusable cystoscope procedures, we note that FDA states that the FDA MAUDE database's MDR data are not intended to be used to evaluate rates of adverse events, evaluate a change in event rates over time, or compare adverse event occurrence rates across devices.[50] FDA explains that the MAUDE database is a passive surveillance system, and that incidence, prevalence, or cause of an event cannot be determined from this surveillance system alone due to under-reporting of events, inaccuracies in reports, lack of verification that the device caused the reported event, and lack of information about frequency of device use.[51] FDA further explains that the submission of an MDR itself does not necessarily demonstrate that the device caused or contributed to the adverse

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[46] Lee, J., Kaplan-Marans, E., Jivanji, D., Tennenbaum, D., & Schulman, A. (2022). Post-cystoscopy infections and device malfunctions in reprocessed flexible cystoscopes in a national database. *Canadian Journal of Urology, 29*(6), 11361–11365. *https://pubmed.ncbi.nlm.nih.gov/36495577*

[47] Muscarella, L. F. (2022, January 28). Contamination of flexible endoscopes and associated infections: A comprehensive review and analysis of FDA adverse event reports. *Discussions in Infection Control. https://lfm-hcs.com/2022/01/contamination-of-flexible-endoscopes-and-associated-infections/*

[48] U.S. Food and Drug Administration. (2021, April 1*). FDA is investigating reports of infections associated with reprocessed urological endoscopes: Agency is taking action to remind health care providers about the proper way to clean certain devices for reuse*. [FDA News Release]. *https://www.fda.gov/news-events/press-announcements/fda-investigating-reports-infections-associated-reprocessed-urological-endoscopes*

[49] U.S. Food and Drug Administration. (2025, January 31). *Update on alert: Endoscope accessories forceps/irrigation plug issue from Olympus. https://www.fda.gov/medical-devices/medical-device-recalls/update-alert-endoscope-accessories-forcepsirrigation-plug-issue-olympus*

[50] U.S. Food and Drug Administration. (2024, June 6). *About the Manufacturer and User Facility Device Experience (MAUDE) database*. U.S. Department of Health and Human Services. *https://www.fda.gov/medical-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities/about-manufacturer-and-user-facility-device-experience-maude-database*

[51] U.S. Food and Drug Administration, 2024, *op. cit.*

outcome or event.[52] Therefore, we question whether these studies can substantiate that the use of single-use, disposable cystoscopes, like the VersaVue™ Single-Use Flexible Cystoscope, would result in substantial clinical improvements over currently available reuseable, reprocessed cystoscopes. Fourth, while the applicant asserted that the FDA News Release (2021, April 1) encouraged manufacturers to transition to single-use, disposable devices, we note that this FDA News Release does not specifically reference single-use, disposable cystoscopes but, rather encouraged manufacturers to transition to devices with features that eliminate the need for reprocessing and provided information to manufacturers on how to modify and validate their reprocessing instructions. As such, we question the assertion that this FDA communication encouraged manufacturers to transition to single-use, disposable cystoscopes, such as the VersaVue™ Single-Use Flexible Cystoscope. We further note that FDA stated that the risk of infection from reuseable, reprocessed urological endoscopes was low based on its data.[53] We also note that the FDA Update (2025, January 31) communicated a medical device recall of the Olympus® endoscope accessory (MAJ-891 Forceps/Irrigation Plug) that is attached to the instrument channel port of a certain endoscope, due to the risk of infection that may result from improper reprocessing, but that this communication made no mention of the use of the nominated device or single-use, disposable devices, instead it appears to be a concern related to a particular reusable device.[54]

While the applicant asserted that the use of single-use, disposable cystoscopes avoids risk of infection associated with improper reprocessing, the applicant did not submit any FDA safety communications directly related to single-use, disposable cystoscopes. We question whether the evidence provided by the applicant directly supports this claim.

Finally, we note that the intent of transitional device pass-through payment, as implemented at § 419.66, is to facilitate access for beneficiaries to the advantages of new and

[52] U.S. Food and Drug Administration, 2024, *op. cit.*
[53] U.S. Food and Drug Administration, 2021, op. cit.
[54] U.S. Food and Drug Administration, 2025, op. cit.

truly innovative devices by allowing for adequate payment for these new devices while the necessary cost data is collected to incorporate the costs for these devices into the procedure APC rate (66 FR 55861). Based on the information provided by the applicant, approximately 510,600 units of single-use, disposable cystoscope devices, like those that would be included in the proposed device category for single-use, disposable cystoscopes, are estimated to have sold annually in the U.S. Moreover, the applicant provided that, of the 2.2 million flexible cystoscopy procedures furnished annually, 23 percent are performed with single-use, disposable cystoscopes, further, single-use, disposable cystoscopes are used in at least 500 hospitals and clinics, including 35 to 50 academic medical centers. Based on the information provided in the application, it appears as though single-use, disposable cystoscopes are widely available and consistently utilized for the purposes of performing cystoscopy procedures in outpatient facilities. As such, we question whether the creation of a device pass-through payment category code for single-use, disposable cystoscopes is consistent with the intent of transitional device pass-through payment and necessary to appropriately incorporate adequate cost data of these devices into the applicable procedure APC.

We question whether the evidence submitted by the applicant demonstrates that the use of single-use, disposable cystoscopes results in improved patient outcomes and reduced patient risk compared to the use of reusable devices. Further, we question whether the VersaVue™ Single-Use Flexible Cystoscope offers a substantial clinical improvement in the treatment of Medicare beneficiaries over other available treatment and whether a transitional device pass-through category for single-use, disposable cystoscopes is in alignment with the intent of the transitional device pass-through payment program policy.

We are inviting public comment on whether the VersaVue™ Single-Use Flexible Cystoscope meets the device category criterion at § 419.66(c)(2).

The third criterion for establishing a device category, at § 419.66(c)(3), requires CMS to determine that the cost of the device is not insignificant, as described in § 419.66(d). Section

419.66(d) includes three cost significance criteria that must each be met. The applicant stated that the VersaVue™ Single-Use Flexible Cystoscope would be reported with HCPCS codes as shown in Table 56.

TABLE 56: HCPCS CODES REPORTED WITH THE VERSAVUE™ SINGLE-USE FLEXIBLE CYSTOSCOPE

HCPCS Code	Long Descriptor	SI	APC
52000	Cystourethroscopy (separate procedure)	J1	5372
52001	Cystourethroscopy with irrigation and evacuation of multiple obstructing clots	J1	5374
52240	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; large bladder tumor(s)	J1	5375
52250	Cystourethroscopy with insertion of radioactive substance, with or without biopsy or fulguration	J1	5374
52260	Cystourethroscopy, with dilation of bladder for interstitial cystitis; general or conduction (spinal) anesthesia	J1	5373
52265	Cystourethroscopy, with dilation of bladder for interstitial cystitis; local anesthesia.	J1	5373
52270	Cystourethroscopy, with internal urethrotomy; female	J1	5373
52275	Cystourethroscopy, with internal urethrotomy; male	J1	5373
52276	Cystourethroscopy with direct vision internal urethrotomy	J1	5373
52277	Cystourethroscopy, with resection of external sphincter (sphincterotomy)	J1	5374
52281	Cystourethroscopy, with calibration and/or dilation of urethral stricture or stenosis, with or without meatotomy, with or without injection procedure for cystography, male or female	J1	5373
52282	Cystourethroscopy, with insertion of permanent urethral stent	J1	5374
52005	Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service	J1	5373
52283	Cystourethroscopy, with steroid injection into stricture	J1	5373
52285	Cystourethroscopy for treatment of the female urethral syndrome with any or all of the following: urethral meatotomy, urethral dilation, internal urethrotomy, lysis of urethrovaginal septal fibrosis, lateral incisions of the bladder neck, and fulguration of polyp(s) of urethra, bladder neck, and/or trigone	J1	5372
52287	Cystourethroscopy, with injection(s) for chemodenervation of the bladder	J1	5373
52290	Cystourethroscopy with ureteral meatotomy, unilateral or bilateral	J1	5373
52300	Cystourethroscopy with resection or fulguration of orthotopic ureterocele(s), unilateral or bilateral	J1	5374
52301	Cystourethroscopy with resection or fulguration of ectopic ureterocele(s), unilateral or bilateral	J1	5374
52305	Cystourethroscopy with incision or resection of orifice of bladder diverticulum, single or multiple	J1	5375
52310	Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); simple	J1	5373
52315	Cystourethroscopy, with removal of foreign body, calculus, or ureteral stent from urethra or bladder (separate procedure); complicated	J1	5373
52317	Litholapaxy: crushing or fragmentation of calculus by any means in bladder and removal of fragments; simple or small (less than 2.5 cm)	J1	5374
52007	Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with brush biopsy of ureter and/or renal pelvis	J1	5374

HCPCS Code	Long Descriptor	SI	APC
52318	Litholapaxy: crushing or fragmentation of calculus by any means in bladder and removal of fragments; complicated or large (over 2.5 cm)	J1	5374
52320	Cystourethroscopy (including ureteral catheterization) with removal of ureteral calculus	J1	5374
52325	Cystourethroscopy (including ureteral catheterization); with fragmentation of ureteral calculus (e.g., ultrasonic or electro-hydraulic technique)	J1	5375
52327	Cystourethroscopy (including ureteral catheterization) with subureteric injection of implant material	J1	5375
52330	Cystourethroscopy (including ureteral catheterization) with manipulation, without removal of ureteral calculus	J1	5374
52332	Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)	J1	5374
52334	Cystourethroscopy with insertion of ureteral guide wire through kidney to establish a percutaneous nephrostomy, retrograde	J1	5374
52341	Cystourethroscopy with treatment of ureteral stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5374
52342	Cystourethroscopy; with treatment of ureteropelvic junction stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5374
52343	Cystourethroscopy with treatment of intra-renal stricture (e.g., balloon dilation, laser, electrocautery, and incision)	J1	5374
52010**	Cystourethroscopy, with ejaculatory duct catheterization, with or without irrigation, instillation, or duct radiography, exclusive of radiologic service	J1	5372
52204	Cystourethroscopy, with biopsy(s)	J1	5373
52214	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) of trigone, bladder neck, prostatic fossa, urethra, or periurethral glands	J1	5374
52224	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) or treatment of minor (less than 0.5 cm) lesion(s) with or without biopsy	J1	5374
52234	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; small bladder tumor(s) (0.5 up to 2.0 cm)	J1	5374
52235	Cystourethroscopy, with fulguration (including cryosurgery or laser surgery) and/or resection of; medium bladder tumor(s) (2.0 to 5.0 cm)	J1	5374

**Denotes that the HCPCS code was not included in Addendum P to the CY 2025 OPPS/ASC final rule with comment period, and therefore, had no CY 2025 HCPCS/CPT code level device offset amount available. We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. Since not all of the HCPCS/CPT codes provided by the applicant had a CY 2025 HCPCS/CPT code level device offset amount available at the time the application was received, we used the CY 2025 HCPCS/CPT code level device offset amount for the HCPCS codes included in Addendum P and listed in Table 56 to assess whether the device meets the cost significance criterion.

To meet the cost criterion for device pass-through payment status, a device must pass all three tests of the cost criterion for at least one APC. As we explained in the CY 2005 OPPS final rule (69 FR 65775), we generally use the lowest APC payment rate applicable for use with the nominated device when we assess whether a device meets the cost significance criterion, thus increasing the probability the device will pass the cost significance test. Beginning in CY 2017, we calculate the device offset amount at the HCPCS/CPT code level instead of the APC level

(81 FR 79657). We note the applicant used the CY 2025 payment rates for the three tests of the cost criterion. For our calculations, we used APC 5372, which had a CY 2025 payment rate of $667.47 at the time the application was received. HCPCS code 52000 in APC 5372 had a device offset amount of $0.87 at the time the application was received. According to the applicant, the cost of the VersaVue™ Single-Use Flexible Cystoscope is $250.00.

Section 419.66(d)(1), the first cost significance requirement, provides that the estimated average reasonable cost of devices in the category must exceed 25 percent of the applicable APC payment amount for the service related to the category of devices. The average reasonable cost of $250.00 for the VersaVue™ Single-Use Flexible Cystoscope is 37.45 percent of the applicable APC payment amount for the service related to the category of devices of $667.47 (($250.00/$667.47) x 100 = 37.45 percent). Therefore, we believe that the VersaVue™ Single-Use Flexible Cystoscope meets the first cost significance requirement.

The second cost significance requirement, at § 419.66(d)(2), provides that the estimated average reasonable cost of the devices in the category must exceed the cost of the device-related portion of the APC payment amount for the related service by at least 25 percent, which means that the device cost needs to be at least 125 percent of the offset amount (the device-related portion of the APC found on the offset list). The estimated average reasonable cost of $250.00 for the VersaVue™ Single-Use Flexible Cystoscope is 28,735.63 percent of the cost of the device-related portion of the APC payment amount for the related service of $0.87 (($250.00/$0.87) x 100 = 28,735.63 percent). Therefore, we believe that the VersaVue™ Single-Use Flexible Cystoscope meets the second cost significance requirement.

The third cost significance requirement, at § 419.66(d)(3), provides that the difference between the estimated average reasonable cost of the devices in the category and the portion of the APC payment amount for the device must exceed 10 percent of the APC payment amount for the related service. The difference between the estimated average reasonable cost of $250.00 for the VersaVue™ Single-Use Flexible Cystoscope and the portion of the APC payment amount for

the device of $0.87 is 37.32 percent of the APC payment amount for the related service of $667.47 (((($250.00 - $0.87)/$667.47) x 100 = 37.32 percent). Therefore, we believe that the VersaVue™ Single-Use Flexible Cystoscope meets the third cost significance requirement.

We are inviting public comment on whether the VersaVue™ Single-Use Flexible Cystoscope meets the cost criterion at § 419.66(c)(3).

B. Device-Intensive Procedures

1. Background

Under the OPPS, prior to CY 2017, device-intensive status for procedures was determined at the APC level for APCs with a device offset percentage greater than 40 percent (79 FR 66795). Beginning in CY 2017, CMS began determining device-intensive status at the HCPCS code level. In assigning device-intensive status to an APC prior to CY 2017, the device costs of all the procedures within the APC were calculated and the geometric mean device offset of all of the procedures had to exceed 40 percent. Almost all of the procedures assigned to device-intensive APCs utilized devices, and the device costs for the associated HCPCS codes exceeded the 40-percent threshold. The no cost/full credit and partial credit device policy (79 FR 66872 through 66873) applies to device-intensive procedures and is discussed in detail in section IV.B.4. of this proposed rule. A related device policy was the requirement that certain procedures assigned to device-intensive APCs require the reporting of a device code on the claim (80 FR 70422) and is discussed in detail in section IV.B.3. of this proposed rule. For further background information on the device-intensive APC policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70421 through 70426).

a. HCPCS Code-Level Device-Intensive Determination

As stated earlier, prior to CY 2017, under the device-intensive methodology we assigned device-intensive status to all procedures requiring the implantation of a device that were assigned to an APC with a device offset greater than 40 percent and, beginning in CY 2015, that met the three criteria as listed. Historically, the device-intensive designation was at the APC level and

applied to the applicable procedures within that APC. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we changed our methodology to assign device-intensive status at the individual HCPCS code level rather than at the APC level. Under this policy, a procedure could be assigned device-intensive status regardless of its APC assignment, and device-intensive APC designations were no longer applied under the OPPS or the ASC payment system.

We believe that a HCPCS code-level device offset is, in most cases, a better representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all of the procedures assigned to an APC. Unlike a device offset calculated at the APC level, which is a weighted average offset for all devices used in all of the procedures assigned to an APC, a HCPCS code-level device offset is calculated using only claims for a single HCPCS code. We believe that this methodological change results in a more accurate representation of the cost attributable to implantation of a high-cost device, which ensures consistent device-intensive designation of procedures with a significant device cost. Further, we believe a HCPCS code-level device offset removes inappropriate device-intensive status for procedures without a significant device cost that are granted such status because of their APC assignment.

Under our existing policy, procedures that meet the criteria listed in section IV.C.1.b. of this proposed rule are identified as device-intensive procedures and are subject to all the policies applicable to procedures assigned device-intensive status under our established methodology, including our policies on device edits and no cost/full credit and partial credit devices discussed in sections IV.C.3. and IV.C.4. of this proposed rule.

b. Use of the Three Criteria to Designate Device-Intensive Procedures

We clarified our established policy in the CY 2018 OPPS/ASC final rule with comment period (82 FR 52474), where we explained that device-intensive procedures require the implantation of a device and additionally are subject to the following criteria:

- All procedures must involve implantable devices that would be reported if device insertion procedures were performed.
- The required devices must be surgically inserted or implanted devices that remain in the patient's body after the conclusion of the procedure (at least temporarily); and
- The device offset amount must be significant, which is defined as exceeding 40 percent of the procedure's mean cost.

We changed our policy to apply these three criteria to determine whether procedures qualify as device-intensive in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), where we stated that we would apply the no cost/full credit and partial credit device policy--which includes the three criteria listed previously--to all device-intensive procedures beginning in CY 2015. We reiterated this position in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), where we explained that we were finalizing our proposal to continue using the three criteria established in the CY 2007 OPPS/ASC final rule with comment period for determining the APCs to which the CY 2016 device intensive policy will apply. Under the policies we adopted in CYs 2015, 2016, and 2017, all procedures that require the implantation of a device and meet the previously described criteria are assigned device-intensive status, regardless of their APC placement.

2. Proposed Device-Intensive Procedure Policy

As part of our effort to better capture costs for procedures with significant device costs, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948), for CY 2019, we modified our criteria for device-intensive procedures. We had heard from interested parties that the criteria excluded some procedures that interested parties believed

should qualify as device-intensive procedures. Specifically, we were persuaded by interested party arguments that procedures requiring expensive surgically inserted or implanted devices that are not capital equipment should qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We agreed that a broader definition of device-intensive procedures was warranted, and made two modifications to the criteria for CY 2019 (83 FR 58948). First, we allowed procedures that involve surgically inserted or implanted single-use devices that meet the device offset percentage threshold to qualify as device-intensive procedures, regardless of whether the device remains in the patient's body after the conclusion of the procedure. We established this policy because we no longer believe that whether a device remains in the patient's body should affect a procedure's designation as a device-intensive procedure, as such devices could, nonetheless, comprise a large portion of the cost of the applicable procedure. Second, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent, to allow a greater number of procedures to qualify as device intensive. We stated that we believe allowing these additional procedures to qualify for device-intensive status will help ensure these procedures receive more appropriate payment in the ASC setting, which will help encourage the provision of these services in the ASC setting. In addition, we stated that this change would help to ensure that more procedures containing relatively high-cost devices are subject to the device edits, which leads to more correctly coded claims and greater accuracy in our claims data. Specifically, for CY 2019 and subsequent years, we finalized that device-intensive procedures will be subject to the following criteria:

- All procedures must involve implantable devices assigned a CPT or HCPCS code;
- The required devices (including single-use devices) must be surgically inserted or implanted; and
- The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost (83 FR 58945).

In addition, to further align the device-intensive policy with the criteria used for device pass-through payment status, we finalized, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

● Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE), and has been classified as a Category B device by FDA in accordance with §§ 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

● Is an integral part of the service furnished;

● Is used for one patient only;

● Comes in contact with human tissue;

● Is surgically implanted or inserted (either permanently or temporarily); and

● Is not either of the following:

++ Equipment, an instrument, apparatus, implement, or item of the type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) (83 FR 58945).

In addition, for new HCPCS codes describing procedures requiring the implantation of devices that do not yet have associated claims data, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658), we finalized a policy for CY 2017 to apply device-intensive status with a default device offset set at 41 percent for new HCPCS codes describing procedures requiring the implantation or insertion of a device that did not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. This default device offset amount of 41 percent was not calculated from claims data;

instead, it was applied as a default until claims data were available upon which to calculate an actual device offset for the new code. The purpose of applying the 41-percent default device offset to new codes that describe procedures that implant or insert devices was to ensure ASC access for new procedures until claims data become available.

As discussed in the CY 2019 OPPS/ASC proposed rule and final rule with comment period (83 FR 37108 through 37109 and 83 FR 58945 through 58946, respectively), in accordance with our policy stated previously to lower the device offset percentage threshold for procedures to qualify as device-intensive from greater than 40 percent to greater than 30 percent, for CY 2019 and subsequent years, we modified this policy to apply a 31-percent default device offset to new HCPCS codes describing procedures requiring the implantation of a device that do not yet have associated claims data until claims data are available to establish the HCPCS code-level device offset for the procedures. In conjunction with the policy to lower the default device offset from 41 percent to 31 percent, we continued our current policy of, in certain rare instances (for example, in the case of a very expensive implantable device), temporarily assigning a higher offset percentage if warranted by additional information such as pricing data from a device manufacturer (81 FR 79658). Once claims data are available for a new procedure requiring the implantation or insertion of a device, device-intensive status is applied to the code if the HCPCS code-level device offset is greater than 30 percent, according to our policy of determining device-intensive status by calculating the HCPCS code-level device offset.

In addition, in the CY 2019 OPPS/ASC final rule with comment period, we clarified that since the adoption of our policy in effect as of CY 2018, the associated claims data used for purposes of determining whether or not to apply the default device offset are the associated claims data for either the new HCPCS code or any predecessor code, as described by CPT coding guidance, for the new HCPCS code. Additionally, for CY 2019 and subsequent years, in limited instances where a new HCPCS code does not have a predecessor code as defined by CPT, but describes a procedure that was previously described by an existing code, we use

clinical discretion to identify HCPCS codes that are clinically related or similar to the new HCPCS code but are not officially recognized as a predecessor code by CPT, and to use the claims data of the clinically related or similar code(s) for purposes of determining whether or not to apply the default device offset to the new HCPCS code (83 FR 58946). Clinically related and similar procedures for purposes of this policy are procedures that have few or no clinical differences and use the same devices as the new HCPCS code. In addition, clinically related and similar codes for purposes of this policy are codes that either currently or previously describe the procedure described by the new HCPCS code. Under this policy, claims data from clinically related and similar codes are included as associated claims data for a new code, and where an existing HCPCS code is found to be clinically related or similar to a new HCPCS code, we apply the device offset percentage derived from the existing clinically related or similar HCPCS code's claims data to the new HCPCS code for determining the device offset percentage. We stated that we believe that claims data for HCPCS codes describing procedures that have minor differences from the procedures described by new HCPCS codes will provide an accurate depiction of the cost relationship between the procedure and the device(s) that are used, and will be appropriate to use to set a new code's device offset percentage, in the same way that predecessor codes are used. If a new HCPCS code has multiple predecessor codes, the claims data for the predecessor code that has the highest individual HCPCS-level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status. Similarly, in the event that a new HCPCS code does not have a predecessor code but has multiple clinically related or similar codes, the claims data for the clinically related or similar code that has the highest individual HCPCS level device offset percentage is used to determine whether the new HCPCS code qualifies for device-intensive status.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94214 through 92419), we finalized a change to our methodology for applying default device offset percentages for new device-intensive procedures. Under our previous policy, if a new CPT/HCPCS code did

not have available claims data, either from the new HCPCS code or any predecessor code or clinically-similar code that uses the same device, and the CPT/HCPCS code otherwise met our criteria for device-intensive status, we would apply a default device offset percentage of 31 percent. However, we were aware of certain situations where the default device offset amount might not adequately reflect the existing device portion of the procedure's costs when compared to the cost of similar devices. A potential large difference between the default device offset amount and the device portion of similar devices might impede our ability to accurately remove device offset amounts from new device-intensive procedures under the OPPS and to set payment rates for device-intensive procedures under the ASC payment system. Therefore, for CY 2025 and subsequent CYs, we finalized our proposal to modify our default device offset percentage policy for new device-intensive procedures. Specifically, for new CPT/HCPCS codes that both describe a procedure that requires the surgical implantation or insertion of a single-use device that exceeds 30 percent of the procedure's cost and that meets our requirements of a device as described above and lack claims data (from either the new HCPCS code or any predecessor code or clinically-similar code that uses the same device), we would apply a default device offset percentage that is the greater of 31 percent or the device offset percentage of the APC to which the procedure has been assigned. We stated that we still believe that a HCPCS code-level device offset is, in most cases, a more accurate representation of a procedure's device cost than an APC-wide average device offset based on the average device offset of all the procedures assigned to an APC. However, because newer device-intensive procedures lack claims data, we believe the APC-wide average device offset percentage is, in many cases, a better reflection of the estimated device costs of the procedure than a default 31 percent offset. Additionally, there can be instances where the typical device costs of procedures in an APC can be significantly greater than the 31 percent default device offset. For these reasons, we finalized our modification to our default device offset percentage for new device-intensive procedures. This methodological change was finalized for both the OPPS and ASC Payment System for CY 2025 and subsequent

CYs and applies to new procedures assigned to clinical APCs, but not to new procedures assigned to New Technology APCs.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 92414 through 92419), we stated that we were persuaded by commenters that the lack of a device edit for device-intensive procedures, particularly new technologies, might lead to an underreporting of device costs and total procedure costs and potentially impede beneficiary access to such new technologies over time. Therefore, in addition to finalizing a modification to our device edits policy for CY 2025, we finalized a modification to our device offset percentage calculation. For procedures subject to our modified device edits policy for CY 2025 that cannot report modifier "CG" to bypass this claims processing edit, the device offset percentages calculated (for the CPT/HCPCS code or its predecessor code) are based on hospital claims that reported a device code. We stated that we believed that hospital outpatient claims that report a device code with such procedures provide, in general, a more accurate representation of the procedures' total costs. We also finalized, for purposes of determining device offset percentages, that we will not use claims data from procedures that had a status indicator of ''E1'' during the calendar year we are using for ratesetting and determining device offset percentages. Lastly, we refined our process for applying device offset percentages to use available claims data from predecessor codes annually, rather than the first year of the successor code's activation date, until we have available claims data from the successor code.

We propose to continue these policies for CY 2026. As we indicated in the CY 2019 OPPS/ASC proposed rule and final rule with comment period, additional information for our consideration of an offset percentage higher than the default of 31 percent (or the APC-wide default offset percentage) for new HCPCS codes describing procedures requiring the implantation (or, in some cases, the insertion) of a device that do not yet have associated claims data, such as pricing data or invoices from a device manufacturer, should be directed to the Division of Outpatient Care, Mail Stop C4–01–26, Centers for Medicare & Medicaid Services,

7500 Security Boulevard, Baltimore, MD 21244–1850, or electronically *outpatientpps@cms.hhs.gov.* Additional information can be submitted prior to issuance of an OPPS/ASC proposed rule or as a public comment (see "DATES" section of this proposed rule) in response to an issued OPPS/ASC proposed rule. Device offset percentages will be set in each year's final rule.

The full listing of the proposed CY 2026 device-intensive procedures can be found in Addendum P to this proposed rule (which is available via the internet on the CMS website). Further, our claims accounting narrative contains a description of our device offset percentage calculation. Our claims accounting narrative for this proposed rule can be found under supporting documentation for the CY 2026 OPPS/ASC proposed rule on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

3. Device Edit Policy

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66795), we finalized a policy and implemented claims processing edits that require any of the device codes used in the previous device-to-procedure edits to be present on the claim whenever a procedure code assigned to any of the APCs listed in Table 5 of the CY 2015 OPPS/ASC final rule with comment period (the CY 2015 device-dependent APCs) was reported on the claim. In addition, in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422), we modified our previously existing policy and applied the device coding requirements exclusively to procedures that require the implantation of a device assigned to a device-intensive APC. In the CY 2016 OPPS/ASC final rule with comment period, we also finalized our policy that the claims processing edits are such that any device code, when reported on a claim with a procedure assigned to a device-intensive APC (listed in Table 42 of the CY 2016 OPPS/ASC final rule with comment period (80 FR 70422)), will satisfy the edit.

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79658 through 79659), we changed our policy for CY 2017 and subsequent years to apply the CY 2016 device

coding requirements to the newly defined device-intensive procedures. For CY 2017 and subsequent years, we also specified that any device code, when reported on a claim with a device-intensive procedure, will satisfy the edit. In addition, we created HCPCS code C1889 to recognize devices furnished during a device-intensive procedure that are not described by a specific Level II HCPCS Category C-code. Reporting HCPCS code C1889 with a device-intensive procedure will satisfy the edit requiring a device code to be reported on a claim with a device-intensive procedure. In the CY 2019 OPPS/ASC final rule with comment period, we revised the description of HCPCS code C1889 to remove the specific applicability to device-intensive procedures (83 FR 58950). For CY 2019 and subsequent years, the description of HCPCS code C1889 is "Implantable/insertable device, not otherwise classified."

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81758 through 81759), we finalized our proposal to establish a procedure-to-device edit for the procedures assigned to APC 5496 (Level 6 Intraocular Procedures) and require hospitals to report the correct device HCPCS codes when reporting any of the four procedures – CPT codes 0308T and 0616T, 0617T, and 0618T. (We note that CPT codes 0617T and 0618T were deleted effective January 1, 2025 and CPT code 0616T was deleted effective January 1, 2025 and replaced with new CPT code 66683.) We have noted that interested parties have previously recommended in past rulemaking that we reestablish all our previous procedure-to-device edits, but we do not expect to extend this policy beyond the procedures assigned to APC 5496 (Level 6 Intraocular Procedures). This APC represents a unique situation – the APC (which was the Level 5 Intraocular APC in previous years) had been a Low Volume APC (fewer than 100 claims in a claims year) since we established our Low Volume APC policy, the procedures associated with this APC have significant procedure costs often greater than $15,000, and the procedures associated with this APC require the implantation of a high-cost intraocular device. In the CY 2025 OPPS/ASC final rule, we finalized to continue this policy for APC 5496 (Level 6 Intraocular Procedures) for CY 2025 and subsequent years.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 92419 through 92422), we finalized a modification to our device edits policy. While historically our device edits policy has only applied to procedures that are device-intensive based on the most recent claims data available, commenters had raised concerns about hospitals underreporting device costs in years when certain device-intensive procedures had lost device-intensive status because the device portion of a procedure can fluctuate above and below our device-intensive threshold of 30 percent. Commenters indicated to us that the presence of the device edit requirement can have a significant impact on the device portion and geometric mean cost of a procedure, particularly for newer technologies. Therefore, for CY 2025 and subsequent CYs, we finalized a policy to apply our device edits policy permanently once a procedure is designated as a device-intensive procedure in a given year. Additionally, we finalized a policy to reinstate our device edits policy for procedures that have been device-intensive since we began assigning device-intensive status at the HCPCS code level on January 1, 2017. We believed that by applying our device edit policy to procedures that were device-intensive on or after January 1, 2017, we might continue to receive device cost information for relatively new procedures with limited claims data, which may have been impacted by our policy to require that only existing device-intensive procedures be subject to our device edits policy. For CY 2026, under our modified device edits policy, our device edits requirement will apply to procedures that are designated as device-intensive in CY 2026 and will apply in subsequent years.

We are not proposing any changes to our device edit policy for CY 2026.

4. Adjustment to OPPS Payment for No Cost/Full Credit and Partial Credit Devices

a. Background

To ensure equitable OPPS payment when a hospital receives a device without cost or with full credit, in CY 2007, we implemented a policy to reduce the payment for specified device-dependent APCs by the estimated portion of the APC payment attributable to device costs (that is, the device offset) when the hospital receives a specified device at no cost or with full

credit (71 FR 68071 through 68077). Hospitals were instructed to report no cost/full credit device cases on the claim using the "FB" modifier on the line with the procedure code in which the no cost/full credit device is used. In cases in which the device is furnished without cost or with full credit, hospitals were instructed to report a token device charge of less than $1.01. In cases in which the device being inserted is an upgrade (either of the same type of device or to a different type of device) with a full credit for the device being replaced, hospitals were instructed to report as the device charge the difference between the hospital's usual charge for the device being implanted and the hospital's usual charge for the device for which it received full credit. In CY 2008, we expanded this payment adjustment policy to include cases in which hospitals receive partial credit of 50 percent or more of the cost of a specified device. Hospitals were instructed to append the "FC" modifier to the procedure code that reports the service provided to furnish the device when they receive a partial credit of 50 percent or more of the cost of the new device. We refer readers to the CY 2008 OPPS/ASC final rule with comment period for more background information on the "FB" and "FC" modifiers payment adjustment policies (72 FR 66743 through 66749).

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), beginning in CY 2014, we modified our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit. For CY 2013 and prior years, our policy had been to reduce OPPS payment by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device. For CY 2014, we reduced OPPS payment, for the applicable APCs, by the full or partial credit a hospital receives for a replaced device. Specifically, under this modified policy, hospitals are required to report on the claim the amount of the credit in the amount portion for value code "FD" (Credit Received from the Manufacturer for a Replaced Device) when the hospital receives a credit for a replaced

device that is 50 percent or greater than the cost of the device. For CY 2014, we also limited the OPPS payment deduction for the applicable APCs to the total amount of the device offset when the "FD" value code appears on a claim. For CY 2015, we continued our policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit and to use the three criteria established in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68072 through 68077) for determining the APCs to which our CY 2015 policy will apply (79 FR 66872 through 66873). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70424), we finalized our policy to no longer specify a list of devices to which the OPPS payment adjustment for no cost/full credit and partial credit devices would apply and instead apply this APC payment adjustment to all replaced devices furnished in conjunction with a procedure assigned to a device-intensive APC when the hospital receives a credit for a replaced specified device that is 50 percent or greater than the cost of the device.

b. Policy for No Cost/Full Credit and Partial Credit Devices

In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79659 through 79660), for CY 2017 and subsequent years, we finalized a policy to reduce OPPS payment for device-intensive procedures, by the full or partial credit a provider receives for a replaced device, when a hospital furnishes a specified device without cost or with a full or partial credit. Under our current policy, hospitals continue to be required to report on the claim the amount of the credit in the amount portion for value code "FD" when the hospital receives a credit for a replaced device that is 50 percent or greater than the cost of the device.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75005 through 75007), we adopted a policy of reducing OPPS payment for specified APCs when a hospital furnishes a specified device without cost or with a full or partial credit by the lesser of the device offset amount for the APC or the amount of the credit. We adopted this change in policy in the preamble of the CY 2014 OPPS/ASC final rule with comment period and discussed it in subregulatory guidance, including chapter 4, section 61.3.6 of the Medicare Claims Processing

Manual. Further, in the CY 2021 OPPS/ASC final rule with comment period (85 FR 86017 through 86018, 86302), we made conforming changes to our regulations at § 419.45(b)(1) and (2) that codified this policy.

We are not proposing any changes to our policies regarding payment for no cost/full credit and partial credit devices for CY 2026.

V. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals

A. Proposed OPPS Transitional Pass-Through Payment for Additional Costs of Drugs, Biologicals, and Radiopharmaceuticals

1. Background

Section 1833(t)(6) of the Act provides for temporary additional payments or "transitional pass-through payments" for certain drugs and biologicals. A "biological" as used in this proposed rule includes (but is not necessarily limited to) a "biological product" or a "biologic" as defined under section 351 of the PHS Act. As enacted by the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), this pass-through payment provision requires the Secretary to make additional payments to hospitals for: current orphan drugs for rare diseases and conditions, as designated under section 526 of the Federal Food, Drug, and Cosmetic Act; current drugs and biologicals and brachytherapy sources used in cancer therapy; and current radiopharmaceutical drugs and biologicals. "Current" refers to those types of drugs or biologicals mentioned above that are hospital outpatient services under Medicare Part B for which transitional pass-through payment was made on the first date the hospital OPPS was implemented.

Transitional pass-through payments also are provided for certain "new" drugs and biologicals that were not being paid for as an HOPD service as of December 31, 1996, and whose cost is "not insignificant" in relation to the OPPS payments for the procedures or services associated with the new drug or biological. For pass-through payment purposes, radiopharmaceuticals are included as "drugs." As required by statute, transitional pass-through

payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug as a hospital outpatient service under Medicare Part B. Proposed CY 2026 pass-through drugs and biologicals and their designated APCs are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available on the CMS website).[55]

Section 1833(t)(6)(D)(i) of the Act specifies that the pass-through payment amount, in the case of a drug or biological, is the amount by which the amount determined under section 1842(o) of the Act for the drug or biological exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological. The methodology for determining the pass-through payment amount is set forth in regulations at 42 CFR 419.64. In accordance with section V.B.9. of this proposed rule, skin substitutes with an approved Biologics License Application (BLA) would be considered under transitional drug pass-through payment status. As such, we propose to amend our regulation at § 419.64 to remove paragraph (a)(4)(iv) "A biological that is not a skin substitute or similar product that aids wound healing." The regulations at 42 CFR 419.64 specify that the pass-through payment equals the amount determined under section 1842(o) of the Act minus the portion of the APC payment that CMS determines is associated with the drug or biological. Section 1847A of the Act establishes the average sales price (ASP) methodology, which is used for payment for drugs and biologicals described in section 1842(o)(1)(C) of the Act furnished on or after January 1, 2005. The ASP methodology, as applied under the OPPS, uses several sources of data as a basis for payment, including the ASP, the wholesale acquisition cost (WAC), and the average wholesale price (AWP). In this proposed rule, the term "ASP methodology" and "ASP-based" are inclusive of all data sources and methodologies described therein. Additional information on the ASP methodology can be found on our website at

[55] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.

The pass-through application[56] and review process for drugs and biologicals is described on our website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/pass-through-payment-status-new-technology-ambulatory-payment-classification-apc.*

2. Transitional Pass-Through Payment Period for Pass-Through Drugs, Biologicals, and Radiopharmaceuticals and Quarterly Expiration of Pass-Through Status

As required by statute, transitional pass-through payments for a drug or biological described in section 1833(t)(6)(C)(i)(II) of the Act can be made for a period of at least 2 years, but not more than 3 years, after the payment was first made for the drug or biological as a hospital outpatient service under Medicare Part B. Drugs and biologicals pass-through applications are accepted and approved on a quarterly basis in which pass-through payments for approved applications could begin on the next available OPPS quarterly update. Furthermore, our current policy, which was finalized in CY 2017 OPPS/ASC final rule with comment period (81 FR 79662), is to allow for quarterly expiration of pass-through payment status for drugs, biologicals, and radiopharmaceuticals to afford a pass-through payment period that is as close to a full 3 years as possible to allow, on a prospective basis, for the maximum pass-through payment period without exceeding the statutory limit of 3 years. Notice of drugs for which pass-through payment status is ending during the calendar year is included in the quarterly OPPS Change Request transmittals.

3. Drugs and Biologicals with Expiring Pass-Through Payment Status in CY 2025

[56] To apply for OPPS transitional Pass-Through Payment Status and New Technology Ambulatory Payment Classification (APC), applicants complete an application that is subject to the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501 *et seq*.). This information collection (CMS-10008) is currently approved under OMB control number of 0938-0802 and has an expiration date of July 31, 2027.

There are 28 drugs and biologicals for which pass-through payment status expires by December 31, 2025, as listed in Table 57. These drugs and biologicals will have received OPPS pass-through payment for 3 years during the period of April 1, 2022 through December 31, 2025. In accordance with the policy finalized in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79662) and described earlier, pass-through payment status for drugs and biologicals approved in CY 2017 and subsequent years will expire on a quarterly basis, with a pass-through payment period as close to 3 years as possible.

With the exception of those groups of drugs and biologicals that are always packaged when they do not have pass-through payment status (specifically, anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[57] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), our standard methodology for providing payment for drugs and biologicals with expiring pass-through payment status in an upcoming calendar year is to determine the product's estimated per day cost and compare it with the OPPS drug packaging threshold for that calendar year, which is proposed to be $140 for CY 2026 for all drugs, biologicals, and therapeutic radiopharmaceuticals (for high-cost diagnostic radiopharmaceuticals, we would provide separate payment when their per day cost greater than the threshold we propose to adopt of $655). These policies are discussed further in section V.B.1. of this proposed rule. If the estimated per day cost for the drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure in the upcoming calendar year. If the estimated per day cost of the drug or biological is greater than the OPPS drug packaging threshold, we provide separate payment at the applicable ASP methodology-based payment amount (which is generally ASP plus 6 percent), as discussed further in section V.B.2. of this proposed rule.

[57] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

TABLE 57: DRUGS AND BIOLOGICALS FOR WHICH PASS-THROUGH PAYMENT STATUS WILL END BY DECEMBER 31, 2025

CY 2025 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0248	Injection, remdesivir, 1 mg	G	9200	04/01/2022	03/31/2025
J9304	Injection, pemetrexed (PEMFEXY), 10mg	G	9442	04/01/2022	03/31/2025
J3299	Injection, triamcinolone acetonide (xipere), 1 mg	G	9358	04/01/2022	03/31/2025
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg	G	9439	04/01/2022	03/31/2025
J9331	Injection, sirolimus protein-bound particles, 1 mg	G	9241	04/01/2022	03/31/2025
J2998	Injection, plasminogen, human-tvmh, 1 mg	G	9206	04/01/2022	03/31/2025
J9273	Injection, tisotumab vedotin-tftv, 1 mg	G	9204	04/01/2022	03/31/2025
C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	G	9440	04/01/2022	03/31/2025
Q2056	Ciltacabtagene autoleucel, up to 100 million autologous b-cell maturation antigen (bcma) directed car-positive t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	9498	07/01/2022	06/30/2025
J1302	Injection, sutimlimab-jome, 10 mg	G	9444	07/01/2022	06/30/2025
A9596	Gallium ga-68 gozetotide, diagnostic, (illuccix), 1 millicurie	G	9443	07/01/2022	06/30/2025
J9274	Injection, tebentafusp-tebn, 1 microgram	G	9446	07/01/2022	06/30/2025
J1306	Injection, inclisiran, 1 mg	G	9004	07/01/2022	06/30/2025
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram	G	9447	07/01/2022	06/30/2025
J2356	Injection, tezepelumab-ekko, 1 mg	G	9008	07/01/2022	06/30/2025
J2777	Injection, faricimab-svoa, 0.1 mg	G	9496	07/01/2022	06/30/2025
J9332	Injection, efgartigimod alfa-fcab, 2 mg	G	9010	07/01/2022	06/30/2025
A9800	Gallium ga-68 gozetotide, diagnostic, (locametz), 1 millicurie	G	9055	10/01/2022	09/30/2025
C9101	Injection, oliceridine, 0.1 mg	G	9049	10/01/2022	09/30/2025
A9607	Lutetium lu 177 vipivotide tetraxetan, therapeutic, 1 millicurie	G	9054	10/01/2022	09/30/2025
J9298	Injection, nivolumab and relatlimab-rmbw, 3 mg/1 mg	G	9057	10/01/2022	09/30/2025
A9602	Fluorodopa f-18, diagnostic, per millicurie	G	9053	10/01/2022	09/30/2025

CY 2025 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1952	Leuprolide injectable, camcevi, 1 mg	G	9050	10/01/2022	09/30/2025
Q5126	Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg	G	9048	10/01/2022	09/30/2025
J0225	Injection, vutrisiran, 1 mg	G	9009	01/01/2023	12/31/2025
J1932	Injection, lanreotide, (cipla), 1 mg	G	9051	01/01/2023	12/31/2025
J2327	Injection, risankizumab-rzaa, intravenous, 1 mg	G	9013	01/01/2023	12/31/2025
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1 mg	G	9017	01/01/2023	12/31/2025

4. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Expiring in CY 2026

We propose to end pass-through payment status in CY 2026 for 52 drugs and biologicals. These drugs and biologicals, which were initially approved for pass-through payment status between April 1, 2023 and January 1, 2024, are listed in Table 57. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that will end by December 31, 2026, are assigned status indicator "G" (Pass-Through Drugs and Biologicals) in Addenda A and B to this proposed rule (which are available on the CMS website).[58] The APCs and HCPCS codes for these drugs and biologicals are assigned status indicator "G" only for the duration of their pass-through status.

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or

[58] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient*.

biological. For CY 2026, we are continuing our policy to pay for pass-through drugs and biologicals using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP, as applicable. This payment rate is generally ASP plus 6 percent, equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2026. We note that, under the OPD fee schedule, separately payable drugs assigned to an APC are generally payable at ASP plus 6 percent. Therefore, a $0 pass-through payment amount will continue to be paid for pass-through drugs and biologicals under the CY 2026 OPPS because the difference between the amount authorized under section 1842(o) of the Act, which is generally ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which is generally ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[59] below the applicable cost threshold that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount will continue to be equal to a payment rate calculated using the ASP methodology, meaning a payment rate based on ASP, WAC, or AWP. This payment rate will generally continue to be ASP plus 6 percent for CY 2026, minus a payment offset for the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. We note that if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We note that in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we modified the regulation text at 42 CFR 419.2(b)(15) to specify that only those diagnostic radiopharmaceuticals with per-day costs at or below the per-day diagnostic

[59] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized the diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

radiopharmaceutical packaging threshold for the applicable year are policy-packaged. Meaning, for these diagnostic radiopharmaceuticals that are below the diagnostic radiopharmaceutical packaging threshold, for purposes of pass-through co-insurance calculations, they are treated like policy packaged drugs. For those diagnostic radiopharmaceuticals above the diagnostic radiopharmaceutical packaging threshold, they are not packaged, and are not considered policy packaged; therefore, for purposes of pass-through co-insurance calculations, they are treated like separately payable drugs assigned to an APC. Accordingly, a $0 pass-through payment amount is assigned consistent with our policy described previously in this section for separately payable drugs assigned to an APC.

We will continue our policy to update pass-through payment rates on a quarterly basis on the CMS website during CY 2026 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass- through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2026, consistent with our CY 2025 policy for diagnostic and therapeutic radiopharmaceuticals, we will continue to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2026, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which is generally ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we will continue to provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a. of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information.

Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a. of this proposed rule. If WAC information also is not available, we will continue to provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

We refer readers to Table 58 for the list of drugs and biologicals with pass-through payment status expiring during CY 2026.

TABLE 58: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING IN CY 2026

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9144	C9144	Injection, bupivacaine (posimir), 1 mg	G	9106	04/01/2023	03/31/2026
C9145	C9145	Injection, aprepitant, (aponvie), 1 mg	G	9107	04/01/2023	03/31/2026
J9063	J9063	Injection, mirvetuximab soravtansine-gynx, 1 mg	G	9109	04/01/2023	03/31/2026
J9347	J9347	Injection, tremelimumab-actl, 1 mg	G	9110	04/01/2023	03/31/2026
J9380	J9380	Injection, teclistamab-cqyv, 0.5 mg	G	9111	04/01/2023	03/31/2026
J9381	J9381	Injection, teplizumab-mzwv, 4 mcg	G	9112	04/01/2023	03/31/2026
J0218	J0218	Injection, olipudase alfa-rpcp, 1 mg	G	9113	04/01/2023	03/31/2026
J1411	J1411	Injection, etranacogene dezaparvovec-drlb, per therapeutic dose	G	9138	04/01/2023	03/31/2026
J1449	J1449	Injection, eflapegrastim-xnst, 0.1 mg	G	9114	04/01/2023	03/31/2026
J1747	J1747	Injection, spesolimab-sbzo, 1 mg	G	9115	04/01/2023	03/31/2026
J1954	J1954	Injection, leuprolide acetate for depot suspension (lutrate depot), 7.5 mg	G	9136	04/01/2023	03/31/2026

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J2403	J2403	Chloroprocaine hcl ophthalmic, 3% gel, 1 mg	G	9116	04/01/2023	03/31/2026
Q5128	Q5128	Injection, ranibizumab-eqrn (cimerli), biosimilar, 0.1 mg	G	9117	04/01/2023	03/31/2026
Q5130	Q5130	Injection, pegfilgrastim-pbbk (fylnetra), biosimilar, 0.5 mg	G	9118	04/01/2023	03/31/2026
J2329	J2329	Injection, ublituximab-xiiy, 1 mg	G	9149	07/01/2023	6/30/2026
J1440	J1440	Fecal microbiota, live - jslm, 1 ml	G	9142	07/01/2023	6/30/2026
Q5129	Q5129	Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	G	9159	07/01/2023	6/30/2026
J9056	J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg	G	9154	07/01/2023	6/30/2026
J0208	J0208	Injection, sodium thiosulfate,100 mg	G	9119	07/01/2023	6/30/2026
J2781	J2781	Injection, pegcetacoplan, 1 mg	G	9158	07/01/2023	6/30/2026
J1961	J1961	Injection, lenacapavir, 1 mg	G	9155	07/01/2023	6/30/2026
J9350	J9350	Injection, mosunetuzumab-axgb, 1 mg	G	9150	07/01/2023	6/30/2026
J0402	J0402	Injection, aripiprazole, (abilify asimtufii), 1 mg	G	9246	10/01/2023	9/30/2026
J7214	J7214	Injection, factor viii/von willebrand factor complex, recombinant (altuviiio), per factor viii i.u.	G	9277	10/01/2023	9/30/2026
J0184	J0184	Injection, amisulpride, 1 mg	G	9247	10/01/2023	9/30/2026
J9058	J9058	Injection, bendamustine hydrochloride (apotex), 1 mg	G	9151	10/01/2023	9/30/2026

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J0577	J0577	Injection, buprenorphine extended-release (brixadi), less than or equal to 7 days of therapy	G	0732	10/01/2023	9/30/2026
J0578	J0578	Injection, buprenorphine extended release (brixadi), greater than 7 days and up to 28 days of therapy	G	0733	10/01/2023	9/30/2026
J9321	J9321	Injection, epcoritamab-bysp, 0.1 mg	G	9250	10/01/2023	9/30/2026
A9608	A9608	Flotufolastat F 18, diagnostic, 1 millicurie	G	9254	10/01/2023	9/30/2026
J1304	J1304	Injection, tofersen, 1 mg	G	9262	10/01/2023	9/30/2026
J2799	J2799	Injection, risperidone, (uzedy), 1 mg	G	9266	10/01/2023	9/30/2026
J7353	J7353	Anacaulase-bcdb, 8.8% gel, 1 gram	G	0742	01/01/2024	12/31/2026
J3401	J3401	Beremagene geperpavec-svdt for topical administration, containing nominal 5 x 10^9 pfu/mL vector genomes, per 0.1 mL	G	0716	01/01/2024	12/31/2026
J7354	J7354	Cantharidin for topical administration, 0.7%, single unit dose applicator (3.2 mg)	G	0707	01/01/2024	12/31/2026
A9601	A9601	Flortaucipir f 18 injection, diagnostic, 1 millicurie	G	0709	01/01/2024	12/31/2026
J0177	J0177	Injection, aflibercept hd, 1 mg	G	0704	01/01/2024	12/31/2026
J2782	J2782	Injection, avacincaptad pegol, 0.1 mg	G	0705	01/01/2024	12/31/2026
J9073	J9073	Injection, cyclophosphamide, (dr. reddy's), 5 mg	G	0719	01/01/2024	12/31/2026
J0589	J0589	Injection, daxibotulinumtoxina-lanm, 1 unit	G	0703	01/01/2024	12/31/2026

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
J1413	J1413	Injection, delandistrogene moxeparvovec-rokl, per therapeutic dose	G	0714	01/01/2024	12/31/2026
J1323	J1323	Injection, elranatamab-bcmm, 1 mg	G	0708	01/01/2024	12/31/2026
J9286	J9286	Injection, glofitamab-gxbm, 2.5 mg	G	0720	01/01/2024	12/31/2026
J0174	J0174	Injection, lecanemab-irmb, 1 mg	G	9157	01/01/2024	12/31/2026
J2508	J2508	Injection, pegunigalsidase alfa-iwxj, 1 mg	G	0715	01/01/2024	12/31/2026
J7165	J7165	Injection, prothrombin complex concentrate, human-lans, per i.u. of factor ix activity	G	0702	01/01/2024	12/31/2026
J0349	J0349	Injection, rezafungin, 1 mg	G	9267	01/01/2024	12/31/2026
J9333	J9333	Injection, rozanolixizumab-noli, 1 mg	G	0721	01/01/2024	12/31/2026
J3055	J3055	Injection, talquetamab-tgvs, 0.25 mg	G	0706	01/01/2024	12/31/2026
J1412	J1412	Injection, valoctocogene roxaparvovec-rvox, per mL, containing nominal 2 × 10^13 vector genomes	G	0713	01/01/2024	12/31/2026
J0217	J0217	Injection, velmanase alfa-tycv, 1 mg	G	0710	01/01/2024	12/31/2026
J9029	J9029	Intravesical instillation, nadofaragene firadenovec-vncg, per therapeutic dose	G	0717	01/01/2024	12/31/2026

5. Drugs, Biologicals, and Radiopharmaceuticals with Pass-Through Payment Status Continuing through CY 2026

We propose to continue pass-through payment status in CY 2026 for 41 drugs and biologicals. These drugs and biologicals, which were approved for pass-through payment status with effective dates beginning between April 1, 2024 and April 1, 2025, are listed in Table 58. The APCs and HCPCS codes for these drugs and biologicals, which have pass-through payment status that would continue after December 31, 2026, are assigned status indicator "G" in Addenda A and B to this proposed rule (which are available on the CMS website).[60]

Section 1833(t)(6)(D)(i) of the Act sets the amount of pass-through payment for pass-through drugs and biologicals (the pass-through payment amount) as the difference between the amount authorized under section 1842(o) of the Act and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is associated with the drug or biological. For CY 2026, we are continuing our policy to pay for pass-through drugs and biologicals at a payment rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but is generally ASP plus 6 percent, which is equivalent to the payment rate these drugs and biologicals would receive in the physician's office setting in CY 2026. We will continue with our policy of paying a $0 pass-through payment amount for pass-through drugs and biologicals that are not policy-packaged under the CY 2026 OPPS, because the difference between the amount authorized under section 1842(o) of the Act, which would generally be ASP plus 6 percent, and the portion of the otherwise applicable OPD fee schedule that the Secretary determines is appropriate, which would also generally be ASP plus 6 percent, is $0.

In the case of policy-packaged drugs (which include the following: anesthesia drugs; drugs, biologicals, and radiopharmaceuticals[61] that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure), their pass-through payment amount would continue to be equal to a payment

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[60] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

[61] In the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948), we finalized a diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

rate based on the ASP methodology, which may be based on ASP, WAC, or AWP, but would generally be ASP plus 6 percent for CY 2026, minus a payment offset for any predecessor drug products contributing to the pass-through payment. We note if not for the pass-through payment status of these policy-packaged products, payment for these products would be packaged into the associated procedure and therefore, there are associated OPD fee schedule amounts for them.

We are continuing our policy to update pass-through payment rates on a quarterly basis on our website during CY 2026 if later quarter ASP submissions (or more recent WAC or AWP information, as applicable) indicate that adjustments to the payment rates for these pass-through payment drugs or biologicals are necessary. For a full description of this policy, we refer readers to the CY 2006 OPPS/ASC final rule with comment period (70 FR 68632 through 68635).

For CY 2026, consistent with our CY 2025 policy for diagnostic and therapeutic radiopharmaceuticals, we propose to continue our policy to provide payment for both diagnostic and therapeutic radiopharmaceuticals that are granted pass-through payment status based on the ASP methodology. As stated earlier, for purposes of pass-through payment, we consider radiopharmaceuticals to be drugs under the OPPS. Therefore, if a diagnostic or therapeutic radiopharmaceutical receives pass-through payment status during CY 2026, we will continue to follow the standard ASP methodology to determine the pass-through payment rate that drugs receive under section 1842(o) of the Act, which would generally be ASP plus 6 percent. If ASP data are not available for a radiopharmaceutical, we would provide pass-through payment at WAC plus 3 percent (consistent with our policy in section V.B.2.a. of this proposed rule), the equivalent payment provided for pass-through drugs and biologicals without ASP information. Additional detail on the WAC plus 3 percent payment policy can be found in section V.B.2.a. of this proposed rule. If WAC information also is not available, we would provide payment for the pass-through radiopharmaceutical at 95 percent of its most recent AWP.

The drugs and biologicals that would have pass-through payment status expire after December 31, 2026, are shown in Table 59.

TABLE 59: DRUGS AND BIOLOGICALS WITH PASS-THROUGH PAYMENT STATUS EXPIRING AFTER CY 2026

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
C9167	J7171	Injection, adamts13, recombinant-krhn, 10 iu	G	0727	04/01/2024	03/31/2027
J9248	J9248	Injection, melphalan (hepzato), 1 mg	G	0730	04/01/2024	03/31/2027
C9168	J2267	Injection, mirikizumab-mrkz, 1 mg	G	0728	04/01/2024	03/31/2027
J2277	J2277	Injection, motixafortide, 0.25 mg	G	0729	04/01/2024	03/31/2027
C9166	J3247	Injection, secukinumab, intravenous, 1 mg	G	0725	04/01/2024	03/31/2027
J3394	J3394	Injection, lovotibeglogene autotemcel, per treatment	G	0748	07/01/2024	06/30/2027
J3393	J3393	Injection, betibeglogene autotemcel, per treatment	G	0746	07/01/2024	06/30/2027
J3263	J3263	Injection, toripalimab-tpzi, 1 mg	G	0745	07/01/2024	06/30/2027
J0911	J0911	Instillation, taurolidine 1.35 mg and heparin sodium 100 units (central venous catheter lock for adult patients receiving chronic hemodialysis)	G	0744	07/01/2024	06/30/2027
J7355	J7355	Injection, travoprost, intracameral implant, 1 microgram	G	0749	07/01/2024	06/30/2027
A9506	A9506	Graphite crucible for preparation of technetium Tc 99m-labeled carbon aerosol, each	G	0760	07/01/2024	06/30/2027
C9172	J1414	Injection, fidanacogene elaparvovec-dzkt, per therapeutic dose	G	0773	10/01/2024	09/30/2027
C9169	J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram	G	0767	10/01/2024	09/30/2027
J9345	J9345	Injection, retifanlimab-dlwr, 1 mg	G	9280	10/01/2024	09/30/2027
Q5133	Q5133	Injection, tocilizumab-bavi (tofidence), biosimilar, 1 mg	G	0786	10/01/2024	09/30/2027

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5135	Q5135	Injection, tocilizumab-aazg (tyenne), biosimilar, 1 mg	G	0784	10/01/2024	09/30/2027
C9170	J9026	Injection, tarlatamab-dlle, 1 mg	G	0768	10/01/2024	09/30/2027
J9172	J9172	Injection, docetaxel (docivyx), 1 mg	G	0757	10/01/2024	09/30/2027
J9324	J9324	Injection, pemetrexed (pemrydi rtu), 10 mg	G	0782	10/01/2024	09/30/2027
J1434	J1434	Injection, fosaprepitant (focinvez), 1 mg	G	0761	10/01/2024	09/30/2027
J1203	J1203	Injection, cipaglucosidase alfa-atga, 5 mg	G	0737	10/01/2024	09/30/2027
C9171	A9615	Injection, pegulicianine, 1 mg	G	0772	10/01/2024	09/30/2027
J2601	J2601	Injection, vasopressin (baxter), 1 unit	G	0778	01/01/2025	12/31/2027
A9697	A9697	Injection, carboxydextran-coated superparamagnetic iron oxide, per study dose	G	0814	01/01/2025	12/31/2027
J0175	J0175	Injection, donanemab-azbt, 2 mg	G	0765	01/01/2025	12/31/2027
C9173	Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram	G	0811	01/01/2025	12/31/2027
J2468	J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms	G	0815	01/01/2025	12/31/2027
J0870	J0870	Injection, imetelstat, 1 mg	G	0813	01/01/2025	12/31/2027
J9329	J9329	Injection, tislelizumab-jsgr, 1mg	G	0816	01/01/2025	12/31/2027
J0138	J0138	Injection, acetaminophen 10 mg and ibuprofen 3 mg	G	2075	04/01/2025	03/31/2028
J3300	J3300	Injection, triamcinolone acetonide, preservative-free, 1 mg	G	1253	04/01/2025	03/31/2028
A9611	A9611	Flurpiridaz f 18, diagnostic, 1 millicurie	G	2065	04/01/2025	03/31/2028

CY 2025 HCPCS Code	CY 2026 HCPCS Code	Long Descriptor	CY 2025 Status Indicator	CY 2025 APC	Pass-Through Payment Effective Date	Pass-Through Payment End Date
Q5147	Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg	G	2068	04/01/2025	03/31/2028
J9072	J9072	Injection, cyclophosphamide (avyxa), 5 mg	G	0719	04/01/2025	03/31/2028
J9292	J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to j9305, 10 mg	G	2076	04/01/2025	03/31/2028
J9054	J9054	Injection, bortezomib (boruzu), 0.1 mg	G	2066	04/01/2025	03/31/2028
C9301	Q2058	Obecabtagene autoleucel, up to 400 million cd19 car-positive viable t cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2061	04/01/2025	03/31/2028
Q2057	Q2057	Afamitresgene autoleucel up to 10 billion mage-a4 tcr positive t-cells, including leukapheresis and dose preparation procedures, per therapeutic dose	G	2067	04/01/2025	03/31/2028
C9302	J9276	Injection, zanidatamab-hrii, 2 mg	G	2062	04/01/2025	03/31/2028
C9303	J1326	Injection, zolbetuximab-clzb, 1 mg	G	2063	04/01/2025	03/31/2028
C9304	J7172	Injection, marstacimab-hncq, subcutaneous, 0.5 mg	G	2064	04/01/2025	03/31/2028

B. Proposed OPPS Payment for Drugs, Biologicals, and Radiopharmaceuticals without Pass-Through Payment Status

1. Criteria for Packaging Payment for Drugs, Biologicals, and Radiopharmaceuticals

a. Proposed Packaging Threshold

In accordance with section 1833(t)(16)(B) of the Act, the threshold for establishing separate APCs for payment of drugs and biologicals was set to $50 per administration during

CYs 2005 and 2006. In CY 2007, we used the four-quarter moving average Producer Price Index (PPI) levels for Pharmaceutical Preparations (Prescription) to trend the $50 threshold forward from the third quarter of CY 2005 (when the Pub. L. 108-173 mandated threshold became effective) to the third quarter of CY 2007. We then rounded the resulting dollar amount to the nearest $5 increment to determine the CY 2007 threshold amount of $55. Using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 through 68086)), we set the packaging threshold for establishing separate APCs for drugs and biologicals at $140 for CY 2025 (89 FR 94237).

Following the CY 2007 methodology, for the CY 2026 OPPS/ASC proposed rule, we propose to use the most recently available four quarter moving average PPI levels to trend the $50 threshold forward from the third quarter of CY 2005 to the third quarter of CY 2026 and round the resulting dollar amount ($141.67) to the nearest $5 increment, which yields a figure of $140. In performing this calculation, we used the most recent forecast of the quarterly index levels for the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IGI. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast various price indexes including the PPI Pharmaceuticals for Human Use (Prescription). Based on these calculations, we propose a packaging threshold for CY 2026 of $140 for drugs, biologicals, and therapeutic radiopharmaceuticals. We also propose that if more recent data subsequently become available after the publication of the CY 2026 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2026 OPPS drug packaging threshold amount in the CY 2026 OPPS/ASC final rule with comment period.

We finalized in section II.A.3.c. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94238 through 94241) to pay separately for diagnostic radiopharmaceuticals with a per-day cost above the packaging threshold for CY 2025 of $630. We also finalized that

starting in CY 2026 and subsequent years, we would update this threshold by the PPI for Pharmaceuticals for Human Use (Prescription) (Bureau of Labor Statistics series code WPUSI07003) from IHS Global, Inc (IGI). For the diagnostic radiopharmaceutical packaging threshold, we finalized using the same methodology as that used in CY 2007 (which is discussed in more detail in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68085 and 68086)) to calculate the update to the OPPS drug packaging threshold. Specifically, we finalized that, starting for the CY 2026 rulemaking, we would use the most recently available four quarter moving average PPI levels to trend the final current year (CY 2025) threshold forward from the third quarter of the data year (CY 2024) to the third quarter of the current year (CY 2025) and round the resulting dollar amount to the nearest $5 increment. We are now proposing a technical refinement to this policy to use the most recently available four-quarter moving average PPI levels to trend the CY 2025 final threshold forward from the third quarter of CY 2025 to the third quarter of the payment year (CY 2026) and round the resulting dollar amount to the nearest $5 increment. We believe using the most recently available four quarter moving average PPI levels more appropriately updates the packaging threshold from CY 2025 for payment in CY 2026. For this CY 2026 OPPS/ASC proposed rule, we are using the most recently available four quarter moving average PPI levels to trend the $630 diagnostic radiopharmaceutical packaging threshold forward from the third quarter of CY 2025 to the third quarter of CY 2026 and we are rounding the resulting dollar amount ($654.23) to the nearest $5 increment, which yields a figure of $655. We also propose that if more recent data subsequently becomes available after the publication of the CY 2026 OPPS/ASC proposed rule, we would use such updated data, if appropriate, to determine the final CY 2026 diagnostic radiopharmaceutical packaging threshold amount in the CY 2026 OPPS/ASC final rule with comment period. For CY 2027 and subsequent updates, we therefore propose to trend the CY 2025 threshold of $630 forward using the four-quarter moving average PPI levels for Pharmaceuticals for Human Use, Prescription for CY 2025 (third quarter)

forward using the PPI for Pharmaceuticals for Human Use, Prescription for the applicable payment year (third quarter).

b. Proposed Packaging of Payment for HCPCS Codes that Describe Certain Drugs, Certain Biologicals, and Certain Radiopharmaceuticals Under the Cost Thresholds

To determine the proposed CY 2026 packaging status for all nonpass-through drugs, biologicals, diagnostic and therapeutic radiopharmaceuticals that are not policy packaged, we calculated, on a HCPCS code-specific basis, the per day cost of all drugs, biologicals, and therapeutic radiopharmaceuticals that had a HCPCS code in CY 2024 and were paid (via packaged or separate payment) under the OPPS. We used data from CY 2024 claims processed through December 31, 2024, for this calculation. However, we did not perform this calculation for those drugs and biologicals with multiple HCPCS codes that include different dosages, as described in section V.B.1.d. of this proposed rule, or for the following policy-packaged items that we propose to continue to package in CY 2026: anesthesia drugs; drugs, biologicals, and contrast agents and other drugs that function as supplies when used in a diagnostic test or procedure; and drugs and biologicals that function as supplies when used in a surgical procedure. Consistent with our policy described in section V.B.5. of this proposed rule, in situations where we have no claims data and must determine if these products exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the ASP methodology to determine whether their payment will be packaged as well as their payment status indicators.

In order to calculate the per day costs for drugs, biologicals, diagnostic radiopharmaceuticals, and therapeutic radiopharmaceuticals to determine their proposed packaging status in CY 2026, we used the methodology that was described in detail in the CY 2006 OPPS proposed rule (70 FR 42723 through 42724) and finalized in the CY 2006 OPPS final rule with comment period (70 FR 68636 through 68638). For each drug and biological HCPCS code, we used an estimated payment rate based on the ASP methodology, which is

generally ASP plus 6 percent (which is the payment rate we proposed for separately payable drugs and biologicals) for CY 2026, as discussed in more detail in section V.A.1. and V.B.2. of this proposed rule to calculate the CY 2026 proposed rule per day costs. We used the manufacturer-submitted ASP data from the fourth quarter of CY 2024 (data that were used for payment purposes in the physician's office setting, effective April 1, 2025) to determine the CY 2026 OPPS/ASC proposed rule per day cost.

As is our standard methodology, for CY 2026, we propose to use payment rates based on the ASP data from the fourth quarter of CY 2024 for budget neutrality estimates, packaging determinations, impact analyses, and completion of Addenda A and B to this proposed rule (which are available via the internet on the CMS website) because these are the most recent data available for use at the time of development of the CY 2026 OPPS/ASC proposed rule. These data also are the basis for drug payments in the physician's office setting, effective April 1, 2025. Exceptions to our standard methodology include:

- For therapeutic radiopharmaceuticals that do not have pass-through status as of April 1, 2025, and do not have an ASP-based payment rate, we did not use a payment rate based on WAC or AWP for those items, consistent with our policy described in section V.B.3.a. of the CY 2025 OPPS/ASC proposed rule. Instead, we used their mean unit cost derived from the CY 2024 hospital claims data to determine their per day cost.

- For diagnostic radiopharmaceuticals that do not have pass-through status as of April 1, 2025, we used their mean unit cost derived from the CY 2024 hospital claims data to determine their per day cost. We did not use an ASP-based, WAC-based, or AWP-based payment rate for those items unless there was no mean unit cost reported for the product, consistent with our proposed policy described in section V.B.3.b of the CY 2025 OPPS/ASC final rule with comment period.

- For items other than diagnostic or therapeutic radiopharmaceuticals that did not have either an ASP-based payment rate, a payment rate based on WAC, or a payment rate based on

AWP, we used mean unit cost of the items derived from the CY 2024 hospital claims data to determine their per day cost.

We propose to package drugs, biologicals, and therapeutic radiopharmaceuticals with a per day cost less than or equal to $140 and identify items with a per day cost greater than $140 as separately payable unless they are policy-packaged. For diagnostic radiopharmaceuticals, we propose to package those items with a per day cost less than or equal to $655 and identify items with a per day cost greater than $655 as separately payable. Consistent with our past practice (72 FR 667580), we cross-walked historical OPPS claims data from the CY 2024 HCPCS codes that were reported to the CY 2024 HCPCS codes that we display in Addendum B to this proposed rule (which is available on the CMS website)[62] for proposed payment in CY 2026.

Our policy during previous cycles of OPPS rulemaking has been to use updated ASP and claims data to make final determinations of the packaging status of HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals for the OPPS/ASC final rule with comment period (71 FR 68086; 78 FR75022; 89 FR 94238). We note that it is also our policy to make an annual packaging determination for a HCPCS code only when we develop the OPPS/ASC final rule with comment period for the update year (71 FR 68086). Only HCPCS codes that are identified as separately payable in the final rule with comment period are subject to quarterly updates. For our calculation of per day costs of HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule, we propose to use ASP data from the fourth quarter of CY 2024, which is the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective April 1, 2025, along with updated hospital claims data from CY 2024. We note that we also propose to use these data for budget neutrality estimates and impact analyses for this proposed rule.

We propose that payment rates for HCPCS codes for separately payable drugs and biologicals included in Addenda A and B of the CY 2026 OPPS/ASC final rule with comment

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[62] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

period would be based on ASP data from the second quarter of CY 2025. These data are the basis for calculating payment rates for drugs and biologicals in the physician's office setting using the ASP methodology, effective October 1, 2025. These payment rates would then be updated in the January 2026 OPPS update, based on the most recent ASP data to be used for physicians' office and OPPS payment as of January 1, 2026. For drugs and biologicals that do not currently have a payment rate based on ASP, WAC, or AWP, for therapeutic radiopharmaceuticals that do not currently have an ASP payment rate, and for all diagnostic radiopharmaceuticals, we will calculate their mean unit cost from all of the CY 2024 claims data and updated cost report information available for the CY 2026 final rule with comment period to determine their final per day cost.

Consequently, the final rule packaging status of some HCPCS codes for drugs, biologicals, and radiopharmaceuticals in this proposed rule may be different from the same drugs' HCPCS codes' packaging status determined based on the data used for this proposed rule. Under such circumstances, we propose to continue to follow the established policies initially adopted for the CY 2005 OPPS final rule with comment period (69 FR 65780) is in order to more equitably pay for those drugs whose costs fluctuate relative to the proposed CY 2026 OPPS drug packaging threshold and the drug's payment status (packaged or separately payable) in CY 2026. These established policies have not changed for many years and are the same as described in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70434). Specifically, for CY 2026 and subsequent years, consistent with our historical practice, we propose to apply the following policies to those HCPCS codes for drugs, biologicals, and therapeutic radiopharmaceuticals whose relationship to the drug packaging threshold changes based on the updated drug packaging threshold and on the final updated data:

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were paid separately in CY 2025 and that are proposed for separate payment in CY 2026, and that then have per day costs equal to or less than the CY 2026 final rule drug packaging threshold or

diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would continue to receive separate payment in CY 2026.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals that were packaged in CY 2025 and that are proposed for separate payment in CY 2026, and that then have per day costs equal to or less than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would remain packaged in CY 2026.

- HCPCS codes for drugs, biologicals, and radiopharmaceuticals for which we proposed packaged payment in CY 2026 but that then have per-day costs greater than the CY 2026 final rule drug packaging threshold or diagnostic radiopharmaceutical packaging threshold, based on the updated ASPs and hospital claims data used for the CY 2026 final rule, would receive separate payment in CY 2026.

c. Policy-Packaged Drugs, Biologicals, and Radiopharmaceuticals

As mentioned earlier in this section, under the OPPS, we package several categories of nonpass-through drugs, biologicals, and radiopharmaceuticals, regardless of the cost of the products. Because the products are packaged according to the policies in 42 CFR 419.2(b), we refer to these packaged drugs, biologicals, and radiopharmaceuticals as "policy-packaged" drugs, biologicals, and radiopharmaceuticals. These policies are either longstanding or based on longstanding principles and inherent to the OPPS and are currently as follows:

- Anesthesia, certain drugs, biologicals, and other pharmaceuticals; medical and surgical supplies and equipment; surgical dressings; and devices used for external reduction of fractures and dislocations (§ 419.2(b)(4));

- Intraoperative items and services (§ 419.2(b)(14));

- Drugs, biologicals, and radiopharmaceuticals that function as supplies when used in a diagnostic test or procedure (including but not limited to, diagnostic radiopharmaceuticals with

per-day costs at or below the per-day diagnostic radiopharmaceutical packaging threshold for the applicable year, contrast agents, and pharmacologic stress agents) (§ 419.2(b)(15)); and

● Drugs and biologicals that function as supplies when used in a surgical procedure (including, but not limited to, skin substitutes and similar products that aid wound healing and implantable biologicals) (§ 419.2(b)(16)).

The policy at § 419.2(b)(16) is broader than the policy at § 419.2(b)(14). As we stated in the CY 2015 OPPS/ASC final rule with comment period: "We consider all items related to the surgical outcome and provided during the hospital stay in which the surgery is performed, including postsurgical pain management drugs, to be part of the surgery for purposes of our drug and biological surgical supply packaging policy" (79 FR 66875). The category described by § 419.2(b)(15) is large and includes diagnostic radiopharmaceuticals that have a per day cost below the finalized diagnostic radiopharmaceutical packaging threshold that we discuss in section II.A.3. of this proposed rule, contrast agents, stress agents, and some other products. The category described by § 419.2(b)(16) currently includes skin substitutes and some other products. We believe it is important to reiterate that cost consideration is not a factor when determining whether an item is a surgical supply (79 FR 66875).

d. Packaging Determination for HCPCS Codes that Describe the Same Drug or Biological but Different Dosages

In the CY 2010 OPPS/ASC final rule with comment period (74 FR 60490 through 60491), we finalized a policy to make a single packaging determination for a drug, rather than an individual HCPCS code, when a drug has multiple HCPCS codes describing different dosages because we believe that adopting the standard HCPCS code-specific packaging determinations for these codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. We continue to believe that making packaging determinations on a drug-specific basis eliminates payment incentives for hospitals to report certain HCPCS codes for drugs and allows hospitals flexibility in choosing to report all HCPCS

codes for different dosages of the same drug or only the lowest dosage HCPCS code. Therefore, we propose to continue our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2026.

In order to propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same drug or biological, we aggregated both our CY 2024 claims data and our pricing information, which is based on the ASP methodology, generally ASP plus 6 percent, across all of the HCPCS codes that describe each distinct drug or biological in order to determine the mean units per day of the drug or biological in terms of the HCPCS code with the lowest dosage descriptor. The following drugs did not have pricing information available for the ASP methodology for this proposed rule; and, as is our current policy for determining the packaging status of other drugs, we used the mean unit cost available from the CY 2024 claims data to make the proposed packaging determinations for them: HCPCS code J3472 (Injection, hyaluronidase, ovine, preservative free, per 1000 usp units); HCPCS code J7100 (Infusion, dextran 40,500 ml); and HCPCS code J7110 (Infusion, dextran 75,500 ml).

For all other drugs and biologicals that have HCPCS codes describing different doses, we then multiplied the proposed weighted average ASP methodology based payment rate, which is generally ASP plus 6 percent, per-unit payment amount across all dosage levels of a specific drug or biological by the estimated units per day for all HCPCS codes that describe each drug or biological from our claims data to determine if the estimated per day cost of each drug or biological is less than or equal to the proposed CY 2026 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be packaged) or greater than the proposed CY 2026 drug packaging threshold of $140 (in which case all HCPCS codes for the same drug or biological would be separately payable). The proposed packaging status of each drug and biological HCPCS code to which this methodology would apply in CY 2026 is displayed in Table 60.

TABLE 60: HCPCS CODES TO WHICH THE CY 2026 DRUG-SPECIFIC PACKAGING DETERMINATION METHODOLOGY APPLIES

CY 2026 HCPCS Code	CY 2026 Long Descriptor	Proposed CY 2026 Status Indicator (SI)
C9257	Injection, bevacizumab, 0.25 mg	K
J9035	Injection, bevacizumab, 10 mg	K
J1460	Injection, gamma globulin, intramuscular, 1 cc	K
J1560	Injection, gamma globulin, intramuscular over 10 cc	K
J1642	Injection, heparin sodium, (heparin lock flush), per 10 units	N
J1644	Injection, heparin sodium, per 1000 units	N
J2788	Injection, rho d immune globulin, human, minidose, 50 micrograms (250 i.u.)	N
J2790	Injection, rho d immune globulin, human, full dose, 300 micrograms (1500 i.u.)	N
J3471	Injection, hyaluronidase, ovine, preservative free, per 1 usp unit (up to 999 usp units)	N
J3472	Injection, hyaluronidase, ovine, preservative free, per 1000 usp units	N
J7030	Infusion, normal saline solution, 1000 cc	N
J7040	Infusion, normal saline solution, sterile (500 ml=1 unit)	N
J7050	Infusion, normal saline solution, 250 cc	N
J7100	Infusion, dextran 40, 500 ml	N
J7110	Infusion, dextran 75, 500 ml	N
J7515	Cyclosporine, oral, 25 mg	N
J7502	Cyclosporine, oral, 100 mg	N

We propose that our policy to make packaging determinations on a drug-specific basis, rather than a HCPCS code-specific basis, for those HCPCS codes that describe the same drug or biological but different dosages in CY 2026 would also apply to diagnostic radiopharmaceuticals. This is because, as with drugs and biologicals, we believe that adopting standard HCPCS code-specific packaging determinations for radiopharmaceutical codes could lead to inappropriate payment incentives for hospitals to report certain HCPCS codes instead of others. To propose a packaging determination that is consistent across all HCPCS codes that describe different dosages of the same diagnostic radiopharmaceutical, we would aggregate our CY 2024 claims data across all of the HCPCS codes that describe each distinct diagnostic radiopharmaceutical in order to determine the mean units per day of the diagnostic radiopharmaceutical in terms of the HCPCS code with the lowest dosage descriptor. We would then analyze the aggregate per day cost of the diagnostic radiopharmaceutical to determine if the

per day cost is less than or equal to the proposed CY 2026 diagnostic radiopharmaceutical packaging threshold of $655 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be packaged) or greater than the proposed CY 2026 diagnostic radiopharmaceutical packaging threshold of $655 (in which case all HCPCS codes for the same diagnostic radiopharmaceutical would be separately payable). There are currently no diagnostic radiopharmaceuticals that this policy would apply to.

2. Proposed payment for Drugs and Biologicals without Pass-Through Status that are Not Packaged

a. Payment for Specified Covered Outpatient Drugs (SCODs) and Other Separately Payable Drugs and Biologicals

Section 1833(t)(14) of the Act defines certain separately payable radiopharmaceuticals, drugs, and biologicals and mandates specific payments for these items. Under section 1833(t)(14)(B)(i) of the Act, a "specified covered outpatient drug" (known as a SCOD) is defined as a covered outpatient drug, as defined in section 1927(k)(2) of the Act, for which a separate APC has been established and that either is a radiopharmaceutical agent or a drug or biological for which payment was made on a pass-through basis on or before December 31, 2002.

Under section 1833(t)(14)(B)(ii) of the Act, certain drugs and biologicals are designated as exceptions and are not included in the definition of SCODs. These exceptions are—

- A drug or biological for which payment is first made on or after January 1, 2003, under the transitional pass-through payment provision in section 1833(t)(6) of the Act.
- A drug or biological for which a temporary HCPCS code has not been assigned.
- During CYs 2004 and 2005, an orphan drug (as designated by the Secretary).

Section 1833(t)(14)(A)(iii) of the Act requires that payment for SCODs in CY 2006 and subsequent years be equal to the average acquisition cost for the drug for that year as determined by the Secretary, subject to any adjustment for overhead costs and considering the hospital

acquisition cost survey data collected by the Government Accountability Office (GAO) in CYs 2004 and 2005, and later periodic surveys conducted by the Secretary as set forth in the statute. If hospital acquisition cost data are not available, the law requires that payment be equal to payment rates established under the methodology described in section 1842(o), section 1847A, or section 1847B of the Act, as calculated and adjusted by the Secretary as necessary for purposes of paragraph (14). We refer to this alternative methodology as the "statutory default." Most physician Part B drugs are paid at ASP plus 6 percent in accordance with section 1842(o) and section 1847A of the Act.

Section 1833(t)(14)(E)(ii) of the Act provides for an adjustment in OPPS payment rates for SCODs to consider overhead and related expenses, such as pharmacy services and handling costs. Section 1833(t)(14)(E)(i) of the Act required MedPAC to study pharmacy overhead and related expenses and to make recommendations to the Secretary regarding whether, and if so how, a payment adjustment should be made to compensate hospitals for overhead and related expenses. Section 1833(t)(14)(E)(ii) of the Act authorizes the Secretary to adjust the weights for ambulatory procedure classifications for SCODs to consider the findings of the MedPAC study.[63]

It has been our policy since CY 2006 to apply the same treatment to all separately payable drugs and biologicals, which include SCODs, and drugs and biologicals that are not SCODs. Therefore, we apply the payment methodology in section 1833(t)(14)(A)(iii) of the Act to SCODs, as required by statute, but we also apply it to separately payable drugs and biologicals that are not SCODs, which is a policy determination rather than a statutory requirement. For CY 2023 and subsequent years, we finalized a policy to apply section 1833(t)(14)(A)(iii)(II) of the Act to all separately payable drugs and biologicals, including SCODs. Although we do not distinguish SCODs in this discussion, we note that we are required to apply section 1833(t)(14)(A)(iii)(II) of the Act to SCODs; but we also are applying this provision to other

[63] Medicare Payment Advisory Committee. June 2005 Report to the Congress. Chapter 6: Payment for pharmacy handling costs in hospital outpatient departments. Available at *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/June05_ch6.pdf.*

separately payable drugs and biologicals, consistent with our history of using the same payment methodology for all separately payable drugs and biologicals.

For a detailed discussion of our OPPS drug payment policies from CY 2006 to CY 2012, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68383 through 68385). In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68386 through 68389), we first adopted the statutory default policy to pay for separately payable drugs and biologicals at ASP plus 6 percent based on section 1833(t)(14)(A)(iii)(II) of the Act. We have continued this policy of paying for separately payable drugs and biologicals at the statutory default for CYs 2014 through 2025.

In the case of a drug or biological during an initial sales period in which data on the prices for sales of the drug or biological are not sufficiently available from the manufacturer, section 1847A(c)(4) of the Act permits the Secretary to make payments that are based on WAC. Under section 1833(t)(14)(A)(iii)(II) of the Act, the amount of payment for a separately payable drug equals the average price for the drug for the year established under, among other authorities, section 1847A of the Act. As explained in greater detail in the CY 2019 PFS final rule, under section 1847A(c)(4) of the Act, although payments may be based on WAC, unlike section 1847A(b) of the Act (which specifies that payments using ASP or WAC must be made with a 6 percent add-on), section 1847A(c)(4) of the Act does not require that a particular add-on amount be applied to WAC-based pricing for this initial period when ASP data are not available. Consistent with section 1847A(c)(4) of the Act, in the CY 2019 PFS final rule (83 FR 59661 to 59666), we finalized a policy that, effective January 1, 2019, WAC-based payments for Part B drugs made under section 1847A(c)(4) of the Act will utilize a 3 percent add-on in place of the 6 percent add-on that was being used according to our policy in effect as of CY 2018. For the CY 2019 OPPS, we followed the same policy finalized in the CY 2019 PFS final rule (83 FR 59661 to 59666). Since CY 2020, we have continued to utilize a 3 percent add-on instead of a 6 percent add-on for drugs that are paid based on WAC pursuant to our authority

under section 1833(t)(14)(A)(iii)(II) of the Act (84 FR 61318 and 85 FR 86039), which provides, in part, that the amount of payment for a SCOD is the average price of the drug in the year established under section 1847A of the Act. We also apply this provision to non-SCOD separately payable drugs, biologicals, and certain radiopharmaceuticals. Because we establish the average price for a drug paid based on WAC under section 1847A of the Act as WAC plus 3 percent instead of WAC plus 6 percent, we believe it is appropriate to price separately payable drugs paid based on WAC at the same amount under the OPPS. Our policy to pay for drugs and biologicals at WAC plus 3 percent, rather than WAC plus 6 percent, applies whenever WAC-based pricing is used for a drug, biological, or radiopharmaceutical under section 1847A(c)(4). We refer readers to the CY 2019 PFS final rule (83 FR 59661 to 59666) for additional background on this policy.

Consistent with our current policy, payments for separately payable drugs, biologicals, and radiopharmaceuticals are included in the budget neutrality adjustments, under the requirements in section 1833(t)(9)(B) of the Act. Also, the budget neutral weight scalar is not applied in determining payments for these separately payable drugs and biologicals.

Separately payable drug, biological, and radiopharmaceutical payment rates are listed in Addenda A and B to this proposed rule (available on the CMS website).[64] These addenda provide the proposed CY 2026 payment rates based on the ASP methodology for separately payable nonpass-through drugs, biologicals, and radiopharmaceuticals, with exceptions for certain radiopharmaceuticals previously discussed, and the ASP methodology for pass-through drugs, biologicals, and radiopharmaceuticals. Except for proposed payment rates for certain radiopharmaceuticals, these rates are based either on ASP information that is the basis for calculating payment rates for drugs and biologicals in the physician's office setting effective April 1, 2025, or WAC, AWP, or mean unit cost from CY 2024 claims data and updated cost report information available for this proposed rule. For nonpass-through therapeutic

[64] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

radiopharmaceuticals, payment rates are based on ASP data or mean unit cost. As we proposed to continue, in section II.A.3.c.(3). of this proposed rule, to pay separately at mean unit cost for diagnostic radiopharmaceuticals with per day costs above the proposed threshold; the payment rates proposed for qualifying diagnostic radiopharmaceuticals are entirely mean unit cost if available. In general, these published proposed payment rates are not the same as the actual January 2026 payment rates. This is because payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals with ASP information for January 2026 will be determined through the standard quarterly process where ASP data submitted by manufacturers for the third quarter of CY 2025 (July 1, 2025, through September 30, 2025) will be used to set the payment rates that are released for the quarter beginning in January 2026 in December 2025. In addition, in Addenda A and B to this proposed rule, payment rates for drugs, biologicals, and therapeutic radiopharmaceuticals for which there was no ASP, WAC, or AWP information available for April 2025, as well as all separately payable diagnostic radiopharmaceuticals, are based on mean unit cost in the available CY 2024 claims data. If new pricing information becomes available for payment for the quarter beginning in January 2026, we will price payment for these drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals based on their newly available information. Finally, there may be drugs, biologicals and therapeutic radiopharmaceuticals that have ASP, WAC, or AWP information available for the proposed rule (reflecting April 2025 ASP data) that do not have ASP, WAC, or AWP information available for the quarter beginning in January 2026. These drugs, biologicals and therapeutic radiopharmaceuticals would then be paid based on mean unit cost data derived from CY 2024 hospital claims. Therefore, the proposed payment rates listed in Addenda A and B to this proposed rule are not for January 2026 payment purposes and are only illustrative of the CY 2026 OPPS payment methodology using the most recently available information at the time of issuance of the CY 2026 OPPS/ASC proposed rule.

We note that payment amounts for most drugs separately payable under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on.

In CY 2025, we clarified that only ASP data or, if ASP data are not available, mean unit cost data, would be used to set payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals under the OPPS. For CY 2026, we are not proposing any changes to our policies for payment for separately payable therapeutic or diagnostic radiopharmaceuticals other than the technical update being proposed to the diagnostic radiopharmaceutical packaging threshold update factor as discussed in section V.B.1. of this proposed rule.

For CY 2026, we are not proposing any changes to our policies for payment for separately payable drugs, biologicals, and radiopharmaceuticals. We propose to continue our payment policy that has been in effect since CY 2013 to pay for separately payable drugs and biologicals in accordance with section 1833(t)(14)(A)(iii)(II) of the Act (the statutory default).

b. Biosimilar Biological Products

For CY 2024, we finalized the exception of biosimilars from the OPPS threshold packaging policy when their reference products are separately paid (88 FR 81783 through 81785). This policy allows for separate payment for biosimilars even if the biosimilar's per-day cost is below the packaging threshold if the biosimilar's reference product is separately paid. This policy removes the financial incentive to use a more expensive separately payable biological and promotes biosimilar use as a lower cost alternative to higher cost reference products.

Payment rates for drugs and biologicals (including biosimilars) under Medicare Part B are determined using the methodology in section 1847A of the Act, and in many cases, payment is based on the average sales price (ASP) plus a statutorily mandated 6 percent add-on. Additionally, section 11403 of the IRA requires that a qualifying biosimilar be paid at ASP plus 8 percent of the reference product's ASP rather than 6 percent during the applicable 5-year

period. Section 1847A(b)(8)(B)(ii) of the Act defines the applicable 5-year period for a qualifying biosimilar for which payment has been made using ASP (that is, payment under section 1847A(b)(8) of the Act) as of September 30, 2022, as the 5-year period beginning on October 1, 2022. For a qualifying biosimilar for which payment is first made using ASP during the period beginning October 1, 2022, and ending December 31, 2027, the statute defines the applicable 5-year period as the 5-year period beginning on the first day of such calendar quarter of such payment (88 FR 81783). These payment rates are published in the quarterly release of Addendum B or ASP pricing files.

c. Invoice Drug Pricing for CY 2026

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94243 to 94244), we finalized without modification that, for separately payable drugs or biologicals for which CMS does not provide a payment rate in Addendum B, which would indicate to MACs that CMS does not have pricing information (specifically, that ASP, WAC, AWP, and mean unit cost information is not available to determine a payment rate), MACs would calculate the payment based on provider invoices. The drug or biological invoice cost would be the net acquisition cost minus any rebates, chargebacks, or post-sale concessions. Before calculating an invoice-based payment amount, MACs would use the provider invoice to determine that: (a) the drug is not policy packaged; and (b) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. If both conditions are met, the MACs would use the provider invoice amount to set a payment rate for the separately payable drug, biological, or radiopharmaceutical until its payment amount becomes available to CMS. We generally expect invoice pricing to be temporary, lasting two to three quarters, for qualified drugs required to report ASP under section 1847A of the Act. For drug products that are not required to report ASP under section 1847A of the Act (i.e., diagnostic pharmaceuticals), invoice pricing may be used on a longer term basis until a MUC can be calculated. We finalized the invoice pricing policy for drugs to be effective

January 1, 2026, with the intent to make technical updates to outpatient hospital claims and to allow providers time to prepare for any operational changes. We noted that National Uniform Billing Committee (NUBC) created a value code that would allow for the reporting of invoice prices of drugs, biologicals, and radiopharmaceuticals for CY 2026 for the purpose of this policy. The NUBC value code create is 92 (Drug/Biologic Invoice Cost), with the definition of: "Invoice Cost of drug/biologic. For use with Revenue Category 0636 when required by federal regulation." We propose a technical clarification to this policy. Previously, we stated that MACs would use the provider invoice to determine that: (1) the drug is not policy packaged; and (2) the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above the threshold packaging amount, as applicable. However, we propose to clarify that CMS will determine whether the first condition is met, whether the drug is not policy packaged; however, the MAC will continue to determine whether the second condition is met, whether the per-day cost of the drug, biological, therapeutic radiopharmaceutical or diagnostic radiopharmaceutical is above threshold packaging amount, as applicable.

3. Payment Policy for Radiopharmaceuticals

For a complete history of the OPPS payment policy for radiopharmaceuticals, we refer readers to the CY 2005 OPPS final rule with comment period (69 FR 65811), the CY 2006 OPPS final rule with comment period (70 FR 68655), and the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524).

a. Payment Policy for Therapeutic Radiopharmaceuticals

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for therapeutic radiopharmaceuticals for CY 2023 and subsequent years. Accordingly, this payment policy for therapeutic radiopharmaceuticals will continue to apply in CY 2026.

Specifically, our policy of paying for separately payable pass-through therapeutic radiopharmaceuticals under the ASP methodology adopted for separately payable drugs and biologicals described in section V.A.1. of this proposed rule will continue to apply for CY 2026. We will pay for separately payable nonpass-through therapeutic radiopharmaceuticals through a modified ASP methodology where we pay at ASP plus 6 percent if ASP data are available. However, if ASP information is unavailable for a separately payable nonpass-through therapeutic radiopharmaceutical, we will continue to base the payment rate on arithmetic mean unit cost data derived from hospital claims. Our policy not to use WAC or AWP to establish payment for separately payable nonpass-through therapeutic radiopharmaceuticals if ASP is not available will continue for CY 2026. We explained our rationale in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60524 through 60525) when we first adopted our policy to apply the principles of separately payable drug pricing to therapeutic radiopharmaceuticals.

For a full discussion of ASP-based payment for therapeutic radiopharmaceuticals, we refer readers to the CY 2010 OPPS/ASC final rule with comment period (74 FR 60520 through 60521). We will rely on CY 2024 mean unit cost data derived from hospital claims data for payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals for which ASP data are unavailable and update the payment rates for these products according to our usual process for updating the payment rates for separately payable drugs and biologicals on a quarterly basis if updated ASP information becomes available.

The proposed CY 2026 payment rates for separately payable nonpass-through therapeutic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).[65]

b. Payment Policy for Diagnostic Radiopharmaceuticals

For CY 2025, we finalized, as described in the CY 2025 OPPS/ASC final rule (89 FR 93948 through 93963), to pay separately at arithmetic mean unit cost for diagnostic

[65] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

radiopharmaceuticals with a per day cost above our proposed diagnostic radiopharmaceutical packaging threshold (proposed at $655 for CY 2026). We also finalized our policy to pay for pass-through diagnostic radiopharmaceuticals based on ASP, WAC, and AWP.

We continue to believe that paying for nonpass-through diagnostic radiopharmaceuticals using arithmetic mean unit cost would appropriately pay for the average price of a nonpass-through separately payable diagnostic radiopharmaceutical. In our view, MUC is an appropriate proxy for the average price for a diagnostic radiopharmaceutical for a given year, as it is calculated based on the average costs for a particular year and is directly reflective of the actual cost data that hospitals submit to CMS. As we stated in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60523), we believe that WAC or AWP is not an appropriate proxy to provide OPPS payment for radiopharmaceuticals because these pricing methodologies do not include discounts. Specifically, the absence of appropriate ASP reporting could result in payment for a separately payable diagnostic radiopharmaceutical based on WAC or AWP indefinitely, a result which we believe would be inappropriate, as these pricing metrics do not capture all of the pricing discounts that may be reflected in the ASP.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93948 through 93963), we finalized to base the initial payment for new diagnostic radiopharmaceuticals with HCPCS codes that do not have pass-through status or claims data on ASP, and on the WAC for these products if ASP data for these diagnostic radiopharmaceuticals are not available. To further clarify, these products will be paid based on ASP plus 6 percent, and at WAC plus 3 or 6 percent according to the policy in section V.B.2.a. of this proposed rule if ASP data are not available.

If the WAC also is unavailable, we proposed to make payment for new diagnostic radiopharmaceuticals at 95 percent of the products' most recent AWP. We believe the volume of products in this category will typically be very low; however, in these rare situations, we believe it would be appropriate to use ASP, WAC, or AWP until a MUC is established for new

diagnostic radiopharmaceuticals with HCPCS codes that do not have passthrough status or claims data.

Please refer to section II.A.3.c of this proposed rule information regarding our payment policies for diagnostic radiopharmaceuticals, including our proposed policy to pay separately for diagnostic radiopharmaceuticals above a certain cost threshold. The proposed CY 2026 payment rates for separately payable nonpass-through diagnostic radiopharmaceuticals are included in Addenda A and B of this proposed rule (which are available on the CMS website).[66]

4. Payment for Blood Clotting Factors

For CY 2026, we propose to continue our established policy to provide payment for blood clotting factors using the same methodology as other separately payable drugs and biologicals under the OPPS and to continue to pay a furnishing fee. For a full discussion of our established payment policy for blood clotting factors, please refer to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71969 through 71970). In accordance with our policy as finalized in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66765), we will announce the actual figure of the percent change in the applicable CPI and the updated furnishing fee calculation based on that figure through the applicable program instructions and posting on the CMS website at *https://www.cms.gov/medicare/payment/fee-for-service-providers/part-b-drugs/average-drug-sales-price.*

5. Payment for Nonpass-Through Drugs, Biologicals, and Radiopharmaceuticals with HCPCS Codes but Without OPPS Hospital Claims Data

In the CY 2023 OPPS/ASC final rule with comment period, we adopted as final our proposal to continue our longstanding payment policy for nonpass-through drugs, biologicals, and radiopharmaceuticals with HCPCS codes but without OPPS hospital claims data for CY 2023 and subsequent years. Therefore, for CY 2026, this policy will continue to apply. For a detailed discussion of the payment policy and methodology, we refer readers to the CY 2016

[66] *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.*

OPPS/ASC final rule with comment period (80 FR 70442 through 70443). Consistent with our policy, because we have no claims data and must determine if these products, drugs, biologicals, therapeutic radiopharmaceuticals, and diagnostic radiopharmaceuticals, exceed the per-day cost threshold, we estimated the average number of units of each product that would typically be furnished to a patient during one day in the hospital outpatient setting and utilized the payment rate for the product, typically the ASP methodology, to determine whether their payment will be packaged as well as their payment status indicators.

6. Requirement in the CY 2026 Physician Fee Schedule Proposed Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. We explain in this CY 2026 OPPS/ASC proposed rule that the CY 2026 PFS proposed rule includes proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our past notices in OPPS/ASC proposed rules, such as in the CY 2025 OPPS/ASC proposed rule (89 FR 59370), we wanted to ensure interested parties were aware of these proposals and knew to refer to the CY 2026 PFS proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals to implement section 90004 of the Infrastructure Act to the CY 2026 PFS proposed rule. We note that public comments on these proposals would be addressed in the CY 2026 PFS final rule with comment period.

7. CY 2026 Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 Through CY 2022 as a Result of the 340B Payment Policy

a. Overview

Under the OPPS, we generally set payment rates for separately payable drugs, and biologicals (hereinafter referred to collectively as "drugs" in this section) under section 1833(t)(14)(A) of the Act). Section 1833(t)(14)(A)(iii)(II) of the Act provides that, if hospital acquisition cost data are not available, the payment amount is the average price for the drug in a year established under sections 1842(o), 1847A, or 1847B of the Act, as the case may be. Payment rates for drugs have usually been established under section 1847A of the Act, which generally sets a default rate of the average sales price (ASP) plus 6 percent. Section 1833(t)(14)(A)(iii)(II) of the Act also provides that the average price for the drug in the year as established under section 1847A of the Act, is calculated and adjusted by the Secretary as necessary for purposes of paragraph (14).

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371), CMS reexamined the appropriateness of paying the ASP plus 6 percent for drugs acquired through the 340B Drug Pricing Program (hereinafter referred to as the "340B Program"), a Health Resources and Services Administration (HRSA)-administered program that allows covered entities to purchase certain covered outpatient drugs at discounted prices from drug manufacturers. Based on findings of the Government Accountability Office (GAO),[67] the HHS Office of the Inspector General (OIG),[68] and the Medicare Payment Advisory Commission (MedPAC)[69] that 340B hospitals were acquiring drugs at a significant discount under the 340B Program, CMS adopted a policy beginning in 2018 generally to pay an adjusted amount of ASP minus 22.5 percent for certain separately payable drugs or biologicals acquired through the 340B

[67] Government Accountability Office. "Medicare Part B Drugs: "Action Needed to Reduce Financial Incentives to Prescribe 340B Drugs at Participating Hospitals." June 2015. Available at *https://www.gao.gov/assets/gao-15-442.pdf.*

[68] Office of Inspector General. "Part B Payment for 340B Purchased Drugs. OEI-12-14-00030". November 2015. Available at: *https://oig.hhs.gov/oei/reports/oei-12-14-00030.pdf.*

[69] Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at Medicare Payment Advisory Commission. March 2016 Report to the Congress: Medicare Payment Policy. March 2016. Available at *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports-may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program-pdf/.*

Program. This adjustment amount was based on our concurrence with an analysis by MedPAC that concluded that the estimated average minimum discount of 22.5 percent of ASP adequately represented the average minimum discount that a 340B participating hospital received for separately payable drugs under the OPPS (82 FR 59354 through 59371). Our intent in implementing this payment reduction was to reflect more accurately the actual costs incurred by participating hospitals in acquiring 340B drugs. We stated our belief that such changes would allow Medicare beneficiaries and the Medicare program to pay a more appropriate amount when hospitals participating in the 340B Program furnished drugs to Medicare beneficiaries that were purchased under the 340B Program (82 FR 59353 through 59371).

b. Payment for 340B Drugs and Biologicals in CYs 2018 through 2022

From January 1, 2018 through September 27, 2022, under the OPPS we generally paid for certain separately payable drugs acquired through the 340B Program at ASP minus 22.5 percent. In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59369 through 59370), we finalized our proposal to adjust the payment rate for separately payable drugs (other than drugs with pass-through payment status and vaccines) acquired under the 340B Program from ASP plus 6 percent to ASP minus 22.5 percent. We also noted that critical access hospitals are not paid under the OPPS and therefore were not subject to the OPPS 340B drug payment adjustment policy. For ease of reference, the OPPS 340B drug payment adjustment policy is hereinafter referred to as the "340B Payment Policy" and refers both to the adjustments made to payment rates for 340B-acquired drugs described here and the corresponding rate adjustment for non-drug services and items described later in section V.B.7.c. We note that rural sole community hospitals, children's hospitals, and PPS-exempt cancer hospitals were exempted from the adjustments made to payment rates for 340B-acquired drugs primarily due to these hospitals receiving special payment adjustments under the OPPS. In addition, as stated in the CY 2018 OPPS/ASC final rule with comment period, this policy change did not apply to drugs with pass-

through payment status, which are required to be paid based on the ASP methodology, or vaccines, which are excluded from the 340B Program.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 58981), we continued the Medicare 340B payment policies that were implemented in CY 2018 and adopted a policy to pay for non-pass-through 340B-acquired biosimilars at ASP minus 22.5 percent of the biosimilar's ASP, rather than the reference biological product's ASP. Additionally, in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022), we finalized a policy to pay ASP minus 22.5 percent for 340B-acquired drugs furnished in non-exempted off-campus provider-based departments (PBDs) paid under the PFS. We adopted this payment policy for CY 2019 and subsequent years. Also, during the CY 2019 OPPS/ASC rulemaking cycle, we clarified that the 340B payment adjustment applied to drugs priced using either wholesale acquisition cost (WAC) or average wholesale price (AWP), and since the policy was first adopted, we applied the 340B payment adjustment to 340B-acquired drugs priced using these pricing methodologies. The 340B payment adjustment for WAC-priced drugs was WAC minus 22.5 percent. 340B-acquired drugs that were priced using AWP were paid an adjusted amount of 69.46 percent of AWP (83 FR 37125).[70]

As discussed further in section V.B.7.f. of this proposed rule, the results of this policy meant that hospitals received an estimated $10.6 billion less in 340B drug payments (including money that would have been paid by Medicare and money that would have come from beneficiaries as copayments) than they would have for drugs provided in CY 2018 through September 27th of 2022 had the 340B Payment Policy not been implemented (88 FR 77162). These reduced payments are detailed in Table 61 and are derived from Addendum AAA published with the 340B Remedy Rule (88 FR 77150).

[70] The 69.46 percent of AWP was calculated by first reducing the original 95 percent of AWP price by 6 percent to generate a value that is similar to ASP or WAC with no percentage markup. Then we applied the 22.5 percent reduction to ASP/WAC-similar AWP value to obtain the 69.46 percent of AWP, which was similar to either ASP minus 22.5 percent or WAC minus 22.5 percent.

TABLE 61: APPROXIMATE IMPACT IN REDUCED OPPS PAYMENT FOR 340B ACQUIRED DRUGS 2018 THROUGH 2022

	2018	2019	2020	2021	2022
Approximate Reduced OPPS Drug Payment (billions)	$1.9	$2.2	$2.3	$2.4	$1.8*
*Amount January 1 to September 27, 2022. Reduced payments under the 340B Payment Policy were not in effect after September 27, 2022.					

For more detailed descriptions of our OPPS payment policy for drugs acquired under the 340B Program during this timeframe, we refer readers to the CY 2018 OPPS/ASC final rule with comment period (82 FR 59353 through 59371); the CY 2019 OPPS/ASC final rule with comment period (83 FR 59015 through 59022); the CY 2020 OPPS/ASC final rule with comment period (84 FR 61321 through 61327); the CY 2021 OPPS/ASC final rule with comment period (85 FR 86042 through 86055); the CY 2022 OPPS/ASC final rule with comment period (86 FR 63640 through 63649); the CY 2023 OPPS/ASC final rule with comment period (87 FR 71972 through 71973); and the CY 2024 OPPS/ASC final rule with comment period 88 FR 81789 through 81792).

c. Payment for Non-Drug Items and Services in CY 2018 through CY 2022

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59216, 59258), to comply with the statutory budget neutrality requirements under sections 1833(t)(9)(B) and (t)(14)(H) of the Act, we finalized our proposal to redistribute our estimated reduction in payments for separately payable drugs as a result of the 340B Payment Policy by increasing the conversion factor used to determine the payment amounts for non-drug items and services. As further described in the CY 2018 OPPS/ASC final rule with comment period, we used updated CY 2016 claims data and a list of 340B-eligible providers to calculate an estimated impact of $1.6 billion based on the final CY 2018 policy to pay for OPPS 340B-acquired drugs at a payment rate of generally ASP minus 22.5 percent. To effectuate the budget neutrality provisions of the OPPS for CY 2018, we redistributed an estimated $1.6 billion in reduced drug payments

from adoption of the final 340B payment methodology to all hospitals paid under the OPPS by increasing the payment rates by 3.19 percent for nondrug items and services furnished by all hospitals paid under the OPPS for CY 2018. We carried through this conversion factor adjustment from CYs 2019 through 2022, increasing payments for non-drug items and services in these CYs. This resulted in approximately $7.769 billion, which for ease of reference in this rule we hereafter refer to as $7.8 billion, in additional spending on non-drug items and services from CYs 2018 through 2022.

d. Litigation History of the 340B Payment Policy

The 340B Payment Policy was the subject of extensive litigation. See the Proposed Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (hereinafter referred to as the "proposed remedy rule") for a more comprehensive summary of the litigation history (88 FR 44079 through 44080).

On June 15, 2022, the Supreme Court held that because we had not conducted a survey of hospitals' acquisition costs, we could not vary the payment rates for outpatient prescription drugs by hospital group. *See Am. Hosp. Ass'n v. Becerra*, 142 S. Ct. 1896, 1906 (2022). The Supreme Court declined to opine on the appropriate remedy, *id*. at 1903, and on September 28, 2022, the district court vacated the reimbursement rate for 340B-acquired drugs for the remainder of 2022. *See Am. Hosp. Ass'n v. Becerra*,1:18-cv-2084-RC, 2022 WL 4534617, at *5.[71] On January 10, 2023, the district court remanded without vacatur to give the agency the opportunity to determine the proper remedy for the reduced payment amounts to 340B hospitals under the payment rates in the final OPPS rules for CY 2018 through CY 2022. *See Am. Hospital Ass'n v. Becerra*, 1:18-cv-2084-RC, 2023 WL 143337, at *6.[72]

e. Payment for 340B-Acquired Drug Claims for September 28, 2022 through CY 2025

[71] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-79.*
[72] *https://ecf.dcd.uscourts.gov/cgi-bin/show_public_doc?2018cv2084-86.*

The agency complied with the district court's September 28, 2022 decision by uploading revised OPPS drug files to pay the default rate (generally ASP plus 6 percent) for all CY 2022 claims for 340B-acquired drugs paid from September 28, 2022, through the end of CY 2022.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71970), we finalized a policy reversing the 340B Payment Policy, so that going forward we would pay for 340B acquired drugs no differently than we pay for drugs that are not acquired through the 340B program. To do so, we first provided that drugs acquired through the 340B Program would be paid at the statutory default rate (generally ASP plus 6 percent) for CY 2023. Second, to ensure budget neutrality for CY 2023 OPPS payment rates as required by statute, we finalized a reduction of 3.09 percent to the 2023 OPPS conversion factor. This one-time adjustment to the conversion factor removed the effect of this aspect of the 340B Payment Policy, as originally adopted in CY 2018, for CY 2023 and subsequent years. This adjustment to the conversion factor reduced the conversion factor to the conversion factor that would have been in place in CY 2023 if the 340B payment policy had never been implemented. For more detail on the payment rate for drugs acquired under the 340B Program for CY 2023 and the corresponding adjustment to the conversion factor to maintain budget neutrality as a result of reversing the 340B adjustment and paying for all separately payable drugs at ASP plus 6 percent (or WAC plus 3 or 6 percent or 95 percent of AWP), we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 71973 through 71976).

For CYs 2024 and 2025, consistent with our policy finalized for CY 2023, we continued to pay the statutory default rate for 340B acquired drugs (88 FR 81789 through 81791).

f. Remedy Payment Adjustment for 340B-Acquired Drugs from CY 2018 Through September 27, 2022

The agency complied with the district court's January 10, 2023, remand order by issuing the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 (hereinafter referred to as the "Final Remedy rule") on November 8, 2023 (88 FR 81540). The

purpose of this rule was to address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022 and to comply with the statutory requirement to maintain budget neutrality under the OPPS.

To address the reduced payment amounts to 340B hospitals under the reimbursement rates in effect for CY 2018 through September 27, 2022, CMS made one-time lump sum payments to affected 340B covered entity hospitals, calculated as the difference between what an affected 340B covered entity hospital received for 340B-acquired drugs from CY 2018 through September 27, 2022 and what they would have received for those drugs if the 340B adjustment had not been in place. These one-time lump sum payments were issued in early 2024. For more information on the calculation and distribution of the one-time lump sum payments, see the Final Remedy rule (88 FR 77156 through 77170).

g. Prospective Adjustment to Payments for Non-Drug Items and Services to Offset the Increased Payments for Non-Drug Items and Services Made in CY 2018 through CY 2022

As previously described under section V.B.7.c. of this proposed rule, to comply with statutory budget neutrality requirements, the decreased payments made to 340B hospitals for drugs in CY 2018 through September 27, 2022 were budget neutralized by corresponding increased payments to all hospitals for non-drug items and services starting in CY 2018 through CY 2022. When these past payments were subsequently increased through the one-time lump sum payments in 2024, the same budget neutrality requirements correspondingly required us to decrease the non-drug item and services payments made from CY 2018 through CY 2022.

To reduce the burden on providers of immediately offsetting the estimated $7.8 billion of increased non-drug item and services payments made from CY 2018 through CY 2022, we decided to implement the offset prospectively over the course of several years. As we explained in the proposed and Final Remedy rules (88 FR 44088, 88 FR 77172), this approach was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the

downward adjustment in the payment rate for drugs acquired under the 340B Program. We finalized in the Final Remedy rule that, beginning in CY 2026, we would reduce the conversion factor for non-drug items and services to all OPPS providers—except any hospital that enrolled in Medicare after January 1, 2018 (as described further below)—by 0.5 percent each year until the total offset was reached (which we estimated would take approximately 16 years (88 FR 77181).

As we stated in the proposed and Final Remedy rule, we believed an annual reduction in the conversion factor would be appropriate because it would balance the need to address the past payments for non-drug items and services to ensure budget neutrality while also ensuring that the offset was not immediately overly financially burdensome on impacted entities, which we believed would be the case if we were to apply an adjustment for the full offset amount in a single year. (88 FR 44087, 88 FR 77170).

Accordingly, the Final Remedy rule finalized changes to the calculation of the OPPS conversion factor applicable to non-drug items and services beginning in CY 2026. Specifically, we codified a 0.5 percent reduction in the OPPS conversion factor applicable to non-drug items and services in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32. This 0.5 percent reduction would remain in effect until the estimated payment reduction reached $7.8 billion, which we estimated would occur in CY 2041. For a fuller discussion of our CY 2026 adjustment to the conversion factor for non-drug items and services, see the Final Remedy rule (88 FR 77156 through 77170).

In finalizing our policy to apply a prospective adjustment, we recognized that any hospital that enrolled in Medicare after January 1, 2018 (hereinafter referred to as a "new provider") received less than the full amount of the increased non-drug item and service payments made during that time than they otherwise would have received if enrolled prior to that date (88 FR 44080). We therefore exempted these providers from the prospective rate reduction, which was predominantly designed to account for non-drug item and service payments made

during CY 2018 through CY 2022. As we explained, that meant that we would calculate payment rates for new providers using the conversion factor before applying the 0.5 percent annual reduction to the conversion factor for non-drug items and services that would apply for hospitals that are not "new providers" for purposes of this policy. For the purpose of designating a new provider, we defined the date of enrollment in Medicare as the provider's CMS certification number (CCN) effective date. We codified the exclusion of these new providers from the prospective payment adjustment to the conversion factor for the duration of its application in the regulations by adding new paragraph (b)(1)(iv)(B)(*12*) to § 419.32. We have reviewed our provider enrollment and OPPS billing records, and based on that data, the providers that would be subject to the proposed payment reduction are listed in Addendum R -340B Remedy Offset Providers to this proposed rule. We welcome comment on the providers listed in Addendum R - 340B Remedy Offset Providers to this proposed rule, and based upon those comments, we propose to publish a final Addendum R - 340B Remedy Offset Providers for CY 2026 in the CY 2026 OPPS/ASC final rule with comment period. Providers not included on this list (providers that began billing Medicare under the OPPS after January 1, 2018) will not be subject to the proposed payment reduction. For a complete discussion of our exclusion of new providers from the prospective payment adjustment, we refer readers to the Final Remedy rule (88 FR 77182 through 77185).

h. CY 2026 Proposed Prospective Payment Adjustment

When we considered how to recover the estimated $7.8 billion in increased payments made for non-drug items and services from 2018 through 2022, we considered several alternatives, including those that would fully recover that amount in a single year. For example, in the Proposed Remedy rule, we rejected an aggregate payment approach which would have implemented budget neutrality requirements through an immediate lump sum payment recoupment that would mirror the lump sum remedy payment because "[s]uch an approach would require immediate, and in many cases large, retroactive recoupments from the majority of

OPPS hospitals and would impose a substantial, immediate burden on these hospitals as well as an uncertain impact on beneficiaries." (88 FR 44083). To avoid imposing such a burden, we elected to reduce payments prospectively until the total offset was reached, which we estimated would take approximately 16 years.

As discussed previously in this section, we considered various methods to implement this prospective payment reduction. In the Final Remedy rule, we made the prospective payment reduction by applying an annual 0.5-percentage point downward adjustment to the OPPS conversion factor. We continue to believe that a downward adjustment to the OPPS conversion factor is a fair way to apportion the $7.8 billion reduction amongst hospitals, because relative hospital utilization of non-drug items and services beginning in 2026 will approximately track the relative hospital utilization for non-drug items and services each hospital received from CY 2018 through CY 2022. The future payment reductions will thus roughly offset the windfall those hospitals received from increased payments from CY 2018 through CY 2022. And as we noted in the final rule, the approach of tethering future payments for each non-drug item and service for each hospital "was similar to the original budget neutrality adjustment in the 340B Payment Policy that increased the payment for every non-drug item and service for CY 2018 through CY 2022 to offset the downward adjustment in the payment rate for drugs acquired under the 340B Program." (88 FR 77172.) Finally, the methodology does so with minimal administrative burden to hospitals and beneficiaries, because we can effectuate the offset by calculating the appropriate payment reduction in annual rulemaking without requiring any subsequent action by hospitals. Other methodologies—like delivering a series of demand letters to each hospital for a share of the $7.8 billion—would not only require us to recalculate the proper amount to apportion to each hospital but would most likely require large lump-sum payments from hospitals after each demand letter. Hospitals may find it financially disruptive to promptly write such one-time checks depending on their financial circumstances when we issue the demand letters, whereas implementing a percentage reduction in their Medicare OPPS

payments over a number of years would be less disruptive. Such one-time payments would impose greater administrative burden on hospitals and possibly introduce complications to our collections efforts if hospitals delay payments.

While we continue to believe that a reduction to the OPPS conversion factor is the best way to effectuate budget neutrality, we are reconsidering whether the timing we selected—a 0.5-percentage point annual reduction for approximately 16 years—best achieves the overarching goal of the Final Remedy rule, which is to restore hospitals to as close to the financial position they would have been in had the 340B Payment Policy never been implemented as is reasonably feasible. In particular, the further away from CY 2018 through CY 2022 the adjustments extend, the less likely that relative hospital utilization of non-drug items and services will correlate to the relative hospital utilization of non-drug items and services from 2018 through 2022. In other words, a hospital's utilization of non-drug items and services is likely going to diverge more from CY 2018 utilization in CY 2041 than it would in CY 2031 or CY 2026. And the more a hospital's utilization of non-drug items and services diverge, the less hospitals would be restored to as close as possible to the approximate financial position as they would have been in had the 340B Payment Policy never been implemented. By beginning the decrease to non-drug item and service payments in CY 2026, there is already an 8-year delay between the first year of the OPPS 340B payment policy and the first year of the prospective offset. Thus, the longer it takes for us to fully recover the $7.8 billion, the less likely that the relative burden on hospitals from the adjustments will match the relevant benefits those hospitals previously received. In addition, it is possible that at least some hospitals that benefited from the increased payments from CY 2018 through CY 2022 will leave the market before 2041, increasing the risk that the remaining hospitals might ultimately account for a larger share of the payment reductions than they would have if the annual reduction to the OPPS conversion factor concluded sooner. We note the $7.8 billion dollar figure calculated in the 340B Remedy Rule (88 FR 77150) does not and will not account for inflation and does not contain interest even though the prospective offset is occurring

many years after both the start of the 340B payment policy in CY 2018 as well as the lump sum remedy payments made in CY 2024.

Accordingly, effective January 1, 2026, we propose to revise the annual reduction to the OPPS conversion factor under § 419.32(b)(1)(iv)(B)(*12*) used to determine the payment amounts for non-drug items and services from 0.5 percent to 2 percent. Under this revised rate, we expect it would take approximately 6 years to reach the total offset of $7.8 billion (see Table 62). Consistent with the Final Remedy rule, this reduction would not apply to new providers. We have also included on Table 62 an alternative policy option with an annual reduction of 5 percent which would reach the total offset of $7.8 billion in approximately 3 years.

We acknowledge that this revised annual reduction would be a change to the approach we finalized in the Final Remedy rule and that, at that time, we considered but did not adopt a suggestion from a commenter requesting that we recover the amount over a shorter timeframe than 16 years. (88 FR 77179.) Our basis for not accepting the suggestion was that the 0.5 percent rate/16-year timeframe "properly reverses the increased payments for non-drug items and services to comply with statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities." We now think that this balancing insufficiently accounted for the main premise of the Final Remedy rule, which is to implement the budget neutrality requirement in a manner that restores affected 340B covered entity hospitals to the financial position they would have been in had the 340B Payment Policy not been implemented in 2018. For the reasons explained above, we believe that a 6-year time frame better achieves that main goal. And we believe this time frame balances better that goal and our budget neutrality obligations against hospital burden and reliance interests. For example, the 16-year timeframe is more than three times longer than the 5-year period the 340B Payment Policy was in place. The 6 years we expect that the revised policy would be in effect, by contrast, is closer to the timeframe the 340B Payment Policy was in place, and the 2 percent payment reduction we propose is still well below

the 3.19 percent payment increase hospitals received for that time period (82 FR 52624 through 52625). Because we are proposing this policy in advance of CY 2026 and before any rate reductions go into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals have in a policy that has not been implemented yet for these payment systems would be minimal and outweighed by the other considerations discussed in this proposed rule.

TABLE 62: ILLUSTRATION OF THE PROPOSED 2 PERCENT AND ALTERNATIVE 5 PERCENT CONVERSION FACTOR ANNUAL REDUCTION TO THE OPPS NON-DRUG ITEMS AND SERVICES BEGINNING CY 2026 TO MAINTAIN BUDGET NEUTRALITY

	CY 2026	CY 2027	CY 2028	CY 2029	CY 2030	CY 2031
Total Applicable OPPS Non-Drug Item and Service Spending (millions)	51,400	55,700	60,300	65,200	70,200	75,500
Proposed 2 Percent Payment Reduction Amount (millions)	1,100	1,200	1,300	1,400	1,600	1,169*
Proposed 2 Percent Payment Reduction Estimated Total Cumulative Offset (millions)	1,100	2,300	3,600	5,000	6,600	7,769
Alternative 5 Percent Payment Reduction Amount (millions)	2,700	3,000	2,069**			
Alternative 5 Percent Payment Reduction Estimated Total Cumulative Offset (millions)	2,700	5,700	7,769			

* Note, the final year's offset is estimated to be less than 2 percent in order to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 62 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing.

** Note, the final year's offset is estimated to be less than 5 percent in order to meet the total estimated offset of $7.769 billion. The amounts illustrated in Table 62 reflect the total amount of reduced spending, which includes both Medicare and Beneficiary cost-sharing.

i. Impact of the Prospective Offset to the OPPS Conversion Factor on the ASC Payment System

As we noted in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71975), budget neutrality adjustments to the OPPS conversion factor do not impact the ASC conversion factor. However, we also noted in that rule that revisions to the OPPS conversion factor can have an indirect impact on the ASC payment system because the ASC standard ratesetting methodology adopts OPPS payment rates and the device portion (or device offset amount). Specifically, because the device portion for device-intensive procedures is held constant with the OPPS and is not calculated with the ASC conversion factor, a reduction to the OPPS conversion factor will lower the device portion for device-intensive procedures, including the payment rates for device-intensive procedures under the ASC payment system. We further clarified, however, that any decline in expenditures for device portions under the ASC payment system would be fully offset through the ASC weight scalar, which increases payment for the non-device portions of all covered surgical procedures and certain covered ancillary services. Together, that means that reducing the OPPS conversion factor can mean that we pay relatively less for device-intensive procedures and relatively more for other surgical procedures.

In the Final Remedy rule (88 FR 77179), a commenter referenced this discussion in the CY 2023 OPPS/ASC final rule with comment period and requested that CMS provide an analysis of the impact of the remedy's proposed OPPS conversion factor reduction on ASC payment rates. Specifically, the commenter requested additional details on the magnitude of the change in payments for device-intensive procedures with and without the OPPS conversion factor reduction. As further discussed in section XIII. of this proposed rule, historically, the ASC payment system has generally adopted the final OPPS conversion factor for a calendar year in determining the OPPS payment rates that are used for determining the device portions for device-intensive procedures under the ASC payment system. A 2 percent reduction in OPPS

payment rates would otherwise reduce ASC payments for device-intensive procedures by approximately one percent; the non-device portions for all covered surgical procedures would otherwise be increased to offset reduction to device portions for device-intensive procedures. For CY 2026, we estimate the reduction to device portions would be approximately $42 million and would otherwise increase the ASC weight scalar by 0.1 percent.

However, we propose to set ASC payment rates based on the OPPS payment rates without the remedy's 2 percent prospective offset. In other words, these payment rates would be based on OPPS payment rates for hospitals that enrolled in Medicare after January 1, 2018. We acknowledge that in the CY 2023 OPPS/ASC rule we stated that "the revised OPPS conversion factor will have an impact on the ASC payment system," but we were responding to a comment asking about how unwinding the 340B Payment Policy would reduce the OPPS conversion factor prospectively beginning in CY 2023, not about how we should approach any temporary reduction in the OPPS conversion factor to unwind the 340B Payment Policy in place from CY 2018 through 2022. (87 FR 71975.) In this context, we believe that selecting the higher OPPS payment rate is more consistent with the history and logic of both the ASC payment system as well as the Final Remedy rule.

As for the ASC payment system, including the 2 percent prospective offset would not be an accurate reflection of the device costs of covered surgical procedures in the ASC setting. Further, we are concerned beneficiaries could have access issues to certain device-intensive procedures in the ASC setting, such as total knee arthroplasty and total hip arthroplasty, if we maintained a 2-percent reduction to the payment rates for device-intensive procedures for each calendar year we applied the prospective offset. The total payment for device portions of device-intensive procedures under the ASC payment system is roughly 27 percent of total ASC payments.

This proposed policy would also be consistent with the logic of the Final Remedy rule. As we have explained, the reduction to the OPPS payment rate is intended to comply with

statutory budget neutrality requirements and was implemented in a manner to place hospitals in as close to the financial position they would have been in had this policy not been implemented in CY 2018 as is reasonably feasible. By contrast, it would not satisfy any similar statutory budget neutrality requirements to pass through this reduction to ASC payment rates. Nor would changing *ASC* payment rates for the next several years help place *hospitals* affected by the 340B Payment Policy in the same position as they have been absent that policy. Even if the agency wanted to extend the Final Remedy rule's logic to ASCs and try to place ASCs—none of whom ever challenged the 340B Payment Policy—in the same position as they would have been absent that policy, we doubt that passing through the 2 percent OPPS payment reduction to the device portion of ASC payment rates would do so. That is because, as discussed previously, doing so would have a purely distributional impact on ASC payment rates that financially favors procedures that are less device-intensive. Therefore, as discussed in section XIII.C.4. of this proposed rule, we propose that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not include the 2-percent prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that we are proposing to implement in this proposed rule.

8. All-Inclusive Rate (AIR) Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

a. Background

In the CY 2000 OPPS final rule (65 FR 18434), CMS implemented the PPS for hospital outpatient services furnished to Medicare beneficiaries, as set forth in section 1833(t) of the Act. In the CY 2000 OPPS final rule, we noted that the OPPS applies to covered hospital outpatient services furnished by all hospitals participating in the Medicare program with a few exceptions. We identified one of these exceptions as "outpatient services provided by hospitals of the Indian Health Service (IHS)." We stated that these services would "continue to be paid under separately established rates which are published annually in the **Federal Register**" and, in the CY 2002

OPPS/ASC final rule (66 FR 59856), we finalized a revision to § 419.20 (Hospitals subject to the hospital outpatient prospective payment system) by adding paragraph (b)(4), which specifies that hospitals of the IHS are excluded from the OPPS.

In the intervening years, IHS and tribal facilities have been paid under the separately established All-Inclusive Rate (AIR). On an annual basis, the IHS calculates and publishes, in the **Federal Register**, calendar year reimbursement rates.[73] Due to the higher cost of living in Alaska, separate rates are calculated for Alaska and the lower 48 States. For CY 2025, the Medicare Outpatient per Visit Rate is $718 for the lower 48 states (hereinafter referred to as "the lower 48 AIR") and $1,193 for Alaska.[74]

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286), we finalized a policy to separately pay IHS and tribal hospitals for high-cost drugs, biologicals, and radiopharmaceuticals (hereinafter referred to as "drugs" for the purpose of this section) furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authority under which the AIR is calculated.[75] We note that the AIR and the add-on payment are paid out of the Part B trust fund and are not subject to OPPS budget neutrality.

We defined high cost drugs (i.e. drugs qualifying for the add-on payment) for the purpose of the policy as all drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS whose per day cost exceeds two times the lower 48 AIR amount in effect at the time of the release of each year's OPPS/ASC final rule. In the CY 2025 OPPS/ASC final rule with comment period, this amount was identified as $1,334 (2 times the CY 2024 lower 48 AIR of $667).

To determine the calculated per day cost for each drug HCPCS code, we employed a

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[73] *https://www.ihs.gov/BusinessOffice/reimbursement-rates/*.
[74] 89 FR 101607 (December 16, 2024); *https://www.federalregister.gov/documents/2024/12/16/2024-29505/reimbursement-rates-for-calendar-year-2025*.
[75] Sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248(a) and 249(b)), Public Law 83-568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

methodology similar to our longstanding methodology used to calculate the per day cost of drugs for OPPS payment purposes. Specifically, to calculate the per day cost for CY 2025, we used an estimated payment rate based on the ASP methodology payment rate, which for purposes of the policy was generally ASP plus 0 percent (which is the payment rate for separately payable IHS drugs under the policy). We then used the manufacturer-submitted ASP data from the fourth quarter of CY 2023 to determine the per day cost. For drugs that did not have either an ASP-based payment rate or a payment rate based on WAC, we used mean unit cost (MUC) of the items derived from the CY 2023 hospital claims data to determine their per day cost.

We finalized that the amount of the add-on payment for a high-cost drug would be the average sales price (ASP) for the drug with no additional payment (i.e., ASP plus zero percent). We note that this add-on payment was implemented on a per-dose basis. In the event ASP pricing information was not available for a particular drug, we paid the Wholesale Acquisition Cost (WAC) plus 0 percent and if WAC pricing information was not available, we paid 89.6 percent of Average Wholesale Price (AWP). We also adopted a drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

To implement this policy, we finalized in the CY 2025 OPPS/ASC final rule with comment period a recurring annual process in which the lower 48 AIR in effect at the time of the release of each year's OPPS/ASC final rule with comment period would be used to create a list of drugs qualifying for the add-on payment for the following calendar year. Once the drugs qualifying for the add-on payment were determined, the payment rate for a unit of the drug would be determined in accordance with the above described pricing hierarchy. The results of that process for CY 2025 were displayed in Addendum Q to the CY 2025 OPPS/ASC final rule with comment period. We additionally finalized that during the calendar year, the list of drugs would be modified on a quarterly basis to add new-to-market drugs with per-day costs that

exceeded two times the lower 48 AIR and to update qualifying drugs' ASPs. For a full discussion of the AIR add-on payment for high cost drugs provided by IHS and tribal hospitals, we refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94280 through 94286).

b. AIR Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities Policy for CY 2026

For CY 2026, as described in the CY 2025 OPPS/ASC final rule with comment period, we would continue to separately pay IHS and tribal hospitals for high-cost drugs furnished in hospital outpatient departments through an add-on payment in addition to the AIR using the authorities under which the AIR is calculated.

We would continue to define high cost drugs (i.e. drugs qualifying for the add-on payment) for the purpose of the policy as any drugs covered under Medicare Part B and for which payment would otherwise be made under the OPPS which have per day costs exceeding two times the lower 48 AIR amount in effect at the time of the release of the CY 2026 OPPS/ASC final rule with comment period. For CY 2026, if the CY 2025 lower 48 AIR amount is in effect at the time of the release of the CY 2026 OPPS/ASC final rule with comment period, this amount would be $1,436 (2 times the CY 2025 lower 48 AIR of $718).

To determine the calculated per day cost for each drug HCPCS code, we would continue using an estimated payment rate based on the ASP methodology payment rate (generally ASP plus 0 percent) and then using the manufacturer-submitted ASP data from the fourth quarter of CY 2024 to determine the per day cost. For drugs that do not have either an ASP-based payment rate or a payment rate based on WAC, we would continue to use the MUC of the items derived from the CY 2024 hospital claims data to determine their per day cost.

With respect to the amount of the add-on payment, we propose to use the same pricing hierarchy that we adopted in the CY 2025 OPPS/ASC final rule with comment period. For CY 2025, we now explain that we adopted a practice of paying the MUC when AWP pricing is not

available for a particular drug, and we propose to continue that practice for CY 2026. We propose for CY 2026 that the amount of the add-on payment for each dose of a high-cost drug will continue to be the average sales price (ASP) for the drug with no additional payment (i.e., ASP plus zero percent). In the event ASP pricing information is not available for a particular drug, we propose to continue to pay the Wholesale Acquisition Cost (WAC) plus 0 percent. If WAC pricing information is not available, we propose to continue to pay 89.6 percent of Average Wholesale Price (AWP). And, consistent with our practice for purposes of CY 2025, if AWP pricing information is not available, we propose to pay the MUC. Finally, we continue the drug packaging threshold exception for biosimilars in which the add-on payment is made for biosimilars whose per-day costs do not exceed the threshold of two times the lower 48 AIR but whose reference products do exceed the threshold.

c. Proposed List of Drugs Qualifying for the Add-on Payment for CY 2026

Using two times the lower 48 AIR amount of $718 that is in effect for CY 2025 and applying the above described per-day cost methodology and pricing hierarchy, we have included as Addendum Q a preliminary list of the drugs qualifying for the proposed add-on payment and their proposed add on payment rates for CY 2026.

We will create a final Addendum Q in the CY 2026 OPPS/ASC final rule with comment period using the claims data (units used per day) and ASPs available at that time. HCPCS codes for drugs that are proposed for separate payment in CY 2026, but then have per day costs equal to or less than $1,436 (2 times $718) in the CY 2026 OPPS/ASC final rule with comment period, based on the updated ASPs and hospital claims data used for the CY 2026 OPPS/ASC final rule with comment period, would still receive separate payment in CY 2026.

Finally, during CY 2026, as we did during CY 2025, we propose to modify the list on a quarterly basis (January, April, July, October) to add new-to-market drugs with per-day costs that exceed two times the lower 48 AIR and to update qualifying drugs' ASPs.

9. Payment for Skin Substitutes

a. Background

The CY 2014 Hospital Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) final rule with comment period describes skin substitutes as "a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers" (78 FR 74930 through 74931). When a procedure utilizing a skin substitute product is performed, providers bill one or more Healthcare Common Procedure Coding System (HCPCS) codes to describe the preparation of the wound, the use of at least one skin substitute product, and application of the skin substitute product through suturing or various other techniques. Specifically, CPT codes 15271 through 15278 describe the application of skin substitutes to various size wounds and anatomical locations.

Recently, several novel industry practices have come to our attention, likely driving substantial and unusual increases in the number of available skin substitute products, the sales and distribution structure for these products, and the rapidity of products changing manufacturer ownership. These industry changes are causing a significant increase in spending under Medicare Part B for skin substitute products in the non-facility setting. According to Medicare claims data, Part B spending for these products rose from approximately $250 million in 2019 to over $10 billion in 2024, a nearly 40-fold increase, while the number of patients receiving these products only doubled. Increases in payment rates, and launch prices for skin substitutes, especially newer products, account for the majority of observed Medicare spending increases on these products. Of note, as part of its workplan, the U.S. Department of Health and Human Services' Office of the Inspector General announced, in November 2024, plans to review Medicare Part B claims for skin substitutes to identify payments that were at risk for noncompliance with Medicare requirements with an expected issue date of fiscal year 2026.[76]

We outlined our HCPCS Level II coding and payment policy objectives for skin substitutes in the CY 2023 OPPS/ASC proposed rule (87 FR 71985) because we concluded it

[76] *https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000894.asp*.

would be beneficial for interested parties to understand our priorities as we work to create a consistent approach for the suite of products we have referred to as skin substitutes. As discussed in the CY 2023 OPPS/ASC proposed rule, we have a number of objectives related to refining our Medicare policies in this area, including: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin substitute products; (3) employing a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material, so we can incorporate payment methodologies that are more consistent; and (4) promoting clarity for interested parties on CMS skin substitutes policies and procedures. Interested parties have asked CMS to address what they have described as inconsistencies in our payment and coding policies, indicating that treating clinically similar products (for example, animal-based and synthetic skin products) differently for purposes of payment is confusing and problematic for healthcare providers and patients. These concerns exist specifically within the non-facility setting; however, interested parties have also indicated that further alignment of our policies across the non-facility and hospital outpatient department settings would reduce confusion.

On April 25, 2024, the Medicare Administrative Contractors (MACs) released a proposed Local Coverage Determination (LCD) to provide appropriate coverage for skin substitute grafts used for chronic non-healing diabetic foot and venous leg ulcers. The MACs issued the collaborative proposed Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers LCD to make sure that Medicare covers, and people with Medicare have access to, skin substitute products that are supported by evidence that shows that they are reasonable and necessary for the treatment of diabetic foot and venous leg ulcers in the Medicare population and that coverage aligns with professional guidelines for appropriately managing these wounds. All of the MACs have delayed the effective date of the final local coverage determinations for cellular and tissue-based products for wounds

in diabetic foot ulcers and venous leg ulcers, moving the implementation date across all MAC jurisdictions to January 1, 2026. For details, please see the final LCD, L36377, titled: Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers at *https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=36377&ver=19*. We note that additional coverage determinations may apply to skin substitute products.

The Medicare statute, regulations, and manual provisions empower the Medicare program to determine if a product is reasonable and necessary for the treatment of a beneficiary's condition and safe and effective, not experimental or investigational, and appropriate and therefore eligible for coverage under Part B. See, e.g., 42 U.S.C. 1395l(e), 1395y(a)(1)(A), 42 CFR 411.15(k)(1), 424.5(a)(6), Medicare Program Integrity Manual Section 3.6.2.2, Medicare Benefit Policy Manual chapter 15, section 50.4.1-50.4.3, and Medicare Program Integrity Manual, chapter 13 section 13.5.3, 13.5.4. The inclusion of a product in this payment rule does not necessarily imply that a determination has been made by CMS or its contractors that it is reasonable and necessary and meets the other preconditions to Medicare coverage. Similarly, the use of short descriptors and associated FDA regulatory categories[77] may reflect current FDA regulation but are not intended to imply that FDA has determined that a product meets any specific FDA statutory or regulatory requirements. FDA's statutory and regulatory framework, including, for example, FDA's findings that a product is "safe and effective," is not controlling of Medicare's determination under its own authorities of whether a product is "reasonable and necessary" for a Medicare beneficiary and meets all preconditions for Medicare coverage and payment. FDA does not make Medicare coverage or payment determinations, nor do FDA statutes and regulations govern Medicare coverage or payment determinations. However, CMS has determined that, when it is setting payment rates on a prospective basis, a different inquiry

[77] The term "FDA regulatory categories" is used in this proposed rule when referring to the basis for CMS' proposed payment policies but is not intended to reflect or imply that the products discussed within this Proposed Rule are characterized as such or grouped together by FDA.

and set of considerations apply and that it makes sense to consider how FDA regulates products that CMS considers to be skin substitutes.

We continue to believe that our existing payment policies are unsatisfactory, unsustainable over the long term, and rooted in historical practice established two decades ago prior to significant evolutions in medical technology and practice. After holding a town hall[78] to provide an opportunity for public input, including discussion of potential approaches to the methodology for payment of skin substitute products, as well as reviewing several years of comments in response to CY rulemaking in 2023, 2024, and 2025 on this subject, we have developed a proposal that addresses our stated objectives as well as many of the comments we have received.

b. Medicare Part B Payment for Skin Substitutes

(1) Payment for Skin Substitutes When Used During a Covered Application Procedure Under the PFS in the Non-facility Setting

CMS has historically considered skin substitutes to be biologicals for payment purposes under Medicare Part B. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108-173) (MMA) established a payment methodology for drugs and biologicals under section 1847A of the Act. Under this methodology, a vast majority of drugs and biologicals separately paid under Medicare Part B are paid at the Average Sales Price (ASP) plus six percent. Section 303 of the MMA, titled "Payment reform for covered outpatient drugs and biologicals," amended Title XVIII of the Act by adding new section 1847A of the Act. In part, this section established the use of the ASP to determine the payment limit for drugs and biologicals described in section 1842(o)(1)(C) of the Act (that is, drugs or biologicals billed by a physician, supplier, or any other person and not paid on a cost or prospective payment basis)

[78] CMS Skin Substitutes Town Hall, which was held virtually on January 18, 2023. More information regarding the CMS Skin Substitutes Town Hall such as links to recording and transcripts is available at *https://www.cms.gov/medicare/payment/fee-schedules/physician/skin-substitutes#:~:text=The%20CMS%20Skin%20Substitutes%20Town,Physician%20Fee%20Schedule%20(PFS).*

furnished on or after January 1, 2005. Because Medicare is currently paying for most skin substitutes as biologicals using the methodology under section 1847A of the Act, each skin substitute product receives a unique billing code (typically, a Level II HCPCS code) and payment limit.

Section 401 of Division CC, Title IV of the Consolidated Appropriations Act, 2021 (Pub. L. 116-260) (CAA, 2021) amended section 1847A of the Act to add new section 1847A(f)(2) of the Act, which requires certain manufacturers without a Medicaid drug rebate agreement, such as certain manufacturers of skin substitutes, to report ASP data to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in sections 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological. Because most skin substitutes are currently paid as biologicals using the methodology described in section 1847A of the Act, manufacturers of these products are currently required to report their ASP data to CMS every quarter. Prior to this, section 1927(b)(3)(A)(iii)(I) of the Act only required manufacturers with a Medicaid drug rebate agreement to report ASP data to CMS for drugs or biologicals described in section 1842(o)(1)(C) of the Act.

Section 1847A of the Act also includes several relevant definitions. While the definition of "single-source drug or biological" provided at section 1847A(c)(6)(D) of the Act includes "a biological," sections 1847A(c)(6)(H) and (I) of the Act offer more insight into the meaning of the term for purposes of this section. Subparagraph (I) defines the term "reference biological product" as a biological product licensed under section 351 of the PHS Act. Subparagraph (H) defines the term "biosimilar biological product" as "a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act."

Section 1927 of the Act, which is referred to multiple times in section 1847A of the Act, also references section 351 of the PHS Act when referencing biologicals. The title of section 303 of the MMA, which added section 1847A to the Act, refers to "covered outpatient drugs," defined in section 1927(k)(2) of the Act. Subparagraph (B) adds biological products to this definition when those products are licensed under section 351 of the PHS Act, among other requirements.

In the CY 2022 PFS final rule, to address the need to establish a payment mechanism for synthetic skin substitutes in the physician office setting and to be responsive to feedback received from commenters, we finalized an approach for payment of each synthetic skin substitute for which we had received a HCPCS Level II coding application. We finalized that those products would be payable in the physician office setting and billed separately from the procedure to apply them using HCPCS A-codes (86 FR 65120).

(2) Payment for Skin Substitutes Under the Outpatient Prospective Payment System (OPPS)

Prior to CY 2014, all products considered to be skin substitutes were separately paid under the OPPS as if they were biologicals according to the ASP methodology (78 FR 74930 through 74931). In the CY 2014 OPPS/ASC final rule with comment period (78 FR 74938), we unconditionally packaged skin substitute products furnished in the hospital outpatient setting into their associated application procedures as part of a broader policy to package all drugs and biologicals that function as supplies when used in a surgical procedure. As part of the policy to package skin substitutes, we also finalized a methodology that divides the skin substitutes into a high-cost group and a low-cost group, to ensure adequate resource homogeneity among APC assignments for the skin substitute application procedures (78 FR 74933). In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66886), we stated that skin substitutes are best characterized as either surgical supplies or devices because of their required surgical application and because they share significant clinical similarity with other surgical devices and supplies.

Skin substitutes assigned to the high-cost group are described by CPT codes 15271 through 15278. Skin substitutes assigned to the low-cost group are described by HCPCS codes C5271 through C5278. Claims billed with primary CPT codes 15271, 15273, 15275, or 15277 are used to calculate the geometric mean costs for procedures assigned to the high-cost group, and claims billed with primary HCPCS codes C5271, C5273, C5275, or C5277 are used to calculate the geometric mean costs for procedures assigned to the low-cost group (78 FR 74935). The graft skin substitute administration add-on codes, which include "each additional 25 sq cm" in the description (i.e., CPT codes 15272, 15274, 15276, and 15278; HCPCS codes C5272, C5274, C5276, and C5278), are packaged into the payment rates for the primary administration codes.

For CY 2025, each of the HCPCS codes described earlier are assigned to one of the following three skin procedure APCs according to the geometric mean cost for the code: APC 5053 (Level 3 Skin Procedures): HCPCS codes C5271, C5275, and C5277; APC 5054 (Level 4 Skin Procedures): HCPCS codes C5273, 15271, 15275, and 15277; or APC 5055 (Level 5 Skin Procedures): HCPCS code 15273. In CY 2025, the payment rate for APC 5053 (Level 3 Skin Procedures) is $612.13, the payment rate for APC 5054 (Level 4 Skin Procedures) is $1,829.23, and the payment rate for APC 5055 (Level 5 Skin Procedures) is $3,660.97. Table 63 lists the APC assignments and CY 2025 payment rates for the HCPCS codes describing the skin substitute application procedures. This information is also available in Addenda A and B of the CY 2025 final OPPS/ASC rule with comment period (the Addenda A and B are available on the CMS website *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

TABLE 63: CY 2025 APC ASSIGNMENTS FOR SKIN SUBSTITUTE APPLICATION HCPCS CODES

APC	APC TITLE	HCPCS CODES	FINAL CY 2025 OPPS PAYMENT RATE
APC 5053	Level 3 Skin Procedures	C5271, C5275, C5277	$612.13

APC 5054	Level 4 Skin Procedures	C5273, CPT codes 15271, 15275, 15277	$1,829.23
APC 5055	Level 5 Skin Procedures	CPT code 15273	$3,660.97

Beginning in CY 2016, we adopted a policy where we determine the high-cost/low-cost status for each skin substitute product based on either a product's geometric mean unit cost (MUC) exceeding the geometric MUC threshold or the product's per day cost (PDC), which is calculated as the total units of a skin substitute multiplied by the mean unit cost and divided by the total number of days, exceeding the PDC threshold. We assign each skin substitute that exceed either the MUC threshold or the PDC threshold to the high-cost group. In addition, we assign any skin substitute with a MUC or a PDC that does not exceed either the MUC threshold or the PDC threshold to the low-cost group (87 FR 71976).

We also assign skin substitutes with pass-through payment status to the high-cost category. We assign skin substitutes with some pricing information but without claims data for which to calculate a geometric MUC or PDC to either the high-cost or low-cost category based on the product's ASP plus 6 percent payment rate as compared to the MUC threshold. If ASP is not available, we use the wholesale acquisition cost (WAC) plus 3 percent to assign a product to either the high-cost or low-cost category. Finally, if neither ASP nor WAC is available, we use 95 percent of average wholesale price (AWP) to assign a skin substitute to either the high-cost or low-cost category.

In the CY 2021 OPPS/ASC final rule with comment period, after the first entirely synthetic skin substitute products were introduced into the market, we revised our description of skin substitutes to include both biological and synthetic products (85 FR 86064 through 86067). Any skin substitute product that is assigned to a code in the HCPCS A2XXX series is assigned to the high-cost skin substitute group, including new products without pricing information. New skin substitutes without pricing information that are not assigned a code in the HCPCS A2XXX

series are assigned to the low-cost category until pricing information is available to compare to the MUC and PDC thresholds (89 FR 94247).

In the CY 2014 OPPS/ASC final rule, we also noted that several skin substitute products are applied as either liquids or powders per milliliter or per milligram and are employed in procedures outside of CPT codes 15271 through 15278. We stated that these products "will be packaged into the surgical procedure in which they are used." (78 FR 74930 through 74931).

We also clarified that our definition of skin substitutes does not include bandages or standard dressings, and that, under the OPPS, these items cannot be assigned to either the high-cost or low-cost skin substitute groups or be reported with either CPT codes 15271 through 15278 or HCPCS codes C5271 through C5278 (85 FR 86066).

c. Current FDA Regulation of Products CMS Considers to be Skin Substitutes

The FDA regulates products that CMS considers to be skin substitutes based on a variety of factors, including product composition, mode of action, and intended use. Relevant categories of FDA regulation for skin substitute products include the following:

(1) Self Determination Under Section 361 of the PHS Act and the Regulations in 21 CFR 1271 (361 HCT/Ps)

Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) are defined in 21 CFR 1271.3(d) as articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient. Examples include bone, ligament, skin, dura mater, heart valve, cornea, hematopoietic stem/progenitor cells derived from peripheral and cord blood, manipulated autologous chondrocytes, epithelial cells on a synthetic matrix, and semen or other reproductive tissue. Pursuant to section 361 of the Public Health Service (PHS) Act, FDA promulgated regulations at 21 CFR 1271, *et seq* that create an electronic registration and listing system for establishments that manufacture HCT/Ps, regulate donor eligibility, and establish current good tissue practice and other procedures to prevent the introduction, transmission, and spread of communicable diseases by HCT/Ps.

A subset of HCT/Ps are those that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 (361 HCT/Ps). The FDA has taken a risk-based, tiered approach in regulating HCT/Ps; as the potential risk posed by a product increases, so does the level of oversight (63 FR 26745). Although FDA is authorized to apply the requirements in the Federal Food, Drug, and Cosmetic Act (FD&C Act) and/or the PHS Act to those products that meet the definition of drug, biological product, or device, under a tiered, risk-based approach, HCT/Ps that meet specific criteria or fall within detailed exceptions do not require premarket review and approval. HCT/Ps that do not meet all the criteria in 21 CFR 1271.10(a) are not regulated solely under section 361 of the PHS Act and the regulations in 21 CFR part 1271. Unless an exception in 21 CFR 1271.15 applies, such products are regulated as drugs, devices, and/or biological products under the FD&C Act and/or the PHS Act and are subject to additional regulation, including applicable premarket review. An HCT/P is regulated solely under section 361 of the PHS Act and 21 CFR Part 1271 if it meets all of the following criteria (21 CFR 1271.10(a)):

- The HCT/P is minimally manipulated;
- The HCT/P is intended for homologous use only, as reflected by the labeling, advertising, or other indications of the manufacturer's objective intent;
- The manufacture of the HCT/P does not involve the combination of the cells or tissues with another article, except for water, crystalloids, or a sterilizing, preserving, or storage agent, provided that the addition of water, crystalloids, or the sterilizing, preserving, or storage agent does not raise new clinical safety concerns with respect to the HCT/P; and

Either:

++ The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function; or

++ The HCT/P has a systemic effect or is dependent upon the metabolic activity of living cells for its primary function, and:

-- Is for autologous use;

-- Is for allogeneic use in a first-degree or second-degree blood relative; or

-- Is for reproductive use.

Establishments that manufacture 361 HCT/Ps, as defined by 21 CFR 1271.3(e), must register and list their 361 HCT/Ps in the FDA's electronic Human Cell and Tissue Establishment Registration System (eHCTERS), but premarket review and approval by FDA is not needed. However, FDA acceptance of an establishment registration and 361 HCT/P listing form does not constitute a determination that an establishment is compliant with applicable FDA rules and regulations, that the FDA has agreed with the manufacturer's self-determination as a 361 HCT/P, or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)). When this proposed rule refers to 361 HCT/Ps, it generally refers to products where an establishment has self-determined that their product is a 361 HCT/P.[79] If an HCT/P does not meet the criteria set out in 21 CFR 1271.10(a), and the establishment that manufactures the HCT/P does not qualify for any of the exceptions in 21 CFR 1271.15, the HCT/P will be regulated as a drug, device, and/or biological product under the FD&C Act, and/or section 351 of the PHS Act (42 U.S.C. 262), and applicable regulations, including 21 CFR Part 1271, and premarket review generally is required.
(2) 510(k) Premarket Notification Submissions, Premarket Approval Applications, and De Novo Requests

"Devices," as defined under 21 U.S.C. 321(h)(1), do not achieve their primary intended purposes through chemical action and are not dependent upon being metabolized for the achievement of their primary intended purposes. Devices may be subject to premarket review through: (1) a 510(k) premarket notification submission (510(k)) in accordance with section 510(k) of the FD&C Act and implementing regulations in subpart E of 21 CFR part 807; (2) a premarket approval application (PMA) under section 515 of the FD&C Act and regulations in 21

[79] We note that establishments may seek feedback from FDA regarding their self-determination analysis and conclusion that a particular product is a 361 HCT/P. See, for example, *https://www.fda.gov/vaccines-blood-biologics/tissue-tissue-products/tissue-reference-group.*

CFR part 814; or, potentially, (3) a De Novo classification request (De Novo request) under section 513(f)(2) of the FD&C Act and regulations in subpart D of 21 CFR part 860. A 510(k) is a premarket submission made to the FDA to demonstrate that the device to be marketed is substantially equivalent to a legally marketed device that is not subject to premarket approval (sections 510(k) and 513(i) of the FD&C Act). Premarket approval is the most rigorous type of review and generally is required for class III medical devices . Class III devices are those devices for which insufficient information exists to determine that general controls and special controls would provide a reasonable assurance of safety and effectiveness and are purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or present potential unreasonable risk of illness or injury (section 513(a)(1)(C) of the FD&C Act). De Novo classification is a marketing pathway for novel medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness, but for which there is no legally marketed predicate device. Devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable.

(3) Biologics License Application

To lawfully introduce or deliver for introduction into interstate commerce a drug that is a biological product, a valid biologics license application (BLA) must be in effect under section 351(a)(1) of the PHS Act, 42 U.S.C. 262(a)(1), unless exempted under 42 U.S.C. 262(a)(3). Such licenses are issued only after showing that the product is safe, pure, and potent. Approval of a biologics license application or issuance of a biologics license shall constitute a determination that the establishment(s) and the product meet applicable requirements to ensure the continued safety, purity, and potency of such products (21 CFR 601.2(d)). Potency has long been interpreted to include effectiveness (21 CFR 600.3(s)).

The definition of the term "biological product" in section 351(i) of the PHS Act is: "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product . . . applicable to the prevention, treatment, or cure of a disease or condition of human beings." (42 U.S.C. 262(i)). In contrast to the registration and listing requirements for a 361 HCT/P or the substantial equivalence requirements for 510(k)s, products licensed under section 351 of the PHS Act are required to meet stringent pre- and post-market requirements to ensure the products' safety and efficacy when marketed. Table 64 lists several other notable differences between the relevant FDA regulatory categories for products CMS considers to be skin substitutes.

TABLE 64: COMPARISON OF FDA CLASSIFICATIONS

CLASSIFICATION	REVIEW GOAL WITHIN	FY2025 STANDARD APPLICATION FEE
361 HCT/P	N/A[80] (registration required)	N/A
510(k)[81]	90 Days	$24,335
PMA	180 or 320 days[82]	$540,783
BLA (original application for products requiring clinical data)	10 months[83]	$4,310,002[84]

d. Proposed Payment of Skin Substitute Products under the PFS and OPPS

1. Separate Payment for Skin Substitute Products as Incident-To Supplies

We have carefully considered our policy objectives, which include: (1) ensuring a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; (2) ensuring that appropriate HCPCS codes describe skin

[80] No premarket authorization is required for 361 HCT/Ps.
[81] *https://www.fda.gov/industry/fda-user-fee-programs/medical-device-user-fee-amendments-mdufa*.
[82] These numbers include either a review within 180 days for decisions without advisory committee input or a review within 320 days for decisions with advisory committee input, respectively.
[83] PDUFA performance goals call for FDA to review and act on 90 percent of original BLA submissions within 10 months of the 60-day filing date. Other regulatory pathways may have different timelines. See *https://www.fda.gov/patients/learn-about-drug-and-device-approvals/fast-track-breakthrough-therapy-accelerated-approval-priority-review; https://www.fda.gov/drugs/development-approval-process-drugs*..
[84] *https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments*.

substitute products; (3) employing a uniform approach across products within the physician office setting, regardless of whether the product is synthetic or comprised of human- or animal-based material; and (4) providing clarity for interested parties on CMS skin substitutes policies and procedures. We propose, starting January 1, 2026, to separately pay for the provision of certain groups of skin substitute products as incident-to supplies when, for those products that are coverable under Medicare's rules, they are used during a covered application procedure paid under the PFS in the non-facility setting or under the OPPS. This proposal does not apply to biological products licensed under section 351 of the PHS Act, which will continue to be paid as biologicals under the ASP methodology in section 1847A of the Act. While we considered proposing to pay separately for skin substitutes initially under just the PFS in non-facility settings consistent with current practice, one of our primary policy objectives is to ensure a consistent payment approach for skin substitute products across the physician office and hospital outpatient department settings; and so, we ultimately determined that the suite of products referred to as skin substitutes should be treated in a uniform manner across different outpatient care settings, to the extent permitted by applicable law, such as section 1833(t)(2)(B) of the Act. The physician, in consultation with his or her patient, decides the site of service for treatment. While many factors are considered as a part of that decision, substantial differences in payment for the application of the same skin substitute product in one site of service versus another, or between similar skin substitute products, should not be one of them. Establishing a consistent framework for how these products are treated within the non-facility and hospital outpatient settings would empower providers to make the best treatment decisions for their patients, ensure equitable access to needed services, and pay appropriately for these services. We also considered bundling payment for skin substitute products in both the PFS and OPPS as part of this proposal. While supplies are generally bundled into the payment of the service in both the physician office and hospital outpatient departments, for many years skin substitute products have been paid separately in the physician office setting, where the majority of these products are currently

applied. So, we have determined that bundling payment for skin substitute products with their administration procedures across both settings under this new proposal, before efforts are made to address improper utilization patterns, would be premature. Depending on whether our proposal is finalized, and the outcomes of a final policy, we may consider packaging skin substitute products with the related application procedure in both the hospital outpatient setting and non-facility setting in future rulemaking. We seek comments on our proposal to separately pay for the provision of certain groups of skin substitute products as well as on our proposal to implement this policy in both the non-facility and hospital outpatient settings. For additional details on the PFS proposal for skin substitutes, please see the CY 2026 PFS proposed rule with comment period; the remainder of this policy proposal will focus on implementation under the OPPS.

In the CY 2014 OPPS/ASC final rule with comment period, we finalized a policy to package the payment for skin substitutes into high- and low-cost administration codes (see 78 FR 74930 through 74931 and 42 CFR 419.2(b)(16)). Under this proposal, the payment for skin substitutes would no longer be packaged into the administration procedures under the OPPS, when performed in the outpatient hospital setting. Rather, we propose to remove skin substitutes from the list of packaged items and services at 42 CFR 419.2(b)(16) and specify that we will continue to package payment for products that aid wound healing that are not skin substitute products. Accordingly, the C-codes describing the low-cost group, HCPCS codes C5271 through C5278, would be deleted; and skin substitutes assigned to the high-cost group, described by HCPCS codes 15271 through 15278, would remain to describe skin substitute administration procedures. As a result of the unbundling of the skin substitute products from HCPCS codes 15271 through 15278, the costs associated with the HCPCS codes may be impacted, resulting in changes in APC assignments. We refer readers to Addendum B to the CY 2026 OPPS/ASC proposed rule with comment period for the APC assignments and associated payment rates for HCPCS codes 15271 through 15278. We also propose to combine the existing claims data

available for the two sets of current OPPS codes, the low-cost and the high-cost administration groups, to set the initial payment rate for the proposed skin substitute administration procedures described by HCPCS codes 15271 through 15278. We believe it is appropriate to combine the available claims data from both the low-cost and high-cost administration groups to calculate the payment rate for the proposed skin substitute administration procedures as both the low-cost and high-cost groups describe skin substitute administration. While HCPCS add-on administration codes 15272, 15274, 15276, and 15278 would still be packaged in the hospital outpatient setting, because add-on codes are generally packaged in the hospital outpatient setting, we anticipate that many of the concerns expressed by presenters at previous meetings of the Advisory Panel on Hospital Outpatient Payment (HOP Panel) and by public commenters on previous rules that providers are discouraged from treating larger wounds in the hospital outpatient setting (89 FR 94247) would be addressed by our proposal to pay separately for codes describing provision of skin substitute products from their associated administration codes. We seek comment on our proposal to pay separately for provision of skin substitutes as incident-to supplies when used as part of an administration procedure in the hospital outpatient setting.

In the CY 2014 OPPS/ASC final rule with comment period, we finalized a policy to treat skin substitutes as biologicals that function as supplies when used in a surgical procedure. Similarly, under this proposal, most skin substitutes would be considered incident-to supplies in accordance with section 1861(s)(2)(A) of the Act. Supplies are a large category of items that typically are either for single use or have a shorter use life span than equipment. Supplies can be anything that is not equipment and include not only minor, inexpensive, or commodity-type items but also include a wide range of products used in outpatient settings, including certain implantable medical devices. “Incident-to supplies” refers to supplies that are furnished as an integral, although incidental, part of the physician’s personal professional services in the course of diagnosis or treatment of an injury or illness (42 CFR 410.26). Because a skin substitute must be used to perform any of the procedures described by a CPT code in the range 15271 through

15278, and the procedure of treating the wound and applying a covering to the wound is the independent service, skin substitute products serve as a necessary supply for these surgical repair procedures.

One purpose of the new proposed policy is to limit some of the current profiteering practices occurring in this industry. For example, as reflected in CMS's ASP Pricing Files, we have observed a dramatic increase in launch prices. It is unclear how these prices could be attached to realistic changes in resource costs as many of these new products are minimally manipulated tissues. Our proposed policy is likely to disincentivize this practice, as well as several other novel industry practices that have come to our attention, by preventing exploitation of skin substitute pricing under section 1847A of the Act, overuse of expensive skin substitute products, and waste resulting from use of more-expensive skin substitute products over clinically-appropriate, less-expensive alternatives. Notably, there has not been significant growth in payments for skin substitutes in the OPPS, due in part to our packaging principles. We note that the relevant statutory provisions, when considered together, do not require all of these kinds of products to be paid as biologicals under section 1847A of the Act. Therefore, under this proposed policy, unless a skin substitute is approved as a drug or as a biological product under section 351 of the PHS Act, in which case we would continue to pay for it consistent with section 1847A of the Act, we would consider it a supply for payment purposes under the OPPS with definitions and rates described below. For Medicare purposes, we propose to codify the definition of "biological" as "a product licensed under section 351 of the Public Health Service Act" at §§ 414.802 and 414.902. We seek comments on our proposal to limit application of section 1847A of the Act to skin substitutes that are approved as a drug or as a biological under section 351 of the PHS Act and our proposed edits to the regulations.

2. Payment Categories Based on FDA Regulatory Pathways

Paying separately for skin substitutes in the non-facility setting has led to dramatic price increases for these products, as noted above. Grouping similar products or services into a single

billing code and using a single payment amount for them, as we do with many services under the OPPS, some services under the PFS, and all multiple-source drugs under section 1847A of the Act, incentivizes hospitals and prescribers to make more cost-efficient, clinically effective decisions. However, we recognize that grouping dissimilar products and/or services to set payment rates, can limit beneficiaries' access to appropriate care, especially when some groups encompass products and services with significant clinical and resource variability. In the case of skin substitutes, no single product among the wide range of products stands out as typical; so, we have reviewed several methods to group or classify skin substitutes to determine which best reflects clinical and resource similarities between these products.

To reflect relevant product characteristics, we propose to group skin substitutes that are not drugs or biologicals (i.e., biological products licensed under section 351 of the PHS Act) using three CMS payment categories based on FDA regulatory categories ((PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. We have previously noted in rulemaking that CMS has no obligation to categorize products based on the FDA's current regulatory framework (74 FR 60476); but, in this case, we have determined that the FDA regulatory categories provide an appropriate level of distinction for a heterogeneous category of products that exhibit clinical and resource variability that can ultimately improve the accuracy of payment under the OPPS. Proposing a payment policy that aligns with FDA's current regulatory framework also provides for predictability and efficiency for purposes of Medicare payment. Payment for new products, as discussed below, could be achieved quickly and consistently by CMS's capacity to immediately recognize the FDA regulatory categories.

a. 361 HCT/Ps

As described previously, 361 HCT/Ps are a subset of HCT/Ps that are regulated solely under section 361 of the PHS Act and the regulations in 21 CFR 1271 and listed in the FDA's eHCTERS. Currently, registered 361 HCT/Ps generally are dressings intended only to cover and protect a wound. They are not intended to act on the wound to mediate, facilitate, or accelerate

wound healing. Their activity is typically limited to that of a physical covering or wrap. A structural tissue intended for wound care is generally limited to the homologous use of cover and protect in order to be a 361 HCT/P.[85] Intended uses such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute would generally be non-homologous uses of structural tissues. Instead, products for such intended uses (for example, the treatment of wounds) generally are subject to PMA or BLA requirements.

b. Devices requiring 510(k)s

A 510(k) is a premarket submission made to the FDA generally by the manufacturer of a device to demonstrate that the device to be marketed is substantially equivalent to legally marketed device that is not subject to premarket approval. (FD&C Act sections 510(k),513(i)). Currently, 510(k)-cleared devices that we are considering for purposes of this proposal generally are dressings intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound. They are not intended to act on the wound to mediate, facilitate, or accelerate wound healing. Their activity is typically limited to that of a physical covering or wrap. When intended only to cover and protect a wound, to absorb exudate, and to maintain appropriate moisture balance within the wound and otherwise meeting the device definition, generally the FDA's Center for Devices and Radiological Health (CDRH) regulates wound dressings composed of natural biomaterials, including animal and human derived tissue as devices, and they are currently subject to 510(k) requirements. At this time, wound dressings have not been 510(k) cleared by FDA for indications such as wound treatment, promotion or acceleration of wound healing, or serving as a skin substitute[86]. Instead, products for such intended uses generally are subject to PMA or BLA requirements.

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[85] See *Regulatory Considerations for HCT/Ps: Minimal Manipulation and Homologous Use, July 2020 (pg. 19).*

[86] FDA Executive Summary Prepared for the October 26 & 27, 2022 Meeting of the General and Plastic Surgery Devices Panel of the Medical Devices Advisory Panel Classification of Wound Dressings with Animal-derived Materials (Section 3). Available at *download.*

For the purposes of this policy, we propose to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s. Similar to products cleared under 510(k)s, De Novo classification is a marketing pathway for medical devices for which general controls alone (class I), or general and special controls (class II), provide reasonable assurance of safety and effectiveness. While products authorized through the De Novo pathway have no legally marketed predicate device, devices that are classified into class I or class II through a De Novo request may be marketed and used as predicates for future premarket notification (that is, 510(k)) submissions, when applicable. Because of this, we would expect skin substitutes authorized through the De Novo pathway and those cleared under 510(k)s to be similar for payment purposes. We seek comment on our proposal to group skin substitutes into three FDA approval categories, PMA, 510(k), and 361 HCT/P, to set payment rates and our proposal to group any skin substitutes authorized through the De Novo pathway with those cleared under 510(k)s for payment purposes.

c. Products subject to PMAs

Premarket approval is the most rigorous type of review and generally is required for class III medical devices. Similar to BLA-approved wound care products, PMA-approved wound care products generally are intended to go beyond a simple wound cover to provide some type of direct treatment effect. The FDA has not defined the term “skin substitute.” However, the term has been used as a descriptor for certain wound care constructs that are currently approved under a BLA or PMA for treatment of burns or skin ulcers, including ulcers that appear to have failed to heal after standard of care. The intended uses of these products may include scaffold claims, reference to matrix attributes that promote endogenous cell binding, migration, differentiation, or proliferation, and/or activities mediated by matrix-associated regulatory factors that facilitate wound healing. Currently, wound care products intended to interact with the wound to facilitate, promote, or accelerate wound healing generally require approval of a BLA or, in some instances, a PMA. Approval of these products requires demonstration of safety and efficacy for the

intended use, which generally requires the performance of clinical studies. So PMA-approved devices can be readily distinguished from 510(k)-cleared devices and 361 HCT/P products, which are intended mainly to cover and protect the wound. They are clinically different, provide different benefits, and would theoretically be used for patients presenting with different clinical scenarios. As discussed, PMA-approved devices also go through a much more rigorous review process before marketing as compared to the substantial equivalence requirements for 510(k)s and lack of premarket review for registered 361 HCT/Ps. This more rigorous review for PMAs, as well as differences in clinical utility, and the associated costs to manufacturers, suggests that the resources involved in furnishing these products could be distinct from 361 HCT/Ps and 510(k)s. We seek comment on our proposal to group skin substitutes into three FDA categories, PMA, 510(k), and 361 HCT/P, to set payment rates.

We note that device pass-through payment status would still be available to new skin substitutes that meet the pass-through payment criteria in the hospital outpatient setting. However, while skin substitutes approved under device pass-through payment status are currently assigned to the high-cost category, because our proposal would eliminate the low- and high-cost groups, we propose to pay for skin substitutes approved under device pass-through payment status consistent with other devices approved under that payment pathway. For the purposes of eligibility of skin substitutes for transitional drug pass-through payment, we propose to define the term "biological" consistent with our interpretation of the term under section 1847A of the Act. Under this proposal, skin substitutes with an approved BLA would be considered under transitional drug pass-through payment status and skin substitutes with PMA or 510(k) clearance would continue to be evaluated under transitional device pass-through payment status. See section IV.A. of this proposed rule for more information on device pass-through payments under the OPPS and see section V.A. of this proposed rule for more information on drug pass-through payments under the OPPS.

Section 1833(t)(2) requires the Secretary to establish groups so that services classified within each group are comparable clinically and with respect to the use of resources. To effectuate this categorization into a payment policy under the OPPS, we propose to create three new APCs for HCPCS codes that describe skin substitute products organized by clinical and resource similarity. These three APCs will divide skin substitutes by their FDA regulatory pathway. Specifically, we propose to create: APC 6000 (PMA Skin Substitute Products); APC 6001 (510(k) Skin Substitute Products); or APC 6002 (361 HCT/P Skin Substitute Products). In addition, as noted previously, we propose to assign any skin substitutes approved through the De Novo pathway to APC 6001 (510(k) Skin Substitute Products) based on our proposed policy of categorizing products with these two regulatory statuses together. We also propose to create three new unlisted C-codes, one to describe skin substitute products in each approval pathway, for new skin substitute product that have received FDA approval or clearance but do not yet have their own code in effect. We propose to create HCPCS placeholder codes QXXX1 (Unlisted PMA skin substitute product) and assign it to APC 6000 (PMA Skin Substitute Products); QXXX2 (Unlisted 510(k) skin substitute product) and assign it to APC 6001 (510(k) Skin Substitute Products); and QXXX3 (Unlisted 361 HCT/P skin substitute product) and assign it to APC 6002 (361 HCT/P Skin Substitute Products). We propose to create these unlisted codes to prevent delays in Medicare payments for new FDA-approved or cleared skin substitute products. We note that unlisted codes should only be reported when there is no other existing CPT or HCPCS code that adequately describes the service being performed.

3. Alternative Payment Categories

As a conceptually possible alternative to our proposal to group skin substitutes based on FDA regulatory categories for purposes of payment, we considered aligning these products based on their composition, for example, whether they are non-synthetic or synthetic. Two examples provided by interested parties include grouping the products as allografts (for example, amniotic products, cellular products), xenografts (for example, collagen products derived from animals),

synthetics (for example, artificial products made from various biomaterials) and grouping the products as human living/cryopreserved tissue, dehydrated human/amniotic tissue, animal xenografts, and synthetics/polymers. However, as noted previously, skin substitutes are a heterogenous group with an increasing intersection between tissue, bioengineered, and synthetic components. With many products now including both non-synthetic and synthetic components, clear categorization of skin substitutes is no longer feasible. This makes this alternative extremely complex to implement because it would be necessary to determine which category would be most appropriate for each individual product based on the components of its composition and an assessment of the importance of each component. In addition, it is unclear if grouping products based solely on their composition would provide accurate differentiation with respect to resource or clinical similarity for the purposes of setting an appropriate payment rate.

Other alternatives we considered include grouping all products together to set a single payment rate or creating two or more categories reflecting product cost, similar to the groupings used currently to set payment rates for skin substitutes in hospital outpatient departments. While these options may offer certain operational advantages for their simplicity, neither recognizes the clinical differences among skin substitutes as reflected by their different intended uses. Paying for similar items and services at a comparable rate is a foundational aspect of our payment systems, but hospital outpatient departments paid under the OPPS and physicians and other practitioners paid under the PFS would instead have a financial incentive to use the least expensive skin substitute or the product offering the greatest discount, which could negatively affect patient outcomes and disincentivize innovation in this space if clinical differences are not recognized and differential payments rates are not set. In addition, dividing products by cost relies on pricing set by manufacturers. Especially in light of the dramatic growth of skin substitutes' ASP-based payment limits, this method is unlikely to accurately reflect skin substitute resource costs or clinical similarity.

We seek comment on whether adding certain subcategories to the three proposed FDA categories would improve clinical or resource similarity. One potential example is creating certain subcategories for payment based on one or more FDA device product codes, which is a categorization process that FDA uses to group similar products together. Other examples that have come to our attention include setting unique payment rates for 361 HCT/Ps based on the number of tissue layers (for example, one layer, two layers, and three or more tissue layers) or entirely synthetic products versus non-synthetic products for 510(k)s. If significant clinical or resource differences were identified between products in one or more of these categories, CMS could create a separate payment grouping for these products for payment purposes.

We also seek comments on whether products that are not in sheet form are appropriately considered skin substitutes for the purposes of providing separate payment under this policy. Examples include gel, powder, ointment, foam, liquid, or injected products listed in the nontraditional units of cc, mL, mg, and cm^3. We request feedback on whether these products could be appropriately used as part of the CPT administration codes in the range 15271 through 15278, despite existing CPT coding guidelines limiting their use, and how these units could be paid using the FDA regulatory category groups. For example, assuming these products were appropriate to administer using the noted CPT administration codes or other administration codes, CMS could include products listed in units of cc, mL, or cm^3 in the applicable FDA categories and equate a single cm^2 unit to each cc, mL, or cm^3 for payment purposes. We seek comments on whether other administration codes could be used to appropriately describe services performed using products with units other than cm^2.

4. Establishing Initial Payment Rates

We propose to establish initial payment rates for the three FDA regulatory categories based on the volume-weighted average ASP, with no additional markup, for skin substitute products in each category as submitted by manufacturers, when available. We have developed initial payment rates for each group based on the weighted, per-unit average of ASPs for the

fourth quarter of calendar year 2024. These initial payment rates are listed in the file titled "Skin Substitute Products by FDA Regulatory Category" on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* When ASP was not available, we used the MUC, which we currently use to determine the high-cost/low-cost status for each skin substitute product in the hospital outpatient setting to calculate the proposed initial rates. We considered using only the MUC data to calculate payment rates for these products. However, when ASP is reported, it may serve as a better estimate of cost across both settings as the ASP reflects sales to physicians as well as hospitals. We seek comment on our proposal to calculate payment rates for skin substitute products in each of the three FDA regulatory categories using ASP, or MUC when ASP is not available, using per-unit averaged pricing data from the fourth quarter of 2024. We also seek comments on whether these calculations, if finalized, should be updated with the most recently available data at the time the final rule is drafted.

As we are proposing to implement this policy for CY 2026 in a site-neutral manner across both the non-facility setting under the PFS and hospital outpatient setting under the OPPS, we are including all products used in either setting to calculate the rates. However, when product-specific utilization across both settings is used to calculate volume-weighted average payments, the result is an apparent rank order anomaly; despite having a more rigorous regulatory review process and receiving indications to treat and heal wounds, the PMA category has the lowest average payment. We are concerned that the use of the novel pricing practices noted above has resulted in a decoupling of actual resource costs from the ASP. To address this, as a short-term measure, we propose to weight the product-specific utilization in calculating the proposed rates using the proportions from only the hospital OPPS data and establish, for CY 2026, a single payment rate that would apply to all skin substitute products in the three FDA regulatory categories, or APCs. We believe the OPPS utilization data may better predict

utilization patterns under our proposed policies for non-facility settings because, similar to our proposals, these products are already grouped together for payment purposes under the OPPS. By grouping skin substitutes into high- and low-cost groups in the OPPS, hospitals are incentivized to choose either the lowest-cost, clinically appropriate product in the low-cost group or the lowest-cost, clinically appropriate product in the high-cost group. No similar incentive currently exists in the non-facility setting for physicians and other suppliers billing under the PFS. As the proposed policies are intended to mitigate the problematic incentives associated with current patterns of use in the non-facility setting by establishing payment rates for the products in groups instead of individually, we do not believe it would reflect the expected resource costs involved in providing care if we were to base the initial rates on utilization data from the non-facility setting that may be skewed by incentives that would no longer exist under our proposals. For these reasons, we propose to initially use hospital outpatient utilization to weight how much each product's price contributes to the proposed payment rates for skin substitutes cleared through the 510(k) pathway, self-determined to be 361 HCT/Ps, or approved under a PMA. We seek comments on the use of these product utilization patterns to set payment rates.

We also propose for CY 2026 to establish the same initial APC payment rate for each group of skin substitutes, including 510(k)-cleared products, registered 361 HCT/Ps, and approved PMAs. To ensure we are not underestimating the resources involved in using these products in furnishing care, we propose to use the highest of the calculated volume-weighted average payment amounts for 510(k)s, 361 HCT/Ps, and PMAs to set initial payment valuations. As the 361 HCT/Ps have the highest volume-weighted average payment amount, this average payment rate is reflected in the proposed initial payment rate below. However, we note that, in future notice and comment rulemaking, we intend to propose using claims data to set payment rates for products in these three categories, which would likely result in payment valuations that diverge based on the updated data. Another alternative is to set the payment rate for products in these categories at the volume-weighted average for all three categories, resulting in a lower

initial payment rate for all three groups of products. We seek comment on our proposal to use the 361 HCT/P volume-weighted average payment amount to set the initial payment rates for products in all three categories as well as the alternative of using a pooled average of the three categories to set the initial payment rates.

Alternatively, while the ASP Pricing Files show that skin substitutes across all three of the FDA regulatory categories have increased in cost substantially since 2019, unlike the self-determined 361 HCT/Ps and 510(k)-cleared devices, there has not been a substantial increase in the number of skin substitutes with approved PMAs. Consequently, it is possible that the non-facility utilization of the skin substitutes with approved PMAs is not as distorted as the utilization of the other kinds of skin substitutes. Setting a separate payment rate for this category using combined product utilization patterns (from both OPPS and non-facility settings), would result in a higher initial payment rate for the PMA category. This would rationally order the FDA regulatory categories, based on clinical considerations and some indicators of resource cost, until pricing data removed from these aberrant financial incentives can be incorporated. We seek comment on this alternative policy option.

The proposed calculation methodology would result in an initial payment rate of $125.38 for all three proposed new APCs based on the FDA categories including PMA-approved devices, 361 HCT/Ps, and 510(k) devices. Specifically, this proposal would result in an initial payment rate of $125.38 for each HCPCS code assigned to APC 6000 “PMA Skin Substitute Products,” APC 6001 “510(k) Skin Substitute Products,” and APC 6002 “361 HCT/P Skin Substitute Products.” We seek comments on these proposed initial payment rates. We determined these proposed rates using product pricing and volume for skin substitutes from paid claims with dates of service in the fourth quarter of 2024 because it is the most recent, substantially complete quarter of data available. For professional claims, we excluded claims without a positive line-level allowed amount, so that we did not inadvertently include volume without presumed costs in the calculation. In addition, in reviewing the ASP pricing files from the first quarter of 2017

through the first quarter of 2025, the most complete ASP reporting is in the fourth quarter of each year. To determine the payment rates, we first used a product's ASP if it was available. If the ASP rate was missing, we used the 2024 MUC for the HCPCS code. We then calculated a single rate for each FDA category by taking the volume-weighted average of the rates for the applicable codes using the hospital outpatient utilization to weight each category. We note that if rather than using the final quarter of CY 2024, we alternatively, were to use pricing and volume from all four quarters of 2024 to determine proposed rates, the rate for all categories would be approximately $114.87. Using a pooled payment rate across all three categories would result in a rate of approximately $65.85, while splitting the categories to pay the PMA category using the combined product utilization patterns and the 510(k) and 361 HCT/P categories using the OPPS utilization patterns would result in rates of approximately $259.47 and $125.38 respectively. We seek comment on our proposed process to calculate initial payment rates as well as these alternatives.

We propose to maintain the current structure of HCPCS codes for skin substitutes, including a process to introduce new product-specific codes and propose initial valuation based on the typical resource costs (i.e., those reflected in ASP and MUC data) of the groups associated with each skin substitute's HCPCS code. We propose to assign each current HCPCS code that describes an individual skin substitute product to one of the three new APCs based on the product's appropriate FDA regulatory category. For a complete list of codes and FDA categories, please see file entitled "Skin Substitute Products by FDA Regulatory Category" available on the CMS website under downloads for the CY 2026 PFS proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Individual HCPCS coding, as provided in the file, remains necessary to provide identification on claims and track each product's cost. This will also allow effectuation of any applicable coverage policies and improve our ability to determine if any refinements in payment categories would be appropriate in future rulemaking.

For the most part, materials or supplies furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker) are not paid separately under the OPPS. However, separate payment for products is not novel, since Medicare pays for various components of services through the use of separate HCPCS codes and/or payment modifiers. The most obvious examples of these kinds of payment and coding splits occur in diagnostic tests, radiation treatment services, and blood product services. For example, under the OPPS, blood products receive specific HCPCS codes and are paid separately from other services. In this case, the procedure of applying or administering a skin substitute product would not be described or paid for by a single code. Rather, when a skin substitute product is applied, both the application code as well as the HCPCS code of the skin substitute that is being applied would be billed under the OPPS. For example, when CPT Code 15271 (application of skin substitute graft, leg or ankle) is billed, we would expect for the hospital outpatient department to also report a skin substitute HCPCS code, which would be paid at a payment rate that includes the resources involved in using the skin substitute product. We propose for skin substitute products to receive a separate payment independent from the payment for the application procedure. To effectuate this proposed payment policy under the OPPS, we propose to create a new status indicator for HCPCS codes describing skin substitutes that are assigned to one of the three new APCs for skin substitutes based on FDA regulatory pathway. Specifically, we propose to create status indicator "S1" to indicate that the skin substitute product is paid separately from other procedure codes under the OPPS. We propose to assign all existing HCPCS codes describing skin substitute products to status indicator "S1" for CY 2026. The proposed status indicator "SI," along with its descriptor and payment status, is listed in Table 65.

TABLE 65: PROPOSED STATUS INDICATOR FOR SKIN SUBSTITUTE PRODUCTS

PROPOSED STATUS INDICATOR	PROPOSED DESCRIPTOR	PROPOSED OPPS PAYMENT STATUS
S1	Skin substitute product paid separately	Paid under OPPS; separate APC payment. Subject to payment based on FDA regulatory pathway.

We also seek comments on whether we should consider treating the codes describing skin substitute products as add-on codes to the current CPT administration codes (CPT codes 15271-15278). This would more clearly indicate that the only skin substitute products to be paid for and treated as supplies by Medicare are those used in conjunction with the already existing CPT administration codes. If we were to treat these codes as add-on codes to the administration codes, we would effectuate this by revising the code descriptors of the skin substitute products to state "list separately in addition to the primary procedure." While we would normally assign the add-on codes to a status indicator that indicates that payment is packaged (i.e. status indicator "N" (Items and Services Packaged into APC Rates)), given our proposal to pay separately for skin substitute products as incident-to supplies, we would still propose to assign status indicator "S1," to the skin substitute codes.

We propose that new HCPCS codes describing skin substitutes would be categorized based on whether they are PMA-approved, 510(k)-cleared, or 361 HCT/Ps and the payment rates that apply to that category would be applied to the new code at the next quarterly update. Currently, HCPCS Level II coding applications are submitted and reviewed during our quarterly and biannual coding cycles. We post our coding determinations for drugs and biologicals on a quarterly basis, and do not routinely review those applications at a HCPCS public meeting. For non-drugs and non-biologicals, we post our coding decisions on a biannual basis. For our biannual cycles for non-drugs and non-biologicals, we post preliminary coding determinations then invite feedback on those preliminary coding determinations at a biannual HCPCS public meeting; final coding determinations are posted following the HCPCS public meeting. CMS has been reviewing skin substitutes marketed as 361 HCT/Ps in the quarterly drugs and biologicals coding cycle and 510(k)-cleared skin substitutes in the biannual, non-drugs and non-biologicals coding cycle. Beginning January 1, 2026, we propose to review HCPCS Level II coding applications for all skin substitutes marketed as 361 HCT/Ps through our biannual coding cycle for non-drugs and non-biological products, rather than on a quarterly basis. Skin substitutes that

received a 510(k) clearance, PMA approval, or a granted De Novo request would continue to be evaluated in the biannual HCPCS Level II coding cycles. Therefore, under this proposal, CMS would evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. Should any products come to market under the BLA, NDA, or ANDA pathways that could potentially be considered skin substitutes, CMS would instead review them in a quarterly HCPCS Level II drugs and biologicals coding cycle.

Before a code is assigned to describe the skin substitute product, not otherwise classified (NOC) codes would be used and the CMS MACs would assign the appropriate payment based on the product's FDA category. We propose to create three new unlisted codes to describe skin substitute products that are FDA authorized or cleared but have not yet received a specific individual HCPCS or CPT code: HCPCS placeholder codes QXXX1 (Unlisted PMA skin substitute product), QXXX2 (Unlisted 510(k) skin substitute product), and QXXX3 (Unlisted 361 HCT/P skin substitute product). We propose to assign the unlisted HCPCS codes to the appropriate APCs based on the product's FDA approval or clearance. Specifically, we propose to assign HCPCS code QXXX1 to APC 6000 (PMA Skin Substitute Products); QXXX2 to APC 6001 (Unlisted 510(k) Skin Substitute Products); and HCPCS Code QXXX3 to APC 6002 (Unlisted 361 HCT/P Skin Substitute Products). and assign it to APC 6002 (361 HCT/P Skin Substitute Products). We propose to create these unlisted codes to prevent delays in Medicare payments for new FDA-approved or cleared skin substitute products that do not yet have a specific HCPCS or CPT code.

If skin substitutes that are not licensed under section 351 of the PHS Act are no longer paid as biologicals using the methodology under section 1847A of the Act, as proposed, then the manufacturers of these products would no longer be required to report ASP data to CMS under section 1847A(f)(2) of the Act. However, when ASP data is reported, it may serve as a better estimate of resources across the hospital outpatient and non-facility settings than hospital outpatient MUC data. We propose to update the rates for the skin substitute categories annually

through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. However, we have concerns that using a single, scheduled quarter of ASP data to set payment rates could encourage gaming. We seek comment on the use of a longer timeframe, such as the most recently available four calendar quarters, to set payment rates in future years. In the event ASP is not available for a particular product, we propose to use the MUC data. If MUC is not available, we propose to use the product's WAC or 89.6 percent of AWP if WAC is also unavailable, similar to other products for which ASP is used to calculate a payment rate.[87] Once updated use patterns reflecting this policy are available to calculate rates, we propose using all relevant products and the combined product utilization patterns (OPPS and non-facility) to determine a weighted average per-unit cost by category to set separate payment rates for each of the three new APC groups. We seek comments on our proposed methodology to set and update the payment rates for skin substitutes as well as the rates themselves.

5. Summary

To implement this policy, we propose, starting January 1, 2026, to separately pay for skin substitute products as incident-to supplies in both the non-facility and hospital outpatient settings. Under the OPPS, we propose to unpackage the skin substitute product from the payment for the administration of the skin substitute product and pay for the administration of the skin substitute product separately from the skin substitute product itself. Accordingly, we propose to delete the C-codes describing the skin substitutes assigned to the low-cost group, HCPCS codes C5271 through C5278. We are not proposing to delete the HCPCS codes assigned to the high-cost group, described by HCPCS codes 15271 through 15278, as they would remain to describe skin substitute administration procedures. We are specifying that HCPCS add-on administration codes 15272, 15274, 15276, and 15278 would still be packaged in the outpatient hospital setting.

[87] 89.6 percent of AWP was calculated by first reducing the usual 95 percent of AWP price by 6 percent to generate a value that is similar to WAC with no percentage markup.

We propose to pay separately for certain groups of skin substitute products as incident-to supplies involved in furnishing services under both the physician non-facility and outpatient hospital settings. Unless a skin substitute meets the definition of a biological in section 1847A, in which case the payment methodology under section 1847A would continue to apply, we propose to create three clinical APCs to pay for skin substitutes based on their FDA regulatory categories: APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products). We propose to use the hospital outpatient utilization patterns to set the payment rates for all three skin substitute APCs, which we propose to combine this year for payment purposes. For CY 2026, this proposal would result in an initial payment rate of $125.38 for APCs 6000 (PMA Skin Substitute Products), 6001 (510(k) Skin Substitute Products), and 6002 (361 HCT/P Skin Substitute Products).

We propose to maintain the current HCPCS codes for skin substitutes and assign the codes to the three APCs based on the product's FDA regulatory category. We propose to create three new unlisted codes to describe skin substitute products that are FDA authorized or cleared but have not yet received a specific individual HCPCS or CPT code: HCPCS placeholder codes QXXX1 (Unlisted PMA skin substitute product), QXXX2 (Unlisted 510(k) skin substitute product), and QXXX3 (Unlisted 361 HCT/P skin substitute product). We propose to assign the unlisted HCPCS codes to the appropriate APCs based on the product's FDA approval or clearance. Specifically, we propose to assign HCPCS code QXXX1 to APC 6000 (PMA Skin Substitute Products); QXXX2 to APC 6001 (Unlisted 510(k) Skin Substitute Products); and HCPCS Code QXXX3 to APC 6002 (Unlisted 361 HCT/P Skin Substitute Products). and assign it to APC 6002 (361 HCT/P Skin Substitute Products). We propose to create these unlisted codes to prevent delays in Medicare payments for new FDA-approved or cleared skin substitute products that do not yet have a specific HCPCS or CPT code. We propose to create a new status indicator, S1, for skin substitute products to allow for separate payment under the OPPS. We

propose to assign status indicator S1 to all skin substitute products assigned to APCs 6000, 6001, and 6002.

We propose to update the rates for the skin substitute categories annually through rulemaking using the most recently available calendar quarter of ASP data, when available, to set the rates. In the event ASP is not available for a particular product, we propose to use the outpatient hospital MUC data. If MUC is not available, we propose to use the product's WAC or 89.6 percent of AWP if WAC is also unavailable. We propose to include all skin substitute products used across both settings as well as the combined product utilization patterns, as soon as data is available that reflects the results of this policy, to determine a weighted average per-unit cost by group to set the payment rates for each of the three categories. We propose to evaluate all complete HCPCS Level II applications for skin substitutes in our biannual cycles. We propose to codify the definition of "biological" as "a product licensed under section 351 of the Public Health Service Act" at §§ 414.802 and 414.902. Finally, we note that these proposed changes for the CY 2026 OPPS skin substitute policy will affect prospective CY 2026 OPPS payments and weights, and as a result will be budget neutralized through the OPPS weight scaler, which accounts for prospective changes in OPPS payments and payment weight. For a discussion of the OPPS budget neutral weight scaler, see section II.A.5. of this proposed rule. We direct readers to section XIII. of this proposed rule for more information on our proposal for payment for skin substitute products applied in the ASC setting.

10. CY 2026 Physician Fee Schedule Proposal Regarding Cell and Gene Therapies

In the CY 2026 PFS proposed rule, we propose that (1) preparatory procedures for tissue procurement required for manufacturing an autologous cell-based immunotherapy or gene therapy be included in the payment of the product itself and (2) that, beginning January 1, 2026, any preparatory procedures for tissue procurement required for manufacturing an autologous

cell-based immunotherapy or gene therapy that were paid for by the manufacturer be included in the calculation of the manufacturer's ASP.

We are making readers aware of this proposal as it may impact therapies paid under the OPPS and ASC payment system. We direct readers to submit their comments on this topic to the CY 2026 PFS proposed rule. Comments submitted to the PFS rule will be responded to in the CY 2026 PFS final rule with comment period along with the finalized policy.

11. Medicare Part B Drugs without a Medicaid National Drug Rebate Agreement (NDRA)

CMS has reviewed drugs, biologicals, and radiopharmaceuticals with HCPCS codes that meet the definition of a covered outpatient drug (defined at 42 CFR 447.502) and are receiving payment under Medicare Part B. In accordance with section 1927(a)(1) of the Social Security Act, for payment to be available under Medicare Part B for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a Medicaid NDRA. As of the writing of this notice, our records indicate that the manufacturers of the single source drugs, biologicals, and radiopharmaceuticals listed in Table 66 do not currently have a Medicaid NDRA in effect. Accordingly, if the manufacturers, or labelers, of these products do not promptly enter into a Medicaid NDRA, Medicare Part B payment will no longer be available for these products, which includes payment under the OPPS and ASC payment system. These HCPCS codes will be assigned to an OPPS status indicator of E1, which indicates a non-payable

status by Medicare when submitted on outpatient claims (any outpatient bill type). Similarly, these HCPCS codes will be assigned to an ASC payment indicator of B5.

TABLE 66: HCPCS CODES DESCRIBING DRUGS MANUFACTURED BY LABELERS WITHOUT A MEDICAID NATIONAL DRUG REBATE AGREEMENT

HCPCS Code	HCPCS Code Long Descriptors
C9293	Injection, glucarpidase, 10 units
J0840	Injection, crotalidae polyvalent immune fab (ovine), up to 1 gram
J1162	Injection, digoxin immune fab (ovine), per vial
J3424	Injection, hydroxocobalamin, intravenous, 25 mg
C9089	Bupivacaine, collagen-matrix implant, 1 mg
C9144	Injection, bupivacaine (posimir), 1 mg
J7674	Methacholine chloride administered as inhalation solution through a nebulizer, per 1 mg
A9521	Technetium tc-99m exametazime, diagnostic, per study dose, up to 25 millicuries
J0716	Injection, centruroides immune f(ab)2, up to 120 milligrams
J0841	Injection, crotalidae immune f(ab')2 (equine), 120 mg
J2850	Injection, secretin, synthetic, human, 1 microgram
C9482	Injection, sotalol hydrochloride, 1 mg
J7353	Anacaulase-bcdb, 8.8% gel, 1 gram
A9592	Copper cu-64, dotatate, diagnostic, 1 millicurie
J1201	Injection, cetirizine hydrochloride, 0.5 mg
J2278	Injection, ziconotide, 1 microgram
J8670	Rolapitant, oral, 1 mg
J9202	Goserelin acetate implant, per 3.6 mg
J9248	Injection, melphalan (hepzato), 1 mg
J9600	Injection, porfimer sodium, 75 mg

12. Add-on Payment for Technetium-99m (Tc-99m) Derived from Domestically Produced Molybdenum-99 (Mo-99)

Radioisotopes are widely used in modern medical imaging, particularly for cardiac imaging and predominantly for the Medicare population. Technetium-99m (Tc-99m), the

radioisotope used in the majority of such diagnostic imaging services, is produced through the radioactive decay of molybdenum-99 (Mo-99). The United States makes up roughly half of global demand for molybdenum-99 (Mo-99). However, 100 percent of this crucial radioisotope is produced outside of the United States. The aging reactors producing it and the fast decay of the radioisotope over long shipping distances leave the United States vulnerable to supply disruptions.

Congress passed the American Medical Isotopes Production Act of 2012 (AMIPA) to support the development of a reliable supply of Mo-99 produced in the United States. In support of this effort, beginning in CY 2013, CMS finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-Highly Enriched Uranium (HEU) sources (77 FR 68323). In the CY 2023 OPPS/ASC final rule with comment period, we stated that we believed the conversion to non-HEU sources of Tc-99m had reached a point where it was necessary to reassess our policy of providing an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (87 FR 71987). As we explained in the CY 2023 OPPS/ASC final rule with comment period (87 FR 71987), we believed that, starting in CY 2025, the Medicare claims data utilized to set payment rates (likely CY 2023 claims data) would only include claims for diagnostic radiopharmaceuticals that utilized non-HEU-sourced Tc-99m, meaning the data would reflect the full cost of the Tc-99m diagnostic radiopharmaceuticals that would be used by providers in CY 2025. As a result, we believed there would no longer be a need for the additional $10 add-on payment for CY 2025 or future years. As such, we adopted a policy in the CY 2024 OPPS final rule with comment period (88 FR 81803) to end the additional $10 add-on payment described by HCPCS code Q9969 for non-HEU-sourced Tc-99m through the end of CY 2025 to continue to ensure adequate payment for non-HEU-sourced Tc-99m.

In the CY 2025 OPPS/ASC final rule (89 FR 94256 through 94259), we shared that the Department of Energy and other interested parties raised another issue affecting the domestic

supply chain for Mo-99 and Tc-99 that, left unaddressed, could cause payment inequity among outpatient hospital providers. Foreign Mo-99 production has historically been subsidized by foreign governments, resulting in prices below the true cost of production. These artificially low, foreign government-subsidized prices have created a disincentive for domestic investments in Mo-99 production infrastructure and a barrier to entry for new producers, including U.S. companies, which in turn has resulted in unreliable production and periodic shortages. Unlike many foreign producers, U.S. companies must price their products high enough to cover the full cost of operating their production facilities. Based in part on these differences in pricing models, U.S. companies have experienced challenges in competing with foreign producers for customers in the past.

Multiple companies have since developed technologies to produce Mo-99 and are expected to enter the market within the coming years. Additionally, U.S. companies have made significant progress towards establishing the infrastructure needed for large-scale Mo-99 production. Currently, there is no domestic production of Mo-99. However, once U.S. companies initiate Mo-99 production, the difference in pricing models will likely create a payment inequity, as hospitals purchasing Tc-99m derived from domestically produced Mo-99 would likely pay higher prices than those purchasing Tc-99m derived from imported Mo-99. Additionally, as domestic companies enter the market, we expect this transition to introduce new costs into the payment system that are not accounted for in the historical claims data.

In the CY 2025 OPPS/ASC final rule (89 FR 94256 through 94259), we finalized our proposal to address the payment inequity resulting from the higher cost of Tc-99m derived from domestically produced Mo-99 by establishing a new add-on payment of $10 per dose for radiopharmaceuticals that use Tc-99m derived from domestically produced Mo-99 starting on January 1, 2026, using our equitable adjustment authority under section 1833(t)(2)(E) of the Act.

We stated that the Department of Energy, National Nuclear Security Administration (DOE/NNSA) would establish the criteria to certify whether the Tc-99m radiopharmaceutical

dose is derived from domestically produced Mo-99 and eligible for the add-on payment, which would be included in this CY 2026 OPPS/ASC proposed rule. We also stated that once requirements are established defining a domestically produced Tc-99m radiopharmaceutical, we will consider in future rulemaking any requirements for providers to document that the Tc-99m radiopharmaceutical used in a procedure was domestically produced and can qualify to receive the add-on payment. While we recognized that there may not be domestic production of Mo-99 and Tc-99m in CY 2026, we stated that we believed it is better to have a regulatory framework for this policy in place for when domestic production of Tc-99m radiopharmaceuticals begins. Specifically, we believe that by having a regulatory framework already in place, providers will be knowledgeable about the availability of additional payments for domestically sourced Tc-99m radiopharmaceuticals. Likewise, producers of domestic Mo-99 will have certainty that the Medicare OPPS payment policy takes into account the additional costs of domestic production of Mo-99.

a. Criteria for Classifying a Tc-99m Radiopharmaceutical Dose as Domestically Produced

As mentioned above, in the CY 2025 OPPS/ASC final rule, CMS stated that DOE/NNSA would establish the criteria to certify whether the Tc-99m radiopharmaceutical dose is derived from domestically produced Mo-99 and eligible for the add-on payment, which would be included in this CY 2026 OPPS/ASC proposed rule. For purposes of this provision, DOE/NNSA recommended, and we propose here, to define a domestically produced dose of Tc-99m, as a dose of Tc-99m generated from domestically produced Mo-99. Similarly, DOE/NNSA recommended, and we propose here, to define domestically produced Mo-99 to mean Mo-99 that was both irradiated and processed in the United States. DOE/NNSA also recommended, and we propose here, to define "irradiated," as the process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99, and to specify that irradiation is typically performed with a nuclear reactor or particle accelerator. Lastly, DOE/NNSA recommended, and

we propose here, to define "processed" in this context to refer to the purification of Mo-99 from irradiated material.

A dose of Tc-99m generated from Mo-99 that was irradiated or processed outside the United States would not qualify for this add-on payment, even if the Mo-99 was loaded into a Tc-99m generator in the United States or if the Tc-99m was eluted[88] at a radiopharmacy in the United States. For example, we note that Mo-99 imported and shipped separately to a US-based generator manufacturer or radiopharmacy, and then loaded in a generator stateside, would not be considered domestically produced Mo-99 for the purposes of this add-on payment. More specifically, although the Mo-99 was loaded into a generator or eluted in the United States, the Mo-99 was irradiated and processed abroad, imported, and then loaded into the domestic generator, and would therefore be excluded from this add-on payment.

In this proposed rule, as part of the implementation process for the add-on payment for Tc-99m derived from domestically produced Mo-99, per DOE/NNSA's recommended definitions for the purpose of this add-on payment, we propose to codify the aforementioned definitions and references for domestically produced Mo-99 to § 419.49 to specify when a dose of Tc-99m generated from domestically produced Mo-99 could be eligible for the add-on payment.

b. Coding and Documentation for the Add-on Payment for Tc-99m Derived from Domestically Produced Mo-99

In CY 2013, we finalized a policy to provide an additional payment of $10 for the marginal cost for radioisotopes produced by non-HEU sources (77 FR 68323). Under this policy, hospitals reported HCPCS code Q9969 (Tc-99m from non-highly enriched uranium source, full cost recovery add-on per study dose) once per dose, along with any diagnostic scan or scans

[88] "Eluted" refers to the process by which Tc-99m is chemically separated from Mo-99 within the generator and collected in an elution vial.

furnished using Tc-99m, as long as the Tc-99m doses used could be certified by the hospital to be at least 95 percent derived from non-HEU sources (77 FR 68323).

In this rule, we propose to establish new HCPCS C-code C917X (Tc-99m from domestically produced non-HEU Mo-99, [minimum 50 percent], full cost recovery add-on, per study dose), effective January 1, 2026. Similar to the implementation plan for the non-HEU add-on payment policy and the reporting of the corresponding HCPCS code Q9969, hospitals will be able to report new HCPCS C-code C917X once per dose, along with any diagnostic scan or scans furnished using Tc-99m derived from domestically produced Mo-99. Hospitals can bill this add-on code if the hospital can certify that at least 50 percent of the Mo-99 in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99.

Similar to the non-HEU add-on payment certification and tracking requirement, we expect that hospitals requesting this additional payment will perform standard due diligence to ensure that their claims are supported by internal records. For example, we believe that facilities could accept a tracking mechanism by a supplier (invoice, label, contract, among others) to track a dose that has been labeled or claimed as both irradiated and processed in the United States as satisfactory proof for the purposes of the facility with minimum administrative burden. We note that the use of the word "certify" in this subsection is meant only to indicate a formal statement by one party to assure another party of the source and composition.

c. Comment Solicitation on the Add-on Payment for Tc-99m Derived from Domestically Produced Mo-99

CMS aims to account for the per-dose cost of Tc-99m derived from domestically produced Mo-99 while limiting administrative burden for hospitals and protecting the Medicare trust fund. We are seeking comment on the following questions:

- Please provide any insight regarding the irradiation and processing required to produce Mo-99 that may be relevant.

- As we mentioned in the CY 2025 OPPS/ASC final rule, available information from the Organization for Economic Co-operation and Development, Nuclear Energy Agency (OECD/NEA) supports an add-on payment amount of $10 as appropriate to address the cost of Tc-99m derived from domestically produced Mo-99 for hospital outpatient departments. However, we are seeking additional information that could further inform the cost differentials between radioisotopes derived from domestic and foreign-produced Mo-99, including, but not limited to, production, transportation, and storage costs that outpatient hospital departments may incur that would not be accounted for in historical claims data. CMS may consider reevaluating the amount of the add-on payment if we receive new, substantial information to inform these cost differential factors of Tc-99m derived from domestically produced Mo-99.

- The threshold for billing the Tc-99m add-on code in this proposed rule is that 50 percent of the Mo-99 used in the Tc-99m generator to produce the Tc-99m was domestically produced Mo-99. Is this the appropriate threshold to use? What are some additional factors that CMS may consider when defining the eligibility threshold?

- What forms and levels of documentation are most viable and efficient for tracking and certifying if the Mo-99 and Tc-99m were domestically produced?

- What additional steps can CMS take to reduce administrative burden or improve tracking of domestically produced Mo-99 for purposes of this add-on payment?

C. Notice of Intent to Conduct Medicare OPPS Drugs Acquisition Cost Survey

As noted above, section 1833(t)(14)(A)(iii) requires the Secretary to set payment rates for specified covered outpatient drugs (SCODs)[89] beginning in 2006 at the amount the Secretary determines to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. To collect the cost survey data for the Secretary to use for 2006 payment rates, section 1833(t)(14)(D)(i)(I) of the Act required the

[89] For the definition of a SCOD, see section 1833(t)(14)(B) of the Act at *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*

Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD. To inform payment rates in later years, section 1833(t)(14)(D)(ii) requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD. In developing that survey, section 1833(t)(14)(D)(i)(II) requires the Secretary to take into account certain recommendations from the Comptroller General regarding frequency and methodology of subsequent surveys.

The GAO conducted the required surveys in 2004 and 2005, and, in reporting the results in 2006, recommended that the Secretary thereafter validate, "on an occasional basis— possibly every 5 or 10 years—ASP data that manufacturers report to CMS for developing SCOD payment rates."[90] CMS has not yet conducted a survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First."[91] Section 5 of the E.O., "Appropriately Accounting for Acquisition Costs of Drugs in Medicare," directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments.

Accordingly, under section 1833(t)(14)(D)(ii) of the Act, we will be conducting a survey of the acquisition costs for each separately payable drug acquired by all hospitals paid under the OPPS, including SCODs, and drugs and biologicals CMS historically treats as SCODs. This survey will be open starting at the end of CY 2025 to early CY 2026. We have reviewed and taken into account the Comptroller General's recommendations regarding the frequency and methodology of these surveys in developing our proposed survey, and we intend for the survey to be completed in time for the survey results to be used to inform policy making beginning with

[90] *https://www.gao.gov/assets/gao-06-372.pdf.*
[91] *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

the CY 2027 OPPS/ASC proposed rule. We intend to propose and seek comment on any payment rates for SCODs based on the survey results in CY 2027 rulemaking.

Under section 1833(t)(14)(D)(iii) of the Act, the surveys must have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug. Consequently, we will seek an adequate response rate to the survey and surveyed hospitals have an obligation to respond to the survey. Hospitals have ample notice in this proposed rule regarding the intent and the details of the OPPS Drug Acquisition Cost Survey, so we expect all hospitals will submit their acquisition costs in a timely manner to CMS. We understand that hospitals have significant drug acquisition costs, and so (consistent with the Comptroller's General experience conducting earlier drug acquisition cost surveys in which 83 percent of the hospitals surveyed provided usable data[92]), we anticipate hospitals would want to respond to this survey to demonstrate to CMS these costs. We request comment from readers on whether we should make responding to the survey a mandatory requirement of all hospitals paid under the OPPS through 1833(t)(14)(D)(iii) of the Act.

We also welcome comment on how we might propose to interpret non-responses to the survey. For example, since a failure on the part of a hospital to respond to the survey could suggest that the hospital has minimal acquisition costs, or has lower acquisition costs than an otherwise similar hospital that responds to the survey and so is withholding its response strategically, we might, if the data so suggests, determine that groups of hospitals who do not respond to the survey have lower acquisition costs for SCODs than their otherwise similar counterparts under section 1833(t)(14)(A)(iii)(I) of the Act. In such instances, we would consider various appropriate ways, taking into account the hospital acquisition cost survey data, to determine the average acquisition cost. One method we might consider, depending on the cost survey data, could be to use the lowest acquisition cost reported among otherwise similar

[92] *https://www.gao.gov/assets/gao-06-372.pdf*. Page 7.

responding hospitals as a proxy for the average acquisition costs for hospitals that do not respond to the survey. We might also consider supplemental data sources to inform our determination of average acquisition costs for hospitals for whom we lack cost acquisition survey data. For example, we might consider using, as available, pricing from the Federal Supply Schedule (FSS)[93]; 340B ceiling price[94]; ASP plus 6 percent, 0 percent or another percentage; or other recognized drug pricing for payment of hospitals that do not respond to the survey.

We could also consider a hospital's non-response to the survey when determining how to package drug costs for particular hospital groups. Under section 1833(t)(2)(B) of the Act, the OPPS establishes groups of covered HOPD services, namely APC groups, and uses them as the basic unit of payment. In the case of much of the care paid under the OPPS, we view a complete service as potentially being reported by a combination of two or more HCPCS codes, rather than a single code, and establish payment policies that support this view. Ideally, we would consider a complete HOPD service to be the totality of care furnished in a hospital outpatient encounter or in an episode of care. We generally package payment for items and services that are typically ancillary and supportive into the payment for the primary diagnostic or therapeutic modalities in which they are used rather than pay for them separately. As noted previously, if a hospital does not submit its acquisition cost data, it could suggest that the hospital has minimal acquisition costs. If the hospital has minimal acquisition costs for drugs, that could support viewing those costs as ancillary or supportive, and we might, if the data supports it, conclude that hospitals who do not report their drug acquisition costs lack meaningful additional, marginal costs related to their acquisition of these drugs and, as such, their drugs costs should not be paid separately but rather should be packaged into the payment for the associated service.

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[93] FSS pricing from the Veteran Affairs' (VA's) pharmaceutical pricing database is publicly available at the NDC level and published at *https:// www.va.gov/opal/nac/fss/pharm Prices.asp*.

[94] section 340B(a)(1) of the Public Health Service Act. *https://www.hrsa.gov/about/faqs/what-difference-between-340b-ceiling-price-package-adjusted-price-which-are-both-published-340b.*

We seek comment broadly on how to approach payment to hospitals for drugs usually paid under the OPPS absent a hospital's response to the survey.

Consistent with E.O. 14273 and Paperwork Reduction Act requirements, additional details of this survey can be found in section XXII. of this proposed rule.

VI. Proposed Estimate of OPPS Transitional Pass-Through Spending for Drugs, Biologicals, Radiopharmaceuticals, and Devices

A. Amount of Additional Payment and Limit on Aggregate Annual Adjustment

Section 1833(t)(6)(E) of the Act limits the total projected amount of transitional pass-through payment for drugs, biologicals, and categories of devices for a given year to an "applicable percentage," currently not to exceed 2.0 percent of total program payments estimated to be made for all covered services under the OPPS furnished for that year. If we estimate before the beginning of the calendar year that the total amount of pass-through payments in that year would exceed the applicable percentage, section 1833(t)(6)(E)(iii) of the Act requires a uniform prospective reduction in the amount of each of the transitional pass-through payments made in that year to ensure that the limit is not exceeded. We estimate the pass-through spending to determine whether payments exceed the applicable percentage and the appropriate pro rata reduction to the conversion factor for the projected level of pass-through spending in the following year to ensure that total estimated pass-through spending for the prospective payment year is budget neutral, as required by section 1833(t)(6)(E) of the Act.

For devices, developing a proposed estimate of pass-through spending in CY 2026 entails estimating spending for two groups of items. The first group of items consists of device categories that are currently eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2026. The CY 2008 OPPS/ASC final rule with comment period (72 FR 66778) describes the methodology we have used in previous years to develop the pass-through spending estimate for known device categories continuing into the applicable update year. The second group of items consists of devices that we know are newly

eligible, or project may be newly eligible, for device pass-through payment in the remaining quarters of CY 2025 or beginning in CY 2026. The sum of the proposed CY 2026 pass-through spending estimates for these two groups of device categories equals the proposed total CY 2026 pass-through spending estimate for device categories with pass-through payment status. We determined the device pass-through estimated payments for each device category based on the amount of payment as required by section 1833(t)(6)(D)(ii) of the Act, and as outlined in previous rules, including the CY 2025 OPPS/ASC final rule with comment period (89 FR 94259 through 94261). We note that, beginning in CY 2010, the pass-through evaluation process and pass-through payment methodology for implantable biologicals newly approved for pass-through payment beginning on or after January 1, 2010, that are surgically inserted or implanted (through a surgical incision or a natural orifice) use the device pass-through process and payment methodology (74 FR 60476). As has been our past practice (76 FR 74335), we include an estimate of any implantable biologicals eligible for pass-through payment in our estimate of pass-through spending for devices. Similarly, we finalized a policy in CY 2015 that applications for pass-through payment for skin substitutes and similar products be evaluated using the medical device pass-through process and payment methodology (76 FR 66885 through 66888). Therefore, as we did beginning in CY 2015, for CY 2026, we also propose to include an estimate of any skin substitutes and similar products in our estimate of pass-through spending for devices.

For drugs and biologicals eligible for pass-through payment, section 1833(t)(6)(D)(i) of the Act establishes the pass-through payment amount as the amount by which the amount authorized under section 1842(o) of the Act (or, if the drug or biological is covered under a competitive acquisition contract under section 1847B of the Act, an amount determined by the Secretary equal to the average price for the drug or biological for all competitive acquisition areas and year established under such section as calculated and adjusted by the Secretary) exceeds the portion of the otherwise applicable fee schedule amount that the Secretary

determines is associated with the drug or biological. Consistent with current policy, we propose to apply a rate of ASP plus 6 percent to most drugs and biologicals for CY 2026, and therefore our estimate of drug and biological pass-through payment for CY 2026 for this group of items is $15.2 million.

Payment for certain drugs,[95] specifically contrast agents without pass-through payment status, is packaged into payment for the associated procedures, and these products are not separately paid. In addition, we policy-package non-pass-through drugs and biologicals that function as supplies when used in a diagnostic test or procedure unless a high-cost diagnostic radiopharmaceutical with a per-day cost greater than the proposed per-day threshold referenced in section II.A.3.c. of this proposed rule is used for the test or procedure. We policy-package all drugs and biologicals that function as supplies when used in a surgical procedure or for anesthesia, and other categories of drugs and biologicals, as discussed in section V.B.1.c. of this proposed rule. Consistent with current policy, for CY 2026, we propose that policy-packaged drugs and biologicals with pass-through payment status will be paid at ASP+6 percent, like other pass-through drugs and biologicals less the policy-packaged drug APC offset amount described below. Our estimate of pass-through payment for policy-packaged drugs and biologicals with pass-through payment status approved prior to CY 2026 is not $0. This is because the pass-through payment amount and the fee schedule amount associated with the drug or biological will not be the same, unlike for separately payable drugs and biologicals. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81774 through 81776), we discussed our policy to determine if the costs of certain policy-packaged drugs or biologicals are already packaged into the existing APC structure. If we determine that a policy-packaged drug or biological approved for pass-through payment resembles predecessor drugs or biologicals already included in the

[95] In the CY 2025 OPPS/ASC final rule with comment period, we finalized the high-cost diagnostic radiopharmaceuticals policy to separately pay those products when the per-day costs are greater than a threshold. Please refer to section II.A.3.c. of this proposed rule for more information regarding this policy.

costs of the APCs that are associated with the drug receiving pass-through payment, we offset the amount of pass-through payment for the policy-packaged drug or biological. For these drugs or biologicals, the APC offset amount is the portion of the APC payment for the specific procedure performed with the pass-through drug or biological, which we refer to as the policy-packaged drug APC offset amount. Consistent with current policy described in section V.A.5. of this proposed rule, if we determine that an offset is appropriate for a specific policy-packaged drug or biological receiving pass-through payment, we propose to reduce our estimate of pass-through payments for these drugs or biologicals by the APC offset amount.

Similar to pass-through spending estimates for devices, the first group of drugs and biologicals requiring a pass-through payment estimate consists of those products that were recently made eligible for pass-through payment and that will continue to be eligible for pass-through payment in CY 2026. The second group contains drugs and biologicals that we know are newly eligible, or project will be newly eligible, in CY 2026. The sum of the CY 2026 pass-through spending estimates for these two groups of drugs and biologicals equals the total CY 2026 pass-through spending estimate for drugs and biologicals with pass-through payment status.

B. Proposed Estimate of Pass-Through Spending for CY 2026

For CY 2026, we propose to set the applicable pass-through payment percentage limit at 2.0 percent of the total projected OPPS payments for CY 2026, consistent with section 1833(t)(6)(E)(ii)(II) of the Act and our OPPS policy from CY 2004 through CY 2025 (89 FR 94260). The pass-through payment percentage limit is calculated using pass-through spending estimates for devices and for drugs and biologicals.

For the first group of devices, consisting of device categories that are currently eligible for pass-through payment and will continue to be eligible for pass-through payment in CY 2026, there are 14 active categories for CY 2026. The active categories are described by HCPCS codes C1600, C1601, C1602, C1603, C1604, C1605, C1606, C8000, C1735, C1736, C1737, C1738,

C1739, and C9610. Based on information from the device manufacturers, we estimated that HCPCS code C1600 will cost $0.3 million in pass-through expenditures in CY 2026, HCPCS code C1601 will cost $5.0 million in pass-through expenditures in CY 2026, HCPCS code C1602 will cost $0.2 million in pass-through expenditures in CY 2026, HCPCS code C1603 will cost $0.1 million in pass-through expenditures in CY 2026, HCPCS code C1604 will cost $2.0 million in pass-through expenditures in CY 2026, HCPCS code C1605 will cost $113.0 million in pass-through expenditures in CY 2026, HCPCS code C1606 will cost $0.3 million in pass-through expenditures in CY 2026, HCPCS code C8000 will cost $2.9 million in pass-through expenditures in CY 2026, HCPCS code C1735 will cost $16.0 million in pass-through expenditures in CY 2026, HCPCS code C1736 will cost $32.8 million in pass-through expenditures in CY 2026, HCPCS code C1737 will cost $34.1 million in pass-through expenditures in CY 2026, HCPCS code C1738 will cost $0.8 million in pass-through expenditures in CY 2026, HCPCS code C1739 will cost $8.5 million in pass-through expenditures in CY 2026, and HCPCS code C9610 will cost $36.0 million in pass-through expenditures in CY 2026. Therefore, we propose an estimate for the first group of devices of $252.0 million.

In estimating our proposed CY 2026 pass-through spending for device categories in the second group, we included the following: (1) device categories that we assumed at the time of the development of the proposed rule would be newly eligible for pass-through payment in CY 2026; (2) additional device categories that we estimated could be approved for pass-through status after the development of this proposed rule and before January 1, 2026; and (3) contingent projections for new device categories established in the second through fourth quarters of CY 2026. For CY 2026, we propose to use the general methodology described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66778), while also taking into account recent OPPS experience in approving new pass-through device categories. For this proposed rule, the

proposed estimate of CY 2026 pass-through spending for this second group of device categories is $319.8 million.

To estimate proposed CY 2026 pass-through spending for drugs and biologicals in the first group, specifically those drugs and biologicals recently made eligible for pass-through payment and continuing on pass-through payment status for at least one quarter in CY 2026, we propose to use the CY 2024 Medicare hospital outpatient claims data regarding their utilization, information provided in their respective pass-through applications, other historical hospital claims data, pharmaceutical industry information, and clinical information regarding these drugs and biologicals to project the CY 2026 OPPS utilization of the products.

For the known drugs and biologicals (excluding policy-packaged contrast agents, drugs, biologicals, radiopharmaceuticals with per-day costs at or below the packaging threshold that function as supplies when used in a diagnostic test or procedure, and drugs and biologicals that function as supplies when used in a surgical procedure) that will be continuing on pass-through payment status in CY 2026, we estimated the pass-through payment amount as the difference between the general payment rate of ASP+6 percent and the payment rate for non-pass-through drugs and biologicals that would be separately paid. Because we propose to utilize a payment rate of ASP plus 6 percent for most separately payable drugs and biologicals in this proposed rule, the proposed payment rate difference between the pass-through payment amount and the non-pass-through payment amount is $0 for this group of drugs.

Because payment for policy-packaged drugs and biologicals is packaged if the product is not paid separately due to its pass-through payment status, we propose to include in the CY 2026 pass-through estimate the difference between payment for the policy-packaged drug or biological at ASP+6 percent (or WAC+6 percent, or 95 percent of AWP, if ASP or WAC information is not available) and the policy-packaged drug APC offset amount, if we determine that the policy-packaged drug or biological approved for pass-through payment resembles a predecessor drug or biological already included in the costs of the APCs that are associated with the drug

receiving pass-through payment. Diagnostic radiopharmaceuticals that currently have pass-through status, but would likely be paid separately because of the policy initially established in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93953) to separately pay for high-cost diagnostic radiopharmaceuticals with per-day costs greater than the proposed per-day threshold and which we propose to continue as discussed in section II.A.3.c of this proposed rule, are not considered to be policy-packaged and therefore are not included in this group. For this first group of policy-packaged drugs and biologicals, we estimated a pass-through spending for CY 2026 of $5.2 million.

To estimate proposed CY 2026 pass-through spending for drugs and biologicals in the second group (that is, drugs and biologicals that we knew at the time of development of this proposed rule were newly eligible or recently became eligible for pass-through payment in CY 2025, additional drugs and biologicals that we estimated could be approved for pass-through status subsequent to the development of this proposed rule and before January 1, 2026, and projections for new drugs and biologicals that could be initially eligible for pass-through payment in the second through fourth quarters of CY 2026), we propose to use utilization estimates from pass-through applicants, pharmaceutical industry data, clinical information, recent trends in the per unit ASPs of hospital outpatient drugs, and projected annual changes in service volume and intensity as our basis for making the CY 2026 pass-through payment estimate. We also propose to consider the most recent OPPS experience in approving new pass-through drugs and biologicals. Using our proposed methodology for estimating CY 2026 pass-through payments for this second group of drugs, we calculated a proposed spending estimate for this second group of drugs and biologicals of approximately $10 million.

We estimate for this proposed rule that the amount of pass-through spending for the device categories and the drugs and biologicals that are continuing to receive pass-through payment in CY 2026 and the amount of pass-through spending for those device categories, drugs, and biologicals that first become eligible for pass-through payment during CY 2026

would be approximately $587.0 million (approximately $571.8 million for device categories and approximately $15.2 million for drugs and biologicals), which represents only 0.59 percent of total projected OPPS payments for CY 2026 (approximately $100 billion). Therefore, we estimate that pass-through spending in CY 2026 will not exceed the 2.0 percent of total projected OPPS CY 2026 program spending limit provided for in section 1833(t)(6)(E) of the Act.

VII. OPPS Payment for Hospital Outpatient Visits and Critical Care Services

For CY 2026, we propose to continue our current clinic and emergency department (ED) hospital outpatient visits payment policies. For a description of these policies, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70298). We also propose to continue our payment policy for critical care services for CY 2026. For a description of this policy, we refer readers to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70298), and for the history of this payment policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75043).

As we stated in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63663), the volume control method for clinic visits furnished by excepted off-campus provider-based departments (PBDs) applies for CY 2022 and subsequent years. More specifically, we finalized a policy to continue to utilize a PFS-equivalent payment rate for the hospital outpatient clinic visit service described by HCPCS code G0463 when it is furnished by these departments for CY 2022 and subsequent years. The PFS-equivalent rate for CY 2026 is 40 percent of the proposed OPPS payment. Under this policy, these departments will be paid approximately 40 percent of the OPPS rate for the clinic visit service in CY 2026. For CY 2026, we propose to implement a volume control method for additional services furnished by excepted PBDs. For more information on this proposal, we refer readers to section X.A. of this proposed rule.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy that excepted off-campus PBDs (departments that bill the modifier "PO" on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as

rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a PFS-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2026, we propose to exempt excepted off-campus PBDs (departments that bill the modifier "PO" on claim lines) of rural SCHs, as described under 42 CFR 412.92 and designated- as rural for Medicare payment purposes, from any additional services subject to our volume control method payment policy. For more information on this proposal, we refer readers to section X.A. of this proposed rule.

III. Payment for Partial Hospitalization and Intensive Outpatient Services

This section discusses payment for partial hospitalization services as well as intensive outpatient services. Since CY 2000, Medicare has paid for partial hospitalization services under the OPPS. Beginning in CY 2024, as authorized by section 4124 of the Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117–328), Medicare began paying for intensive outpatient services furnished by hospital outpatient departments, community mental health centers, federally qualified health centers, and rural health clinics in addition to opioid treatment programs. Additional background on the partial hospitalization and intensive outpatient benefits is included in the following paragraphs.

A. Background

1. Partial Hospitalization

A partial hospitalization program (PHP) is an intensive outpatient program of psychiatric services provided as an alternative to inpatient psychiatric care for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and substance use disorders (SUD). Section 1861(ff)(1) of the Act defines partial hospitalization services as the items and services described in paragraph (2) prescribed by a physician and provided under a program described in paragraph (3) under the supervision of a

physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan.

Section 1861(ff)(2) of the Act describes the items and services included in partial hospitalization services. Section 1861(ff)(3)(A) of the Act specifies that a PHP is a program furnished by a hospital to its outpatients or by a community mental health center (CMHC), as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting.

Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding PHP.

PHP policies and payment have been addressed under OPPS since CY 2000. In CY 2008, we began efforts to strengthen the PHP benefit through extensive data analysis, along with policy and payment changes, by implementing two refinements to the methodology for computing the PHP median. For a detailed discussion on these policies, we refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66670 through 66676). In CY 2009, we implemented several regulatory, policy, and payment changes. For a detailed discussion on these policies, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68688 through 68697). In CY 2010, we retained the two-tier payment approach for partial hospitalization services and used only hospital-based PHP data in computing the PHP APC per diem costs, upon which PHP APC per diem payment rates are based (74 FR 60556 through 60559). In CY 2011 (75 FR 71994), we established four separate PHP APC per diem payment rates: two for CMHCs (APC 0172 and APC 0173) and two for hospital-based PHPs (APC 0175 and APC 0176). We also instituted a 2-year transition period for CMHCs to the CMHC APC per diem payment rates. For a detailed discussion, we refer

readers to section X.B. of the CY 2011 OPPS/ASC final rule with comment period (75 FR 71991 through 71994). In CY 2012, we determined the relative payment weights for partial hospitalization services provided by CMHCs based on data derived solely from CMHCs and the relative payment weights for partial hospitalization services provided by hospital-based PHPs based exclusively on hospital data (76 FR 74348 through 74352). In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal to base the relative payment weights that underpin the OPPS APCs, including the four PHP APCs (APCs 0172, 0173, 0175, and 0176), on geometric mean costs rather than on the median costs. For a detailed discussion on this policy, we refer readers to the CY 2013 OPPS/ASC final rule with comment period (77 FR 68406 through 68412).

In the CY 2014 OPPS/ASC proposed rule (78 FR 43621 and 43622) and CY 2015 OPPS/ASC final rule with comment period (79 FR 66902 through 66908), we continued to apply our established policies to calculate the four PHP APC per diem payment rates based on geometric mean per diem costs using the most recent claims data for each provider type. For a detailed discussion on this policy, we refer readers to the CY 2014 OPPS/ASC final rule with comment period (78 FR 75047 through 75050). In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70453 through 70467), we described our extensive analysis of the claims and cost data and ratesetting methodology, corrected a cost inversion that occurred in the final rule data with respect to hospital-based PHP providers, and renumbered the PHP APCs. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79687 through 79691), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs and finalized a policy to combine the Level 1 and Level 2 PHP APCs for CMHCs and for hospital-based PHPs. We also implemented an eight-percent outlier cap for CMHCs to mitigate potential outlier billing vulnerabilities. For a comprehensive description of PHP payment policy, including a detailed methodology for determining PHP per diem amounts, we refer readers to the CY 2016 and CY 2017 OPPS/ASC final rules with

comment period (80 FR 70453 through 70455 and 81 FR 79678 through 79680, respectively).

In the CYs 2018 and 2019 OPPS/ASC final rules with comment period (82 FR 59373 through 59381 and 83 FR 58983 through 58998, respectively), we continued to apply our established policies to calculate the PHP APC per diem payment rates based on geometric mean per diem costs, designated a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, and proposed updates to the PHP allowable HCPCS codes. We finalized these proposals in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61352).

In the CY 2020 OPPS/ASC final rule with comment period (84 FR 61339 through 61350), we finalized a proposal to use the calculated CY 2020 CMHC geometric mean per diem cost and the calculated CY 2020 hospital-based PHP geometric mean per diem cost, but with a cost floor equal to the CY 2019 final geometric mean per diem costs as the basis for developing the CY 2020 PHP APC per diem rates. Also, we continued to designate a portion of the estimated 1.0 percent hospital outpatient outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS, excluding outlier payments.

In the April 30, 2020 interim final rule with comment (85 FR 27562 through 27566), effective as of March 1, 2020 and for the duration of the COVID–19 Public Health Emergency (PHE), hospital and CMHC staff were permitted to furnish certain outpatient therapy, counseling, and educational services (including certain PHP services), incident to a physician's services, to beneficiaries in temporary expansion locations, including the beneficiary's home, as long as the location met all conditions of participation to the extent not waived. A hospital or CMHC could furnish such services using telecommunications technology to a beneficiary in a temporary expansion location if that beneficiary was registered as an outpatient. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72247), we confirmed that these provisions applied only for the duration of the COVID–19 PHE. On May 11, 2023, the COVID–19 PHE

ended, and accordingly, these flexibilities ended as well.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86073 through 86080), we continued our current methodology to utilize cost floors, as needed. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63665 and 63666), as a result of the COVID–19 PHE, we finalized our proposal to calculate the PHP per diem costs using the year of claims consistent with the calculations that would be used for other OPPS services, by using the CY 2019 claims and the cost reports that were used for CY 2021 final rulemaking to calculate the CY 2022 PHP per diem costs. In addition, for CY 2022 and subsequent years, we finalized our proposal to use cost and charge data from the Hospital Cost Report Information System (HCRIS) as the source for the CMHC cost-to-charge ratios (CCRs), instead of using the Outpatient Provider Specific File (OPSF) (86 FR 63666).

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71995), we finalized our proposal to use the latest available CY 2021 claims but use the cost information from prior to the COVID–19 PHE for calculating the CY 2023 CMHC and hospital-based PHP APC per diem costs. The application of the OPPS standard methodology, including the effect of budget neutralizing all other OPPS policy changes unique to CY 2023, resulted in the final calculated CMHC PHP APC payment rate being unexpectedly lower than the CY 2022 final CMHC PHP APC rate. Therefore, we finalized utilizing the equitable adjustment authority of section 1833(t)(2)(E) of the Act to appropriately pay for CMHC PHP services at the same payment rate as for CY 2022, that is, $142.70. In addition, we clarified the payment under the OPPS for new HCPCS codes that designate non-PHP services provided for the purposes of diagnosis, evaluation, or treatment of a mental health disorder and are furnished to beneficiaries in their homes by clinical staff of the hospital that would not be recognized as PHP services; however, none of the PHP regulations would preclude a patient that is under a PHP plan of care from receiving other reasonable and medically necessary non-PHP services from a hospital (87 FR 72001 and 72002).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81811), we revised the regulation at § 424.24(e)(1)(i) to require the physician certification for PHP services to include a certification that the patient requires such services for a minimum of 20 hours per week, as required by section 1861(ff)(1) of the Act, as amended by section 4124(a) of Division FF of the CAA, 2023. In addition, we modified the regulations for PHP at § 410.43 to include references to SUD. In the same CY 2024 OPPS/ASC final rule with comment period, we also established separate payment rates for PHP days with 3 services and days with 4 or more services. Accordingly, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital--based PHPs for 4-service days (APC 5863 and APC 5864, respectively). We also finalized a policy to utilize the separate CMHC rates for 3-service and 4-service PHP days as the Medicare Physician Fee Schedule (MPFS) rates, depending upon whether a nonexcepted- off-campus hospital outpatient department furnishes 3 or 4 PHP services in a day. Lastly, we finalized several changes beginning in CY 2024 to align coding, billing, and payment between PHPs and intensive outpatient programs.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94266 through 94268), we maintained the coding and billing policies for PHP as established in the CY 2024 OPPS/ASC final rule with comment period.

2. Intensive Outpatient Program Services

Section 4124(b) of the CAA, 2023 established Medicare coverage for intensive outpatient services effective for items and services furnished on or after January 1, 2024. An intensive outpatient program (IOP) is a distinct and organized program of psychiatric services for individuals who have an acute mental illness, which includes, but is not limited to, conditions such as depression, schizophrenia, and SUD. Intensive outpatient services are not required to be provided in lieu of inpatient hospitalization. Section 1861(ff)(4) of the Act defines intensive

outpatient services as the items and services described in paragraph (2) prescribed by a physician for an individual determined (not less frequently than every other month) by a physician to have a need for such services for a minimum of 9 hours per week and provided under a program described in paragraph (3) under the supervision of a physician pursuant to an individualized, written plan of treatment established and periodically reviewed by a physician (in consultation with appropriate staff participating in such program), which plan sets forth the physician's diagnosis, the type, amount, frequency, and duration of the items and services provided under the plan, and the goals for treatment under the plan. Section 1861(ff)(2) of the Act describes the items and services included in intensive outpatient services. Section 1861(ff)(4)(C) of the Act specifies that an IOP is a program furnished by a hospital to its outpatients, by a CMHC, by a Federally qualified health center (FQHC), or by a rural health clinic (RHC) as a distinct and organized intensive ambulatory treatment service, offering less than 24-hour-daily care, in a location other than an individual's home or inpatient or residential setting. Section 1861(ff)(3)(B) of the Act defines a CMHC for purposes of this benefit. We refer readers to sections 1833(t)(1)(B)(i), 1833(t)(2)(B), 1833(t)(2)(C), and 1833(t)(9)(A) of the Act and 42 CFR 419.21, for additional information regarding IOP.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81812 through 81857), we established payment and program requirements for the IOP benefit furnished by a hospital to its outpatients, or by a CMHC, an FQHC, or an RHC. In addition, we established Medicare Part B coverage for IOP services provided by Opioid Treatment Programs (OTPs) for the treatment of opioid use disorder (OUD).

Consistent with the statutory definition of intensive outpatient services under section 1861(ff)(2) of the Act, we finalized regulations at 42 CFR 410.44 to set forth the conditions and exclusions applicable for intensive outpatient services, and at § 424.24 to set forth the content of the certification and plan of treatment requirements for intensive outpatient services. We also revised certain existing regulations at §§ 410.2, 410.3, 410.10, 410.27, 410.150, and 419.21 to

add a regulatory definition of intensive outpatient services and to include intensive outpatient services in the regulations for medical and other health services paid for under Medicare Part B, and in the case of § 419.21, under the OPPS. Additionally, we created regulations at § 410.111 to establish the requirements for coverage of IOP services furnished in CMHCs, and at § 410.173 to establish conditions of payment for IOP services furnished in CMHCs. Lastly, we revised § 410.155 to exclude IOP services from the outpatient mental health treatment limitation, consistent with the statutory requirement of section 1833(c)(2) of the Act, as amended by section 4124(b)(3) of the CAA, 2023.

In addition, as discussed in greater detail in the following sections, we established coding, billing, and payment policies for IOP that align with the policies established for PHP provided in the same settings. Specifically, we established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively). Similar to the policy finalized for PHP, we finalized a policy to utilize the CMHC rates for 3-service and 4-service IOP days as the MPFS rates, depending upon whether a nonexcepted hospital outpatient department furnishes 3 or 4 IOP services in a day.

For IOP services provided by an RHC or FQHC, we established a 3-service per day payment rate based on the same rate as APC 5861, which is the 3-service hospital-based IOP rate (§ 405.2462(j)). In the CY 2025 PFS final rule, we established a 4 or more services per day payment rate for an IOP provided by an RHC or FQHC based on the same rate as APC 5862, which is the 4 or more services hospital-based IOP rate (89 FR 98017 and 98018). Information regarding payment policies for IOP services furnished by FQHCs and RHCs, including information regarding proposed CY 2026 policies for those settings, can be found in the MPFS proposed rule, which is published elsewhere in the **Federal Register**.

Furthermore, in the CY 2024 OPPS/ASC final rule, we established a payment adjustment for IOPs provided by an OTP based on three times the payment rate for APC 5861 beginning in CY 2024 (§ 410.67(d)(4)(i)(F)). We finalized regulations at § 410.67(d)(4)(ii) to add that the payment amount for OTP intensive outpatient services will be geographically adjusted using the Geographic Adjustment Factor (GAF) described in § 414.26. Lastly, we amended § 410.67(d)(4)(iii) to add that payment for OTP intensive outpatient services is updated annually using the Medicare Economic Index described in § 405.504(d). Payment rates for IOP provided in the OTP setting are updated as part of the OTP fee schedule and are not addressed in this CY 2026 OPPS/ASC proposed rule.

Lastly, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94266 through 94268), we maintained the coding and billing policies for IOP as established in the CY 2024 OPPS/ASC final rule with comment period.

B. Coding and Billing for PHP and IOP Services under the OPPS

In the CY 2024 OPPS/ASC final rule with comment period, we finalized a billing requirement that all providers use condition code 41 to indicate that a claim is for partial hospitalization services and use condition code 92 to identify intensive outpatient claims, effective January 1, 2024. Since the statutory definitions of both IOP and PHP generally include the same types of items and services covered, we stated in the CY 2024 OPPS/ASC final rule with comment period that we believe it is appropriate to align the programs using a consistent list of services, so that level of intensity would be the only differentiating factor between partial hospitalization services and intensive outpatient services. The use of condition codes 41 for PHP claims and 92 for IOP claims allows us to differentiate between these services for billing purposes.

We recognize that the level of intensity of mental health services that a patient requires may vary over time; therefore, we believe utilizing a consolidated list of HCPCS codes to identify services under both the IOP and PHP benefits supports a smooth transition for patients

when a change in the intensity of their services is necessary to best meet their needs. For example, a patient receiving IOP services may experience an acute mental health need that necessitates more intense services through a PHP. Alternatively, an IOP patient that no longer requires the level of intensity provided by the IOP can access less intense mental health services, such as individual mental health services. The full list of HCPCs codes recognized under the PHP and IOP benefits can be found in the Medicare Claims Processing Internet Only Manual, Chapter 4, sections 260.1 and 261.1, respectively, and their subsections, available at *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c04.pdf*.

To qualify for payment for the IOP APC (5851, 5852, 5861, or 5862) or the PHP APC (5853, 5854, 5863, or 5864), one service provided that day must be from the Partial Hospitalization and Intensive Outpatient Primary list. We refer readers to the CY 2024 OPPS final rule with comment period for further discussion regarding our expectation that at least one of the services on the PHP and IOP Primary list will be indicated per day for patients who need the level of care offered by a PHP or IOP program. The PHP and IOP Primary List can be found in the CY 2024 OPPS/ASC final rule with comment period at 88 FR 81821.

Beginning in CY 2024, we recognized caregiver training services and Principal Illness Navigation (PIN) services as PHP and IOP services. We explained that the reported costs associated with providing such services are included when we calculate the PHP and IOP payment rates; however, these services do not count toward the determination of whether a PHP or IOP day is paid at the 3-service or 4-service rate. We refer readers to the CY 2024 OPPS/ASC final rule with comment period for a detailed discussion of this policy (88 FR 81823 through 81825).

As finalized in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81821 and 81822), if new codes are established that represent the PHP and IOP services described under §§ 410.43(a)(4) and 410.44(a)(4), respectively, such codes are added to the list of codes recognized for payment for PHP or IOP through sub-regulatory guidance. We note that coding

updates frequently occur outside of the standard rulemaking timeline. We adopted this sub-regulatory process in order to pay expeditiously when new codes are created that describe any of the services enumerated at §§ 410.43(a)(4) and 410.44(a)(4), which PHPs and IOPs, respectively, would provide. We explained that this policy applies to new codes that are cross walked to a previously included code, or whose code descriptor is substantially similar to a descriptor for a code on the list or describes a service on the list. We stated that any additional services not described at § 410.43(a)(4) or § 410.44(a)(4) would be added to the lists in regulation through notice and comment rulemaking.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94266 through 94268), we did not add any new services not described at § 410.43(a)(4) or § 410.44(a)(4) to the list of PHP and IOP services.

C. Proposed CY 2026 Payment Rates for PHP and IOP

We propose for CY 2026 to maintain the current payment rate methodology that we use for calculating PHP and IOP payment rates for hospital-based providers. For CMHCs, we propose to revise our methodology for calculating PHP and IOP payment rates. Specifically, we propose to apply the 40 percent MPFS Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs. Under this proposed methodology, we would multiply the CY 2026 rates for the hospital-based PHP and IOP APCs by 0.4 to calculate the payment rates for the CMHC PHP and IOP APCs.

1. Background on the Current Payment Rate Methodology for PHP and IOP

Beginning in CY 2024, we established four separate PHP APC per diem payment rates: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5853 and APC 5854, respectively), and one for hospital-based PHPs for 3-service days and another for hospital-based PHPs for 4-service days (APC 5863 and APC 5864, respectively). In addition, for hospital-based PHPs, we finalized a policy to calculate payment rates using the broader OPPS data set, instead of using hospital-based PHP data only. We explained that using the

broader OPPS data set allows CMS to capture data from claims not identified as PHP, but that also include the service codes and intensity required for a PHP day. Because we established consistent coding and payment between the PHP and IOP benefits, we considered all OPPS data for PHP days and non-PHP days that include 3 or more of the same service codes. We established four separate IOP APC per diem payment rates at the same rates we proposed for the PHP APCs: one for CMHCs for 3-service days and another for CMHCs for 4-service days (APC 5851 and APC 5852, respectively), and one for hospital-based IOPs for 3-service days and another for hospital-based IOPs for 4-service days (APC 5861 and APC 5862, respectively).

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81829 and 81830), we noted that the standard PHP day is typically four services or more per day. We explained that we have historically provided payment for three services a day for extenuating circumstances when a beneficiary would be unable to complete a full day of PHP treatment. As we stated in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66672), it was never our intention that days with only three units of service should represent the number of services provided in a typical PHP day. Our intention was to cover days that consisted of three units of service only in certain limited circumstances. For example, as we noted in the CY 2009 OPPS/ASC proposed rule (73 FR 41513), we believe 3-service days may be appropriate when a patient is transitioning towards discharge (or days when a patient is at the beginning of his or her PHP stay). Another example of when it may be appropriate for a program to provide only three units of service in a day is when a patient is required to leave the PHP early for the day due to an unexpected medical appointment.

In the same CY 2024 OPPS/ASC final rule with comment period, we also explained that prior to CY 2024, we historically prepared the data by first applying PHP-specific trims and data exclusions and assessing CCRs. We direct the reader to the CY 2016 OPPS/ASC final rule with comment period (80 FR 70463 through 70465) for a more complete discussion of these trims, data exclusions, and CCR adjustments. In prior rules, we typically included a discussion of

PHP-specific data trims, exclusions, and CCR adjustments; we did not include that discussion in the CY 2024 OPPS/ASC proposed rule or final rule with comment period. We stated that these PHP-specific data trims and exclusions addressed limitations as well as anomalies in the PHP data. However, as noted earlier, we finalized a methodology for CY 2024 to calculate hospital-based PHP payment rates for 3 services per day and 4 services per day based on cost per day using the broader OPPS data set. Accordingly, we did not apply PHP-specific trims and data exclusions, but rather we applied the same trims and data exclusions consistent with the OPPS.

We stated in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81830) that while no IOP benefit existed prior to the CAA, 2023, the types of items and services included in IOP had been, and were, paid for by Medicare either as part of the PHP benefit or under the OPPS more generally. Additionally, we stated that prior to the CAA, 2023, CMS had begun gathering information from interested parties on IOP under Medicare. In the CY 2023 OPPS/ASC proposed rule (87 FR 44679), we issued a comment solicitation on intensive outpatient mental health treatment, including SUD treatment furnished by IOPs, to collect information regarding whether there are any gaps in coding that may be limiting access to needed levels of care for treatment of mental health disorders or SUDs for Medicare beneficiaries, and specific information about IOP services, such as the settings of care in which these programs typically furnish services, the range of services typically offered, and the range of practitioner types that typically furnish these services.

In addition, in the same CY 2024 OPPS/ASC final rule with comment period, we explained that along with the requirements for IOP mandated by the CAA, 2023, we took into consideration information we received from the comment solicitation to construct an appropriate data set to develop proposed rates for IOP. Since IOPs furnish the same types of services as PHP, just at a lower intensity, we stated that we believe it was appropriate to use the same data and methodology for calculating payment rates for both PHP and IOP for CY 2024. We explained that although PHP claims can be specifically identified, there was no specific identifier

or billing code to indicate IOP services that may have been provided before CY 2024. However, we noted that hospitals have been permitted to furnish and bill for many of these services as outpatient services under the OPPS. Thus, we analyzed a broader set of data that included both PHP and non-PHP days with 3 or more services in order to calculate proposed payment for PHP services. In order to establish consistent payment between PHP and IOP, we set IOP payment rates at the same rates as PHP. We stated that the primary goal in developing the payment rate methodology for IOP and PHP services was to pay providers an appropriate amount relative to the patients' needs, and to avoid cost inversion in future years. We stated that setting the IOP payment rates equal to the PHP payment rates was appropriate because IOP was a newly established benefit, and we did not have definitive data on utilization. However, we explained that both programs utilize the same services, but furnish them at different levels of intensity, with different numbers of services furnished per day and per week, depending on the program. Therefore, we stated that we expect it would be appropriate to pay the same per diem rates for IOP and PHP services unless future data analysis supports calculating rates independently.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81833) we established a policy of applying the 4-service day payment rate (that is, payment for PHP APCs 5854 for CMHCs and 5864 for hospitals, and IOP APCs 5852 for CMHCs and 5862 for hospitals) for days with 4 or more services. For days with three or fewer services, we apply the 3-service day payment rate (that is, payment for PHP APCs 5853 for CMHCs and 5863 for hospitals, and IOP APCs 5851 for CMHCs and 5861 for hospitals). As we noted in the CY 2024 OPPS/ASC final rule with comment period, we expect days with fewer than three services would be very infrequent, and we intend to monitor the provision of these days among providers and individual patients.

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269), for beneficiaries in a PHP or IOP, we maintained the payment rate methodology finalized in the CY 2024 OPPS/ASC final rule with comment period.

2. Analysis of PHP and IOP Costs under the Current Methodology

Following the current structure, the calculated CY 2026 geometric mean per diem cost for hospital-based PHP and IOP providers that provide 3 services per day is $340.90, which we propose to use for calculating the payment rate for the 3-service day hospital-based PHP APC 5863 and the 3-service day hospital-based IOP APC 5861, as discussed in the following section. The calculated CY 2026 geometric mean per diem cost for hospital-based PHP and IOP providers that provide 4 services per day is $424.60, which we propose to use for calculating the payment rate for the 4-service day hospital-based PHP APC 5864 and the 4-service day hospital-based IOP APC 5862, as discussed in the following section.

The calculated CY 2026 geometric mean per diem cost for CMHC PHP and IOP providers resulted in an inversion, with the CMHC 3-service geometric mean per diem costs equaling $191.83 and the CMHC 4-service geometric mean per diem costs equaling $110.39. We believe the inverted geometric mean per diem costs are influenced by the small number of CMHCs that bill Medicare for PHP and IOP services, as well as CMHCs with low costs that first began billing Medicare for services in CY 2024. Table 67 summarizes the PHP and IOP geomean costs calculated using the current methodology.

TABLE 67: CY 2026 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS USING CURRENT METHODOLOGY

CY 2026 APC	Group Title	PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$191.83
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$110.39
5853	Partial Hospitalization (3 services per day) for CMHCs	$191.83
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$110.39
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$340.90
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$424.60
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$340.90
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$424.60

3. Proposed CY 2026 Payment Rate Methodology for PHP and IOP

For CY 2026, we propose to maintain our current methodology of calculating separate

rates for hospitals and CMHCs. For the four hospital-based PHP and IOP APCs (that is, APCs 5861, 5862, 5863, and 5864), we propose using the latest available cost information, from cost reports beginning three fiscal years prior to the year that is the subject of the rulemaking, and CY 2024 OPPS claims to update the payment rates. This proposal is consistent with the overall proposed use of cost data for the OPPS, which is discussed in section II.A.1.a. of this proposed rule.

In accordance with the methodology finalized in the CY 2024 OPPS/ASC final rule with comment period, we propose to base the payment rate for each hospital-based PHP APC on the geometric mean per diem cost for days with three services and four or more services. We propose to use the broader set of OPPS data to calculate the geometric mean costs for hospital outpatient departments, and we propose to apply the same trims and exclusions consistent with the OPPS. We also propose to set the payment rates for the hospital-based IOP APCs based on the geometric mean per diem cost for PHP days with three services and four or more services.

For the four CMHC PHP and IOP APCs (that is, APCs 5851, 5852, 5853, and 5854), we propose to calculate the CY 2026 geometric mean per diem costs based on 40 percent of the corresponding hospital-based PHP and IOP APCs (APCs 5861, 5862, 5863, and 5864, respectively). We propose this change in methodology for calculating the four CMHC PHP and IOP APCs because using the current methodology would result in inverted costs for CMHCs (that is, the cost for 3-service days would be greater than the cost for 4-service days), as discussed in the preceding section. As we discuss further in the following section of this proposed rule, we believe this proposed methodology would be generally appropriate for estimating CMHC costs and would align with the methodology that is used for other nonexcepted OPPS services furnished by a nonexcepted off-campus hospital outpatient department.

Lastly, we propose that if more recent hospital cost data subsequently become available after the publication of the CY 2026 OPPS/ASC proposed rule, we would consider using such

updated data to determine the CY 2026 payment rates for the four PHP APCs and the four IOP APCs.

4. Proposed CY 2026 PHP and IOP APC Geometric Mean Per Diem Costs

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81831), we anticipated there would be significant differences between CMHCs' and hospitals' costs of furnishing IOP, based on our observation of CMHCs incurring significantly different costs than hospitals in the provision of PHP services. Our longstanding payment policies reflect those differences. For CY 2026, we continue to observe significant cost structure differences between hospitals and CMHCs in the provision of PHP and IOP services. That is, we continue to see lower PHP and IOP costs in the CMHC setting as compared to the hospital setting. However, as we noted earlier in this proposed rule, if we were to apply our current methodology for calculating the CY 2026 geometric mean per diem costs for CMHC PHP and IOP APCs, those costs would be inverted (that is, the cost for 3-service days would be greater than the cost for 4-service days).

We believe it is appropriate to continue to recognize the differences in cost structures for different providers of PHP and IOP. This is of particular importance not only to the Medicare program, but also for the Medicare beneficiaries that CMHCs serve, who are subject to a 20 percent coinsurance requirement on all PHP and IOP services under Part B. However, as we previously explained, one of our goals is to avoid cost inversion because we would expect that the geometric mean per diem costs when providing three services per day would be lower than the geometric mean per diem costs when providing four or more services per day. We note that our current estimates are significantly impacted by a small number of CMHCs with low estimated costs who first began billing Medicare for services in CY 2024.[96] We are concerned that these cost estimates may not best reflect the costs of providing PHP and IOP in CY 2026.

[96] As we discussed in the CY 2023 OPPS/ASC final rule, our longstanding ratesetting methodology defaults any CMHC CCR that is not available or any CMHC CCR greater than one to the statewide hospital CCR associated with the provider's urban/rural designation and their state location.

As such, we believe that using CMHC data to establish the CMHC payment rates would not be appropriate for CY 2026, given the cost inversion. For this CY 2026 OPPS/ASC proposed rule, we considered alternative methodological approaches to estimate the costs for PHP and IOP services furnished by CMHCs.

Section 1833(t)(9)(A) of the Act requires the Secretary to annually review and revise the relative payment weights by taking into account new cost data, and other relevant information and factors. We note that in creating the original APC for PHP services (APC 0033), the initial relative payment weight for PHP services provided in hospital-based and CMHC-based settings was based on hospital data only. Subsequently, CMS has, in prior rulemaking, exercised its authority under section 1833(t)(9)(A) of the Act to change the data source for the relative payment weights for hospital-based and CMHC-based PHP services as new cost data became available. We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74350 and 74351) for more details on the history of changes in the data sources for relative payment weights for PHP services.

For this proposed rule, we considered alternative methodological approaches for calculating the CMHC costs that could avoid cost inversions and provide greater stability for CMHC payment rates. We believe the stability of CMHC payment rates and the avoidance of cost inversions are important for CMHCs to more easily anticipate future payments associated with the PHP and IOP benefits. For this CY 2026 OPPS/ASC proposed rule, we considered whether the 40 percent MPFS Relativity Adjuster would appropriately estimate CMHC PHP and IOP costs.

First, we considered the similarities between CMHCs and nonexcepted off-campus hospital outpatient departments. CMHCs are freestanding entities that are not part of a hospital, but they provide the same PHP and IOP services as hospital-based PHP and IOPs. As we noted in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79717), this is similar to the differences between freestanding entities paid under the MPFS that furnish other services also

provided by hospital-based entities. Similar to other entities currently paid for their technical component services under the MPFS, we believe CMHCs would typically have lower cost structures than hospital-based PHP and IOPs, largely due to lower overhead costs and other indirect costs such as administration, personnel, and security.

The 40 percent MPFS Relativity Adjuster was established in the CY 2018 PFS final rule (82 FR 53030) and applies to payments for nonexcepted items and services furnished in nonexcepted off-campus provider-based departments, including a hospital outpatient department. In that same final rule, we discussed our rationale for finalizing the MPFS Relativity Adjuster at 40 percent (82 FR 53026 through 53030). We explained that we believe a 40 percent adjuster would reflect a middle ground between the CY 2017 PFS Relativity Adjuster of 50 percent (selected to ensure adequate payment to hospitals) and the proposed CY 2018 PFS Relativity Adjuster of 25 percent (selected to ensure that hospitals are not paid more than others would be paid through the PFS non-facility rate).

If we were to apply the 40 percent MPFS Relativity Adjuster to determine the CMHC geometric mean per diem costs, the relative payment weights for PHP and IOP services furnished by CMHCs would be based on hospital cost data, which we note has been more stable than CMHC cost data in recent years. The stability of the hospital cost data is primarily driven by the larger number of providers and the fact that hospital-based providers more consistently bill for PHP and IOP services from one year to the next. We believe this methodology would appropriately stabilize CMHC payment rates by setting them relative to hospital-based rates, while avoiding cost inversions in future years. We also believe applying the 40 percent MPFS Relativity Adjuster to calculate payment rates for the CMHC PHP and IOP APCs would support our longstanding goal to pay providers an appropriate amount relative to the patients' needs.

If we applied the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP geometric mean per diem costs, it would result in proposed CY 2026 CMHC costs of $136.36 for a 3-service day and $169.84 for a 4-service day. These proposed CY 2026 CMHC

costs are generally in line with the CY 2025 CMHC costs, which were $112.59 for a 3-service day and $170.37 for a 4-service day. Additionally, we observed on average, the CY 2024 and CY 2025 geometric mean costs for the CMHC PHP and IOP APCs were 40 percent of the CY 2024 and CY 2025 geometric mean costs for the hospital-based PHP and IOP APCs. Therefore, we believe that applying the 40 percent Relativity Adjuster to hospital-based PHP and IOP costs would better approximate CMHC cost structures than the latest available CMHC cost data would. As we previously noted, the latest available CMHC cost data is influenced by the small number of CMHCs that bill Medicare for PHP and IOP services, as well as by CMHCs with low costs that first began billing Medicare for services in CY 2024.

Therefore, for the reasons discussed in the prior paragraphs, we propose to apply the 40 percent MPFS Relativity Adjuster to the hospital-based PHP and IOP costs for the purposes of calculating the proposed geometric mean per diem costs for the CMHC PHP and IOP APCs for CY 2026 and subsequent years.

Given the requirements of section 1833(t)(9)(A) of the Act, we believe it would be appropriate to revise our methodology for setting the relative payment weights for the OPPS rates for PHP and IOP services furnished by CMHCs based on new cost data and other relevant information and factors. Specifically, we propose to base this calculation on hospital cost data and the observed relationship between PHP and IOP costs in the hospital and CMHC settings, which as we noted earlier has been approximately 40 percent in recent years.

We intend to monitor the provision of services in both PHP and IOP programs to better understand utilization patterns, and would reevaluate our payment rate methodology, if necessary. We note that if more recent data becomes available for the CY 2026 OPPS/ASC final rule that mitigates the cost inversion for CMHC geometric mean per diem costs, we may consider using such data as a basis for finalizing a payment rate methodology based on CMHC costs, rather than based on hospital costs adjusted by the 40 percent MPFS Relativity Adjuster.

We solicit comments on our current and proposed payment rate methodologies for PHP

and IOP services furnished by CMHCs. We are also soliciting comments on potential methodological changes or changes to data that could avoid or mitigate future cost inversions and instability for CMHC payment rates. Table 68 shows the proposed calculated geometric mean per diem costs for hospital-based PHP and IOP APCs, and the proposed geometric mean per diem costs for CMHC PHP and IOP APCs based on our proposal to apply the 40 percent MPFS Relativity Adjuster for this CY 2026 OPPS/ASC proposed rule. Additional information about the data trims, data exclusions, and CCR adjustments applicable to the data used for this proposed rule can be found online at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html*.[97]

TABLE 68: PROPOSED CY 2026 PHP AND IOP APC GEOMETRIC MEAN PER DIEM COSTS

CY 2026 APC	Group Title	Proposed PHP and IOP APC Geometric Mean Per Diem Costs
5851	Intensive Outpatient (3 services per day) for CMHCs	$136.36
5852	Intensive Outpatient (4 or more services per day) for CMHCs	$169.84
5853	Partial Hospitalization (3 services per day) for CMHCs	$136.36
5854	Partial Hospitalization (4 or more services per day) for CMHCs	$169.84
5861	Intensive Outpatient (3 services per day) for hospital-based IOPs	$340.90
5862	Intensive Outpatient (4 or more services per day) for hospital-based IOPs	$424.60
5863	Partial Hospitalization (3 services per day) for hospital-based PHPs	$340.90
5864	Partial Hospitalization (4 or more services per day) for hospital-based PHPs	$424.60

D. Outlier Policy for CMHCs

For CY 2026, we propose to maintain the calculations of the CMHC outlier percentage, cutoff point and percentage payment amount, outlier reconciliation, outlier payment cap, and fixed dollar threshold according to previously established policies to include PHP and IOP services. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 81834 through 81836) for more details on CMHC outlier policies, and to section II.G.1.

[97] Click on the link labeled "CY 2026 OPPS/ASC Notice of Proposed Rulemaking", which can be found under the heading "Hospital Outpatient Prospective Payment System Rulemaking" and open the claims accounting document link at the bottom of the page, which is labeled "2026 NPRM OPPS Claims Accounting (PDF)".

of this proposed rule for our general policies for hospital outpatient outlier payments.

1. Background

As discussed in the CY 2004 OPPS final rule with comment period (68 FR 63469 and 63470), we created a separate outlier policy specific to the estimated costs and OPPS payments provided to CMHCs. We designated a portion of the estimated OPPS outlier threshold specifically for CMHCs, consistent with the percentage of projected payments to CMHCs under the OPPS each year, excluding outlier payments, and established a separate outlier threshold for CMHCs.

2. CMHC Outlier Percentage

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), we described the current outlier policy for hospital outpatient payments and CMHCs. We note that we also discussed our outlier policy for CMHCs in more detail in section VIII.C of that same final rule (82 FR 59381). We set our projected target for all OPPS aggregate outlier payments at 1.0 percent of the estimated aggregate total payments under the OPPS (82 FR 59267). This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61350), and the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082). We are not proposing any changes to the CMHC outlier percentage policy for CY 2026.

3. Cutoff Point and Percentage Payment Amount

Also described in the CY 2018 OPPS/ASC final rule with comment period (82 FR 59381), our policy has been to pay CMHCs for outliers if the estimated cost of the day exceeds a cutoff point. In CY 2006, we set the cutoff point for outlier payments at 3.4 times the highest CMHC PHP APC payment rate implemented for that calendar year (70 FR 68551). For CY 2018, the highest CMHC PHP APC payment rate was the payment rate for CMHC PHP APC 5853. In addition, in CY 2002, the final OPPS outlier payment percentage for costs above the multiplier threshold was set at 50 percent (66 FR 59889). In CY 2018, we continued to apply

the same 50 percent outlier payment percentage that applies to hospitals to CMHCs and continued to use the existing cutoff point (82 FR 59381). Therefore, for CY 2018, we continued to pay for partial hospitalization services that exceeded 3.4 times the CMHC PHP APC payment rate at 50 percent of the amount of CMHC PHP APC geometric mean per diem costs over the cutoff point. This same policy was also reiterated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 58996 and 58997), the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86082 and 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63670), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), and the CY 2024 OPPS/ASC final rule with comment period (88 FR 81835). In the CY 2024 OPPS/ASC final rule with comment period, we extended this policy to intensive outpatient services. We are not proposing any changes to the cutoff point and payment amount policy for CY 2026.

4. Outlier Reconciliation

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68594 through 68599), we established an outlier reconciliation policy to address charging aberrations related to OPPS outlier payments. We addressed vulnerabilities in the OPPS outlier payment system that led to differences between billed charges and charges included in the overall CCR, which are used to estimate cost and would apply to all hospitals and CMHCs paid under the OPPS. We initiated steps to ensure that outlier payments appropriately account for the financial risk when providing an extraordinarily costly and complex service but are only being made for services that legitimately qualify for the additional payment.

For a comprehensive description of outlier reconciliation, we refer readers to the CY 2023 OPPS/ASC and CY 2019 OPPS/ASC final rules with comment period (83 FR 58874 and 58875 and 81 FR 79678 through 79680, respectively). We are not proposing any changes to the outlier reconciliation policy for CY 2026.

5. Outlier Payment Cap

In the CY 2017 OPPS/ASC final rule with comment period, we implemented a CMHC outlier payment cap to be applied at the provider level, such that in any given year, an individual CMHC will receive no more than a set percentage of its CMHC total per diem payments in outlier payments (81 FR 79692 through 79695). Our analysis of CY 2014 claims data found that CMHC outlier payments began to increase similarly to the way they had prior to CY 2004. This was due to inflated costs from three CMHCs that accounted for 98 percent of all CMHC outlier payments that year and received outlier payments that ranged from 104 percent to 713 percent of their total per diem payments. To balance our concern about disadvantaging CMHCs with our interest in protecting the benefit from excessive outlier payments and to mitigate potential inappropriate outlier billing vulnerabilities, we finalized the CMHC outlier payment cap at 8 percent of the CMHC's total per diem payments (81 FR 79694 and 79695) to limit the impact of inflated CMHC charges on outlier payments. This cap was established after detailed analysis of claims data, which showed that a cap set at 8 percent would effectively address excessive outlier payments while minimally impacting CMHCs with legitimate high-cost cases. The cap applies to each CMHC's total per diem payments, which include both the Medicare payment portion and the beneficiary cost-sharing amount. The 8 percent cap continues to be calculated and applied on a calendar year basis, with outlier payments monitored throughout the year to ensure compliance with the cap.

This outlier payment cap only affects CMHCs; it does not affect other provider types (that is, hospital-based PHPs), and is in addition to and separate from the current outlier policy and reconciliation policy in effect. We are not proposing any changes to the outlier payment cap for CY 2026.

6. Fixed-Dollar Threshold

In the CY 2018 OPPS/ASC final rule with comment period (82 FR 59267 and 59268), for the hospital outpatient outlier payment policy, we set a fixed-dollar threshold in addition to an APC multiplier threshold. Fixed-dollar thresholds are typically used to drive outlier payments

for very costly items or services, such as cardiac pacemaker insertions. Currently, for CY 2025, CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852) are the only APCs for which CMHCs may receive payment under the OPPS, and these APCs are for providing a defined set of services that are relatively low cost when compared to other OPPS services. Because of the relatively low cost of CMHC services that are used to comprise the structure of CMHC PHP APCs (5853 or 5854) and IOP APCs (5851 or 5852), it is not necessary to also impose a fixed-dollar threshold on CMHCs. Therefore, in the CY 2018 OPPS/ASC final rule with comment period, we did not set a fixed-dollar threshold for CMHC outlier payments (82 FR 59381). This same policy was also reiterated in the CY 2020 OPPS/ASC final rule with comment period (84 FR 61351), the CY 2021 OPPS/ASC final rule with comment period (85 FR 86083), the CY 2022 OPPS/ASC final rule with comment period (86 FR 63508), the CY 2023 OPPS/ASC final rule with comment period (87 FR 72004), the CY 2024 OPPS/ASC final rule with comment period (88 FR 81836), and the CY 2025 OPPS/ASC final rule with comment period (89 FR 94271). We are not proposing any changes to the fixed-dollar threshold policy for CY 2026.

IX. Services That Will Be Paid Only as Inpatient Services

A. Background

The Inpatient Only (IPO) list was established in rulemaking as part of the initial implementation of the Outpatient Prospective Payment System (OPPS) in 2000, pursuant to the Secretary's authority under section 1833(t)(1)(B)(I) of the Act (65 FR 18455). The IPO list was created to identify services for which Medicare will make payment only when furnished in the inpatient hospital setting because of the invasive nature of the procedures, the underlying physical condition of the Medicare patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged (70 FR 68695). The creation of the IPO list was based on the premise (rooted in the practice of medicine at that time) that Medicare should not pay for procedures furnished as outpatient services which are

performed on an inpatient basis virtually all of the time for the Medicare population because performing these procedures on an outpatient basis would not be safe or appropriate, and therefore not reasonable and necessary under Medicare rules (86 FR 63671; 63 FR 47571). Designation of a service as inpatient only does not preclude the service from being furnished in a hospital outpatient setting but means that Medicare will not make payment for the service if it is furnished to a Medicare beneficiary in the hospital outpatient setting (65 FR 18443). Conversely, the absence of a procedure from the list should not be interpreted as identifying that procedure as appropriately performed only in the hospital outpatient setting (70 FR 68696). Rather, from the beginning, we have emphasized our expectation that, in every case, the physician or surgeon and hospital will exercise their professional judgment and assess the risk of the procedure or service to the individual patient, taking into account the site of service and act in that patient's best interest (65 FR 18456). We have also previously stated that for procedures that are not included on the inpatient list, we rely on the practitioner's judgment to determine on a patient-by-patient basis whether or not a particular procedure would be most appropriately performed in the inpatient setting (70 FR 68698).

The IPO list policy has elicited both opposition and support in public comments since its establishment in CY 2000. In 2000, some commenters stated that they believed that CMS (then, the Health Care Financing Administration) was making decisions, such as the site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18455). In 2011, certain comments suggested that regulations should not supersede the physician's level of knowledge and assessment of the patient's condition, and that the physician can appropriately determine whether a procedure can be performed in a hospital outpatient setting, and many commenters suggested that the inpatient only list be eliminated in its entirety (76 FR 74354). Again in 2013, some commenters requested that the IPO list be eliminated in its entirety (78 FR 75055). From the beginning, several interested parties have also stated that the exclusion of services from payment under the OPPS is unnecessary and could have an adverse

effect on advances in surgical care (65 FR 18442). Others have noted that the existence of the IPO list suggests that services that are not on the list or have been removed from the list should be/must be provided in the outpatient setting, regardless of the clinical judgment of the physician or the needs of the patient (85 FR 86084). Other commenters have defended the need for the list, stating that the IPO list serves as an important programmatic safeguard and maintains a common standard in the Medicare program (85 FR 86086).

In the CY 2021 OPPS/ASC final rule with comment period, published in the **Federal Register** on December 29, 2020 (85 FR 86084 through 86088), we finalized a policy to eliminate the IPO list over the course of 3 years (85 FR 86093). We revised our regulation at 42 CFR 419.22(n) to state that, effective January 1, 2021, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition. As part of the first phase of this elimination of the IPO list, we removed 298 codes, including 266 musculoskeletal-related services, from the list beginning in CY 2021.

In the 2022 OPPS/ASC final rule with comment period, published on November 16, 2021, we halted the elimination of the IPO list and, after clinical review of the services removed from the IPO list in CY 2021 as part of the first phase of eliminating the IPO list, we returned most services removed from the IPO list in 2021 back to the IPO list beginning in CY 2022 (86 FR 63671 through 63736). We amended the regulation at § 419.22(n) to remove the reference to the elimination of the list of services and procedures designated as requiring inpatient care through a 3-year transition. We also finalized our proposal to codify the five longstanding criteria for determining whether a service or procedure should be removed from the IPO list in the regulation at § 419.23 (86 FR 63678). For CY 2023 through CY 2025, we maintained the IPO list and continued to evaluate services brought forth by interested parties for removal using the five longstanding criteria (87 FR 72004 through 72012; 88 FR 81858 through 81863; and 89 FR 94271 through 92475).

B. Current Methodology for Identifying Appropriate Changes to the IPO List

Currently, there are approximately 1,731 services on the IPO list. Under our longstanding policy and current regulations, we annually review the IPO list to identify any services that should be removed from, or added to, the list, based on the most recent data and medical evidence available. We have established five criteria to determine whether a procedure should be removed from the IPO list (65 FR 18455), which we codified in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63676). As noted in the CY 2012 OPPS/ASC final rule with comment period (76 FR 74353), we assess whether a procedure or service met these criteria to determine if it should be removed from the IPO list and assign to an APC group for payment under the OPPS when provided in the hospital outpatient setting. We have explained that while we only require a service to meet one criterion to be considered for removal, satisfying only one criterion does not guarantee that the service will be removed; instead, the case for removal is strengthened with the more criteria the service meets. The criteria for assessing procedures for removal from the IPO list are:

- Most outpatient departments are equipped to provide the service or procedure to the Medicare population.
- The simplest service or procedure described by the code may be performed in most outpatient departments.
- The service or procedure is related to codes that CMS has already removed from the Inpatient Only list.
- CMS determines that the service or procedure is being performed in numerous hospitals on an outpatient basis.
- CMS determines that the service or procedure can be appropriately and safely performed in an ambulatory surgical center, and is specified as a covered ambulatory surgical procedure, or CMS has proposed to specify it as a covered ambulatory surgical procedure.

We encouraged interested parties, including professional societies, hospitals, surgeons, hospital associations, and beneficiary advocacy groups, to evaluate the IPO list and determine whether services should be added to or removed from the list. We requested that they submit corresponding evidence in support of their claims that a code or group of codes met the longstanding criteria for removal from the IPO list and is safe to perform on the Medicare population in the hospital outpatient setting—including, but not limited to case reports, operative reports of actual cases, peer-reviewed medical literature, medical professional analysis, clinical criteria sets, and patient selection protocols (67 FR 66740). Our clinicians thoroughly review all information submitted within the context of the established criteria and if, following this reviewed, we determined that there was sufficient evidence to confirm that the medical procedure represented by the code could be safely and appropriately performed on an outpatient basis, we assigned the service to an APC and included it as a payable procedure under the OPPS(67 FR 66740). We determine the APC assignment for services removed from the IPO list by evaluating the clinical similarity and resource costs of the service compared to other services paid under the OPPS and reviewing the Medicare Severity Diagnosis Related Groups (MS-DRG) rate for the service under the IPPS. It should be noted, however, that we would generally expect the cost to provide a service in the outpatient setting to be less than the cost to provide the service in the inpatient setting (67 FR 66740).

As we have stated in prior rulemaking, over time, given advances in technology and surgical technique, we will continue to evaluate services to determine whether they should be removed from the IPO list. We have made it clear that, insofar as advances in medical practice mitigate concerns about these procedures being performed on an outpatient basis, we are prepared to remove procedures from the IPO list and provide for payment for them under the OPPS (65 FR 18443).

C. Proposed CY 2026 Changes to IPO List

1. CY 2026 Proposal to Eliminate the IPO List

Since the IPO list was established in 2000, it has been our policy that, regardless of how a procedure is classified for the purposes of payment, we expect in every case the surgeon and the hospital will assess the risk of a procedure or service to the individual patient, taking site of service into account, and will act in that patient's best interests (65 FR 18456). We have reiterated this expectation in rulemaking over the years, including in our discussion of the removal of total knee arthroplasty (TKA) from the IPO list in the CY 2018 OPPS/ASC final rule with comment period, total hip arthroplasty (THA) from the IPO list in the CY 2020 OPPS/ASC final rule with comment period, and lumbar spine fusion, shoulder joint reconstruction, and ankle reconstruction in CY 2021 (82 FR 59383; 84 FR 61354; 85 FR 86093). In those rules, we stated that the decision regarding the most appropriate care setting for a given surgical procedure is a complex medical judgment made by the physician based on the beneficiary's individual clinical needs and preferences and on the general coverage rules requiring that any procedure be reasonable and necessary.

Over the course of the years since the establishment of the IPO list, we have received comments from some interested parties who believe that we should eliminate the IPO list entirely and, instead, defer to the clinical judgment of physicians for decisions regarding site of service. For example, in the CY 2000 final rule with comment period, in response to the establishment of the IPO list, certain commenters stated that they believed CMS was making decisions, such as the appropriate site of service for a particular medical procedure, that should be left to the discretion of surgeons and their patients (65 FR 18442 and 18455). In its 2001 and 2002 public meetings, the Advisory Panel on APC Groups supported eliminating the IPO list (67 FR 66722). We refer readers to the CY 2021 OPPS/ASC final rule with comment period for additional discussion of the opposition to the IPO list, including its lack of deference to physician judgment, its adverse effect on advances in surgical care, and the expectation it can create that non-IPO services must be furnished in the outpatient setting (85 FR 86084 through 86089).

Other interested parties have supported maintaining the IPO list and consider it an important tool to indicate which services are appropriate to furnish in the outpatient setting and to ensure that Medicare beneficiaries receive quality care. They have stated that many of the procedures that we currently designated as "inpatient only" are currently performed appropriately and safely only in the inpatient setting (65 FR 18442). We refer readers to the CY 2022 OPPS/ASC final rule with comment period for a summary of recent commenter concerns related to patient safety and quality of care in the absence of the IPO list (86 FR 63674).

Interested parties have also supported the use of the IPO list because services included on the IPO list are an exception to the 2-midnight rule and, as such, are considered appropriate for payment under Medicare Part A, regardless of the expected length of stay. As a result, many procedures are not subject to medical review by the Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC-QIOs) for "patient status" (that is, site-of-service). We note that, in the CY 2020 OPPS/ASC final rule with comment period, we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities for 2 calendar years following their removal from the IPO list. In the CY 2021 OPPS/ASC final rule with comment period, we finalized a policy to indefinitely exempt such procedures from those medical review activities while the IPO list was eliminated over 3 years.

For CY 2026 and subsequent years, we propose to eliminate the IPO list through a 3-year transition, completing the elimination by January 1, 2029. While we agreed with commenters in previous rulemakings that the IPO list was necessary, and that it would be inappropriate for us to establish payment rates for those services under the OPPS (78 FR 75055, 86 FR 63673), we have reconsidered the various comments from interested parties requesting that we eliminate the IPO list, and reevaluated the need for CMS to restrict payment for certain procedures in the hospital outpatient setting. As a result of that reconsideration, we no longer believe there is a need for the IPO list to identify services that require inpatient care. We agree with past commenters that the

physician should use clinical knowledge and judgment, together with consideration of the beneficiary's specific needs, to determine whether a procedure can be performed appropriately in a hospital outpatient setting or whether inpatient care is required for the beneficiary, subject to the general coverage rules requiring that any procedure be reasonable and necessary. We believe that this change would ensure maximum availability of services to beneficiaries in the outpatient setting.

Although we decided to halt the elimination of the IPO list in the 2022 OPPS/ASC final rule with comment period, for the reasons we discuss later in this section, we have come to believe with greater certainty that, since the IPO list was established, there have been significant developments in the practice of medicine that have allowed numerous services to now be provided safely and effectively in the outpatient setting. We acknowledged in the CY 2000 OPPS/ASC final rule with comment period that we believed that emerging new technologies and innovative medical practice were blurring the difference between the need for inpatient care and the sufficiency of outpatient care for many services (65 FR 18456). We also stated in the CY 2001 OPPS/ASC interim final rule with comment period that, over time, given advances in technology and surgical technique, many of the procedures that were on the IPO list at the time may eventually be performed safely in a hospital outpatient setting and that we would continue to evaluate services to determine whether they should be removed from the IPO list (65 FR 67826). Specifically, we stated that, insofar as advances in medical practice mitigate concerns about these services being furnished on an outpatient basis, we would be prepared to remove them from the IPO list and provide for payment under the OPPS (65 FR 67826).

Over the course of the last 25 years, these expectations have been borne out. There have been many new technologies and advances in surgical techniques and surgical care protocols, including the use of minimally invasive surgical procedures such as laparoscopy, improved perioperative anesthesia, expedited rehabilitation protocols, as well as significant enhancements to postoperative processes such as improvements in pain management, that have reduced the

inpatient length of stay and the need for postoperative care following a surgical service. In consideration of these advancements, we have removed certain services from the IPO list that were previously considered to require inpatient care, including musculoskeletal procedures such as TKA in CY 2018 (82 FR 59385), THA in CY 2020 (84 FR 61355), and lumbar spine fusion, shoulder joint reconstruction, and ankle reconstruction in CY 2021 (85 FR 86093).

Since we previously considered elimination of the IPO list in the CY 2021 OPPS/ASC rule final rule with comment period, there have also been other innovations in the practice of medicine; for example, innovations in infection control spurred by the COVID-19 PHE (87 FR 72194). During that time, CMS issued flexibilities in the furnishing of acute hospital services at different locations, including the patient's home. While this Acute Hospital at Home Initiative was originally spurred by the necessity of expanding hospital capacity, it has demonstrated an increased ability to deliver certain services outside of the traditional inpatient setting. Congress accordingly extended this initiative through 2024 in section 4140 of the Further Consolidated Appropriations Act, 2023 (Pub. L. No. 117-328 (Dec. 29, 2022)). These advances have heightened awareness of practices that can increase patient safety across provider types, ensuring that clinicians emphasize these considerations in the practice of medicine, including site of service decisions. As medical practice continues to develop, we believe that the difference between the need for inpatient care and the appropriateness of outpatient care will continue to be less and less distinct for many services. Therefore, we believe that the IPO list is no longer necessary to identify services that require inpatient care.

In recent years, there have also been certain procedures which we have decided to remove from the IPO list multiple times. For example, we removed several maxillofacial procedures in CY 2023, after originally removing them from the IPO list in CY 2021 and adding them back in CY 2022 (87 FR 72009). This frequency of change in policy can cause an uncertain regulatory landscape in which hospitals and providers are unclear on the policy and whether or not certain procedures are paid for in the hospital outpatient setting, potentially

impacting access to care for beneficiaries . Eliminating the IPO list and the related annual review process would mitigate this issue, offering more regulatory certainty for Medicare beneficiaries and providers.

Enabling IPO list services to be delivered outside of the inpatient setting, when clinically appropriate, can also advance important goals related to access to care. In the past, we have noted longstanding concerns over the closures of rural hospitals, which has prompted other policy actions to maximize access to care in rural or underserved areas (87 FR 72160). The experience of the COVID-19 PHE has also highlighted the importance of assisting areas and populations that suffer from a lower supply of medical services, which we addressed with temporary flexibilities during the COVID-19 P H E. Allowing for a greater exercise of clinical judgment will increase the ability of hospitals to provide Medicare-reimbursed services on an outpatient basis when clinically appropriate, while preserving inpatient beds for individual patients who truly need to be admitted. This will increase the availability of such services and additionally provide facilities with greater experience and flexibility that can be particularly crucial during future public health emergencies that constrict the supply of medical care.

We acknowledge the seriousness of the concerns regarding patient safety and quality of care that various interested parties have expressed regarding removing procedures from the IPO list or eliminating the IPO list altogether. However, we believe that the evolving nature of the practice of medicine has mitigated, and continues to mitigate, patient safety and quality of care risks. That allows more procedures to be performed on an outpatient basis with a shorter recovery time. This trend, combined with physician judgment, state and local licensure requirements, accreditation requirements, hospital conditions of participation (CoPs), medical malpractice laws, and CMS quality and monitoring initiatives and programs, will continue to ensure the safety of beneficiaries in both the inpatient and outpatient settings, even in the absence of the IPO list. As mentioned previously in this section, we have consistently believed that it is important for physicians to exercise their clinical expertise based on the circumstances of individual patients

and in light of these protections. We refer readers to the CY 2021 OPPS/ASC final rule with comment period for a full discussion of how these factors provide extensive safeguards for patients receiving services from Medicare enrolled providers, including hospital CoPs in 42 CFR part 482 (such as the requirement at § 482.30 that hospitals conduct a utilization review on medical necessity of admission, length of stay, and services rendered, and the most efficient use of available health facilities and services) (85 FR 48910). 2. CY 2026 Proposal to Use a 3-Year Transition to Eliminate the IPO list

We propose to eliminate the IPO list over a 3-year transition period, beginning in CY 2026. We also propose eliminating the criteria for removing procedures from the IPO list currently codified at § 419.23, as a conforming change.

Given the significant number of services on the list and that we would establish new reimbursement rates for those services under the OPPS, we recognize that interested parties may need time to adjust to the removal of procedures from the list. Providers may need time to prepare to furnish newly removed procedures on an outpatient basis, update their billing systems, and gain experience with newly removed procedures eligible to be paid under either the IPPS or OPPS. Therefore, we propose to transition services off of the IPO list over a 3-year period, with the list completely eliminated by CY 2029. In accordance with this proposal, we propose to amend § 419.22(n) to state that effective beginning on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the full list eliminated in its entirety by January 1, 2029.

For CY 2026, we propose that musculoskeletal services would be the first group of services that would be removed from the IPO list, as we had done in the CY 2021 OPPS/ASC final rule with comment period. We believe it is appropriate to remove this group of services first for several reasons. In recent years, due to new technologies and advances in surgical care protocols, expedited rehabilitation protocols, improved infection control practices, and significant enhancements to postoperative processes, we have removed TKA and THA, both

musculoskeletal services, from the IPO list. During the COVID-19 PHE, there was an accelerated decrease in short-length inpatient stays associated with musculoskeletal procedures — a decrease which was about four times faster than before the COVID-19 PHE (14.5 percent from 2020 to 2021). The number of Medicare ASCs specializing in orthopedic or musculoskeletal services also roughly doubled between 2016 and 2021. These trends suggest a shift in musculoskeletal services from inpatient to outpatient settings.[98]

Furthermore, during the notice and comment process of removing TKA and THA from the IPO list, interested parties continually requested that CMS remove other musculoskeletal services from the IPO list as well, citing shortened length of stay times, advancements in technologies and surgical techniques, and improved postoperative processes. Additionally, we note that, more often than not, interested parties' historical requests for removals of medical procedures from the IPO list were for musculoskeletal services. Further, there is already a set of C-APCs for musculoskeletal services for payment in the outpatient setting, which facilitates the removal of these types of services from the IPO list for CY 2026. Specifically, because we have previously removed codes corresponding to musculoskeletal services from the IPO list that are similar clinically and in terms of resource cost and assigned them to these C-APCs, these APCs generally describe appropriate ranges and placements for these musculoskeletal codes being proposed for removal in CY 2026, which will allow for appropriate payment. As discussed in section III.E.3. of this rule, we also propose to establish a 7 level Musculoskeletal Procedures APC series, which will allow for the assignment of musculoskeletal procedures removed from the IPO list to an APC with an applicable range of estimated costs. We had previously finalized the removal of 266 musculoskeletal procedures from the IPO list in the 2021 OPPS/ASC final rule. Although we largely reversed this action in the 2022 OPPS/ASC final rule based on our halting of the elimination of the IPO list and re-evaluation of our removal criteria at the time, we maintained the removal of seven musculoskeletal procedures, and their related anesthesia

[98] *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf*.

services, from the IPO list. In the CY 2023 OPPS/ASC final rule, we removed 11 more musculoskeletal services from the IPO list. As we have explained, we now believe the entire IPO list should be eliminated over a 3-year transition period. Our previous consideration of removing musculoskeletal procedures from the IPO list, and the continued removal of such procedures from it, suggests that we should begin the elimination and transition from the IPO list with the removal of these procedures from the list.

For CY 2026, we have identified 285 mostly musculoskeletal services that we propose to remove from the IPO list, including 16non-musculoskeletal services that were recommended by the 2020 HOP Panel and removed from the IPO list in CY 2021 (85 FR 86089 through 86092). These 16 services, which include cardiovascular, lymphatic, digestive, gynecological, and endovascular procedures, were added back to the IPO list when the elimination of the IPO list was halted in CY 2022. The 285 services that we propose to remove from the IPO list for CY 2026 and subsequent years, including the CPT/HCPCS code, long descriptor, and the proposed CY 2026 payment indicators, are included in Table 69. These services and their proposed status indicators and APC assignments (if applicable) are included in Addendum B of this proposed rule as well. The complete list of codes that describe services that will be paid by Medicare in CY 2026 as inpatient only services is included as Addendum E to this CY 2026 OPPS/ASC proposed rule, which is available on the CMS website.[99]

3. Effect on Beneficiary Cost-Sharing

As noted in the CY 2021 OPPS/ASC final rule, some interested parties have shared concerns with us that removing procedures from the IPO list and allowing them to be paid under the OPPS when performed in the outpatient setting may result in an increased financial burden for beneficiaries for certain complex services (85 FR 86086). Under current law, the OPPS cost-sharing for a service is capped at the applicable Part A hospital inpatient deductible amount for

[99] In this rulemaking, we propose to eliminate, the IPO list, beginning in CY 2026, with all services being removed from the list over the course of a three-year transition period. The CY 2026 IPO List can be found here: Hospital Outpatient PPS, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.*

that year for each service. This cap applies to individual services, and some commenters have expressed concern in the past that if a Medicare beneficiary receives multiple separately payable OPPS services, it is possible that the aggregate cost-sharing for a beneficiary may be higher for services provided in the outpatient setting than it would be had the services been furnished during an inpatient stay. However, we emphasize that services included on the IPO list tend to be surgical procedures that would typically be the focus of the hospital outpatient stay and would likely be assigned to a comprehensive APC (C-APC) when they are removed from the IPO list. As such, these services would likely be considered a single episode of care with one payment rate and one copayment amount, instead of multiple copayments for each individual service. In most instances, we expect that beneficiaries will not be responsible for multiple copayments for individual ancillary services removed from the IPO list since, because of their assignment to C-APCs, the inpatient deductible cap will apply to the entire hospital claim which is billed and paid as a comprehensive service or procedure. In the event there are separately payable OPPS services included on a claim with a service assigned to a C-APC, the policy that the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service remains applicable, which is that the OPPS cost-sharing for an individual service is capped at the applicable Part A hospital inpatient deductible amount for that year for each service. For further information regarding beneficiary copayments, please refer to section II.I. of this proposed rule.

4. Exemption From Certain Medical Review Activities For Services Removed From the IPO List

To further address concerns from interested parties, we propose to continue to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule until the Secretary determines that the service or procedure is more commonly performed in the Medicare population in the outpatient setting. Specifically, we propose to continue the indefinite exemption from site-of-service claim denials, referrals to Recovery Audit Contractors (RACs), and RAC reviews for “patient status” for

procedures that are removed from the IPO list under the OPPS beginning on January 1, 2021, as part of the transition away from the IPO list (85 FR 86120). Pursuant to this exemption, initial medical review contractors may continue to review claims for procedures previously on the IPO list in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but will not deny claims identified as noncompliant with respect to the site-of-service under Medicare Part A. We propose that this exemption will continue for all services or procedures removed from the IPO list until the Secretary determines that the exemption is no longer appropriate for each specific service or procedure because it is more commonly performed in the outpatient setting. We are also seeking comment on whether other exemption periods may be more warranted. For more information on this proposal and the 2-Midnight rule, please refer to section X.D. of this proposed rule.

Although we believe it is important to pause certain medical review activities related to patient status to allow providers time to adjust to the proposed changes to the IPO list, we note that initial medical review contractors routinely address, and will continue to address, any beneficiary quality of care complaints that include concerns about treatment as a hospital inpatient or outpatient, not receiving expected services, early discharge, and discharge planning. CMS's case management system currently allows initial medical review contractors and CMS to monitor the frequency and status of beneficiary quality of care complaints and other beneficiary appeals by topic, provider type, and geographic area. These numbers are currently compiled by the BFCC-QIO national coordinating and oversight review contractor and reported to the QIOs and CMS leadership on a weekly basis for monitoring purposes. As previously noted, although we propose to continue to indefinitely exempt procedures removed from the IPO list beginning on January 1, 2021, from site-of-service claim denials, referrals to RACs, and RAC reviews of "patient status," medical review contractors would continue to conduct initial medical reviews concerning the medical necessity of both the services and the site of service, and will continue to be permitted and expected to deny claims if the service itself is determined not to be reasonable

and medically necessary, as noted in the CY 2021 OPPS/ASC final rule (85 FR 86118). Therefore, given CMS's increasing ability to measure the safety of procedures performed in the outpatient setting and to monitor the quality of care, in addition to the other safeguards detailed previously in this section, we now believe that quality of care is unlikely to be negatively affected by the elimination of the IPO list. However, we request that commenters submit evidence on what effect, if any, they believe eliminating the IPO list may have on the quality of care.

5. Comment Solicitation on Order of Removal of Additional Clinical Families from the IPO List During the Transition to Complete Elimination of the IPO List

As stated previously in this section, we propose to eliminate the current IPO list of 1,731 services, starting with the 285 mostly musculoskeletal-related services as provided in Table 69. We are requesting comments from the public on whether 3 years is an appropriate time frame for the transition, whether there are other services that would be ideal candidates for removal from the IPO list in the near term, given known technological and other advances in care, and the order of removal of additional clinical families of services, and/or specific services, for each of the CY 2027 and CY 2028 rulemakings, until the IPO list is completely eliminated. Additionally, we seek comment on whether we should restructure or create any new APCs or C-APCs to allow for efficient OPPS payment for services that are removed from the IPO list.

6. Comment Solicitation on Changes to IPO List Removal Criteria

In addition to our proposal to eliminate the IPO list over a 3-year period, we propose to eliminate the codified criteria for removing procedures from the IPO list at § 419.23. As mentioned previously in this section, we finalized the adoption of these longstanding criteria for removal procedures from the list in the CY 2022 OPPS/ASC final rule with comment period when we decided to halt the elimination of the IPO list (86 FR 63678). However, if we finalize our proposal to eliminate the IPO list in its entirety, there would no longer be any need to maintain a list of criteria for removing individual procedures from the list in any given year.

However, we acknowledge that some commenters may disagree with our proposed approach to the IPO list. Therefore, we wish to consider other methods to provide greater deference to the medical judgment of clinicians besides eliminating the IPO list completely. We solicit comment on other approaches to provide greater flexibility in making site-of-service decisions, such as updating the list of criteria for removing procedures from the IPO list.

In summary, given the developments in surgical technique and technological advances in the practice of medicine, as well as the various safeguards discussed previously in this section, we propose to eliminate the IPO list over the course of the next 3 years, starting with the removal of 285 mostly musculoskeletal-related services, as provided in Table 69, in CY 2026. We propose to amend § 419.22(n) to state that, effective beginning on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition period, with the list eliminated in its entirety by January 1, 2029. We believe that there are a number of safety mechanisms that would continue to ensure the safety of our beneficiaries and the quality of care, including physician judgment, State and local regulations, accreditation requirements, medical malpractice laws, hospital conditions of participation, and other CMS initiatives.

TABLE 69: PROPOSED PROCEDURES FOR REMOVAL FROM THE IPO LIST FOR CY 2026

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
00192	Anesthesia for procedures on facial bones or skull; radical surgery (including prognathism)	N	N/A
00474	Anesthesia for partial rib resection; radical procedures (eg, pectus excavatum)	N	N/A
00604	Anesthesia for procedures on cervical spine and cord; procedures with patient in the sitting position	N	N/A
00904	Anesthesia for; radical perineal procedure	N	N/A
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N	N/A
01140	Anesthesia for interpelviabdominal (hindquarter) amputation	N	N/A
01150	Anesthesia for radical procedures for tumor of pelvis, except hindquarter amputation	N	N/A
01212	Anesthesia for open procedures involving hip joint; hip disarticulation	N	N/A
01232	Anesthesia for open procedures involving upper two-thirds of femur; amputation	N	N/A
01234	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	N	N/A
01274	Anesthesia for procedures involving arteries of upper leg, including bypass graft; femoral artery embolectomy	N	N/A
01404	Anesthesia for open or surgical arthroscopic procedures on knee joint; disarticulation at knee	N	N/A
01634	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; shoulder disarticulation	N	N/A
01636	Anesthesia for open or surgical arthroscopic procedures on humeral head and neck, sternoclavicular joint, acromioclavicular joint, and shoulder joint; interthoracoscapular (forequarter) amputation	N	N/A
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
01756	Anesthesia for open or surgical arthroscopic procedures of the elbow; radical procedures	N	N/A
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	J1	5115
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	J1	5115
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	J1	5115
0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments	J1	5116
0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or more vertebral segments	J1	5116

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	J1	5116
20661	Application of halo, including removal; cranial	Q1	5112
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	Q1	5112
20802	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	J1	5116
20805	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	J1	5116
20808	Replantation, hand (includes hand through metacarpophalangeal joints), complete amputation	J1	5116
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	J1	5112
20824	Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	J1	5112
20827	Replantation, thumb (includes distal tip to mp joint), complete amputation	J1	5112
20838	Replantation, foot, complete amputation	J1	5116
20955	Bone graft with microvascular anastomosis; fibula	J1	5114
20956	Bone graft with microvascular anastomosis; iliac crest	J1	5114
20957	Bone graft with microvascular anastomosis; metatarsal	J1	5114
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	J1	5114
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	J1	5114
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	J1	5114
21045	Excision of malignant tumor of mandible; radical resection	J1	5165
21145	Reconstruction midface, lefort i; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21146	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)	J1	5165
21147	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)	J1	5165
21151	Reconstruction midface, lefort ii; any direction, requiring bone grafts (includes obtaining autografts)	J1	5165
21154	Reconstruction midface, lefort iii (extracranial), any type, requiring bone grafts (includes obtaining autografts); without lefort i	J1	5165

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
21155	Reconstruction midface, lefort iii (extracranial), any type, requiring bone grafts (includes obtaining autografts); with lefort i	J1	5165
21159	Reconstruction midface, lefort iii (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without lefort i	J1	5165
21160	Reconstruction midface, lefort iii (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with lefort i	J1	5165
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	J1	5165
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	J1	5165
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	J1	5165
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	J1	5165
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	J1	5165
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	J1	5165
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)	J1	5165
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	J1	5165
21343	Open treatment of depressed frontal sinus fracture	J1	5165
21344	Open treatment of complicated (eg, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	J1	5165
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	J1	5165
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	J1	5165
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	J1	5165
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	J1	5165

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
21433	Open treatment of craniofacial separation (lefort iii type); complicated (eg, comminuted or involving cranial nerve foramina), multiple surgical approaches	J1	5165
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (eg, head cap, halo device, and/or intermaxillary fixation)	J1	5165
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	J1	5165
21510	Incision, deep, with opening of bone cortex (eg, for osteomyelitis or bone abscess), thorax	J1	5113
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	J1	5114
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	J1	5114
21615	Excision first and/or cervical rib;	J1	5114
21616	Excision first and/or cervical rib; with sympathectomy	J1	5114
21620	Ostectomy of sternum, partial	J1	5113
21627	Sternal debridement	J1	5113
21630	Radical resection of sternum	J1	5114
21705	Division of scalenus anticus; with resection of cervical rib	J1	5114
21740	Reconstructive repair of pectus excavatum or carinatum; open	J1	5114
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	J1	5114
21825	Open treatment of sternum fracture with or without skeletal fixation	J1	5114
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	J1	5114
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	J1	5114
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	J1	5114
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	J1	5114
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	J1	5114
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); thoracic	J1	5114

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); lumbar	J1	5114
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	J1	5114
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	J1	5114
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	J1	5114
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N	N/A
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	J1	5114
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	J1	5114
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	J1	5114
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	J1	5115
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	J1	5115
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	J1	5115
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	J1	5115
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	J1	5115
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N	N/A

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5115
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5116
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N	N/A
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	J1	5115
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J1	5116
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J1	5117
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J1	5116
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	J1	5115
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	J1	5115
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	J1	5116
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	J1	5116
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	J1	5116
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	J1	5116
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	J1	5116
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	J1	5116
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	J1	5116
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	J1	5116
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	J1	5116
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	J1	5116
22830	Exploration of spinal fusion	J1	5114
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	J1	5116
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	J1	5116

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	J1	5116
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N	N/A
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N	N/A
22849	Reinsertion of spinal fixation device	J1	5115
22850	Removal of posterior nonsegmental instrumentation (eg, harrington rod)	J1	5114
22852	Removal of posterior segmental instrumentation	J1	5114
22855	Removal of anterior instrumentation	J1	5114
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	J1	5116
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (list separately in addition to code for primary procedure)	N	N/A
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5116
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5116
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J1	5114
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J1	5114
23200	Radical resection of tumor; clavicle	J1	5114
23210	Radical resection of tumor; scapula	J1	5114
23220	Radical resection of tumor, proximal humerus	J1	5114
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	J1	5073
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	J1	5115
23900	Interthoracoscapular amputation (forequarter)	J1	5115
23920	Disarticulation of shoulder;	J1	5115
24900	Amputation, arm through humerus; with primary closure	J1	5115
24920	Amputation, arm through humerus; open, circular (guillotine)	J1	5115

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
24930	Amputation, arm through humerus; re-amputation	J1	5114
24931	Amputation, arm through humerus; with implant	J1	5115
24940	Cineplasty, upper extremity, complete procedure	J1	5115
25900	Amputation, forearm, through radius and ulna;	J1	5114
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	J1	5114
25915	Krukenberg procedure	J1	5114
25920	Disarticulation through wrist;	J1	5113
25924	Disarticulation through wrist; re-amputation	J1	5113
25927	Transmetacarpal amputation;	J1	5113
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	J1	5114
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	J1	5114
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	J1	5114
26556	Transfer, free toe joint, with microvascular anastomosis	J1	5114
26992	Incision, bone cortex, pelvis and/or hip joint (eg, osteomyelitis or bone abscess)	J1	5113
27005	Tenotomy, hip flexor(s), open (separate procedure)	J1	5113
27025	Fasciotomy, hip or thigh, any type	J1	5113
27030	Arthrotomy, hip, with drainage (eg, infection)	J1	5114
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	J1	5114
27054	Arthrotomy with synovectomy, hip joint	J1	5113
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (eg, osteomyelitis or bone abscess); superficial	J1	5113
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (eg, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	J1	5113
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	J1	5114
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	J1	5114
27077	Radical resection of tumor; innominate bone, total	J1	5114
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	J1	5114
27090	Removal of hip prosthesis; (separate procedure)	J1	5114
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	J1	5115
27120	Acetabuloplasty; (eg, whitman, colonna, haygroves, or cup type)	J1	5115
27122	Acetabuloplasty; resection, femoral head (eg, girdlestone procedure)	J1	5114

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	J1	5115
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	J1	5115
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	J1	5115
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	J1	5115
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	J1	5115
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	J1	5114
27146	Osteotomy, iliac, acetabular or innominate bone;	J1	5114
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	J1	5114
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	J1	5114
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	J1	5114
27158	Osteotomy, pelvis, bilateral (eg, congenital malformation)	J1	5114
27161	Osteotomy, femoral neck (separate procedure)	J1	5114
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	J1	5114
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	J1	5114
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	J1	5113
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	J1	5113
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	J1	5113
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	J1	5113
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	J1	5114
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	J1	5113
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	J1	5114
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	T	5111
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	J1	5114
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	J1	5114

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	J1	5114
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	J1	5112
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	J1	5114
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	J1	5112
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	J1	5114
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	J1	5114
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	J1	5114
27253	Open treatment of hip dislocation, traumatic, without internal fixation	J1	5113
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	J1	5113
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	J1	5113
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	J1	5113
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	J1	5112
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	J1	5114
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed	J1	5116
27282	Arthrodesis, symphysis pubis (including obtaining graft)	J1	5113
27284	Arthrodesis, hip joint (including obtaining graft);	J1	5115
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	J1	5115
27290	Interpelviabdominal amputation (hindquarter amputation)	J1	5116
27295	Disarticulation of hip	J1	5116
27303	Incision, deep, with opening of bone cortex, femur or knee (eg, osteomyelitis or bone abscess)	J1	5113
27365	Radical resection of tumor, femur or knee	J1	5113
27448	Osteotomy, femur, shaft or supracondylar; without fixation	J1	5114
27450	Osteotomy, femur, shaft or supracondylar; with fixation	J1	5114

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (eg, sofield type procedure)	J1	5114
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	J1	5114
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	J1	5114
27465	Osteoplasty, femur; shortening (excluding 64876)	J1	5114
27466	Osteoplasty, femur; lengthening	J1	5114
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (eg, compression technique)	J1	5114
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J1	5114
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	J1	5115
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	J1	5115
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	J1	5115
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	J1	5114
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	J1	5114
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	J1	5114
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	J1	5114
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	J1	5114
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J1	5114
27519	Open treatment of distal femoral epiphyseal separation, includes internal fixation, when performed	J1	5114
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	J1	5114
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	J1	5114
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	J1	5114
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	J1	5114

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J1	5114
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair, with augmentation/reconstruction	J1	5114
27580	Arthrodesis, knee, any technique	J1	5115
27590	Amputation, thigh, through femur, any level;	J1	5113
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	J1	5113
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	J1	5113
27596	Amputation, thigh, through femur, any level; re-amputation	J1	5113
27598	Disarticulation at knee	J1	5113
27645	Radical resection of tumor; tibia	J1	5113
27646	Radical resection of tumor; fibula	J1	5113
27703	Arthroplasty, ankle; revision, total ankle	J1	5116
27712	Osteotomy; multiple, with realignment on intramedullary rod (eg, sofield type procedure)	J1	5115
27715	Osteoplasty, tibia and fibula, lengthening or shortening	J1	5115
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	J1	5114
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	J1	5114
27727	Repair of congenital pseudarthrosis, tibia	J1	5113
27880	Amputation, leg, through tibia and fibula;	J1	5114
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	J1	5113
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	J1	5113
27886	Amputation, leg, through tibia and fibula; re-amputation	J1	5113
27888	Amputation, ankle, through malleoli of tibia and fibula (eg, syme, pirogoff type procedures), with plastic closure and resection of nerves	J1	5113
28800	Amputation, foot; midtarsal (eg, chopart type procedure)	J1	5113
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	J1	5184
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	J1	5184
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	J1	5193
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	J1	5184
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	J1	5092
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	J1	5303

HCPCS Code	Long Descriptor	Proposed CY 2026 SI	Proposed CY 2026 APC
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	J1	5302
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	T	5055
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	T	5055
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	T	5055
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	J1	5303
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	J1	5342
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	J1	5342
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	J1	5415
56630	Vulvectomy, radical, partial;	J1	5415
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	J1	5194
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	J1	5114
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	J1	5114
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	J1	5113

X. Nonrecurring Policy Changes

A. Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments (PBDs)

1. Background

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59004 through 59014), we adopted a method to control unnecessary increases in the volume of the clinic visit

services furnished in excepted off-campus provider-based departments (PBDs). We refer readers to the CY 2019 OPPS/ASC final rule with comment period for a detailed discussion of the background, legislative provisions, and payment policies we developed to address increases in the volume of covered outpatient department (OPD) services. Below we discuss the policy we finalized in the CY 2019 OPPS/ASC final rule with comment period and its application under the OPPS for CY 2020 and subsequent years.

In the CY 2019 OPPS/ASC final rule with comment period, we finalized a policy to use our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered outpatient department services. We applied an amount equal to the site-specific Medicare Physician Fee Schedule (PFS) payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate) for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). However, we phased-in the application of the reduction in payment for the clinic visit service described by HCPCS code G0463 in the excepted provider-based department setting over 2 years. For CY 2019, the payment reduction was phased-in by applying 50 percent of the total reduction in payment that would have applied if these departments were paid the site-specific PFS rate for the clinic visit service. The PFS equivalent rate was 40 percent of the OPPS payment for CY 2019 (that is, 60 percent less than the OPPS rate). We provided for a 2-year phase-in of this policy under which one-half of the total 60 percent payment reduction (a 30-percent reduction) was applied in CY 2019. These departments were paid approximately 70 percent of the OPPS rate (100 percent of the OPPS rate minus the 30 percent payment reduction that was applied in CY 2019) for the clinic visit service in CY 2019.

For CY 2020, the second year of the 2-year phase-in, we stated that we would apply the total reduction in payment that is applied if these departments (departments that bill the modifier "PO" on claims lines) are paid the site specific PFS rate for the clinic visit service described by

HCPCS code G0463. For CY 2020 and subsequent years, the PFS-equivalent rate was 40 percent of the proposed OPPS payment (that is, 60 percent less than the OPPS rate).

In addition, as we stated in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59013), this policy was implemented in a non-budget neutral manner. In order to effectively establish a method for controlling the unnecessary growth in the volume of clinic visits furnished by excepted off-campus PBDs that does not simply increase other expenditures that are unnecessary within the OPPS and drive different service-distorting decisions, we believed that this method had to be adopted in a non-budget neutral manner consistent with the OPPS statute.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 71748), we finalized a policy which provided that off-campus PBDs (departments that bill the modifier "PO" on claim lines) of rural Sole Community Hospitals (SCHs), as described under 42 CFR 412.92 and designated as rural for Medicare payment purposes, are exempt from the clinic visit payment policy that applies a Physician Fee Schedule-equivalent payment rate for the clinic visit service, as described by HCPCS code G0463, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act. For the full discussion of this policy, we refer readers to the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051). For CY 2024 and CY 2025, we continued to exempt excepted off-campus PBDs of rural SCHs from the clinic visit payment policy.

We continue to believe that section 1833(t)(2)(F) of the Act provides authority to implement this policy. The U.S. Court of Appeals for the District of Columbia Circuit held in *American Hospital Association v. Azar*, that a service-specific, non-budget-neutral reduction of the reimbursement rate for OPD services "qualifies as a 'method for controlling unnecessary increases in the volume of covered [outpatient] services'" under that provision. 964 F.3d 1230, 1245 (D.C. Cir. 2020) (quoting 42 U.S.C. § 1395*l*(t)(2)(F)). The D.C. Circuit reasoned in part that because "[t]he lower the reimbursement rate for a service, the less the incentive to provide it,

all else being equal[,] [r]educing particular the reimbursement rate . . . is naturally suited to addressing unnecessary increases in the overall volume of a service provided by hospitals." *Id.* at 1241. It ultimately concluded that the policy "falls comfortably within the plain text" of section 1833(t)(2)(F) of the Act "and fit[s] the design of the statute as a whole and its object and policy." *Id.* at 1241, 45 (cleaned up). Our interpretation of the Act was, and still is, the best one that falls well within the Act's delegation to the Secretary to "develop a method for controlling unnecessary increases in the volume of covered OPD services." We proceed on that basis here.

2. Expanding the Method to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider-Based Departments

As described in the CY 2019 OPPS/ASC final rule with comment period, we found that previous rulemaking efforts were insufficient to control the unnecessary growth of covered OPD services and as a result we implemented a method to control for unnecessary growth in covered OPD services by adjusting the payment rate for clinic visits in excepted off-campus PBDs to be at the PFS-equivalent rate rather than the higher OPPS rate. While this regulatory change and related legislative enactments have had a positive impact, there is evidence of continued growth in the volume of OPD services driven by site of service payment differentials. Volume increases that seek to take advantage of financial incentives created by payment policy rather than clinical need are unnecessary and therefore warrant policy changes to halt and address these increases. As the D.C. Circuit explained, "[i]t is reasonable to think that Congress . . . would have wanted the agency to avoid causing unnecessary volume growth with its own reimbursement practices." *Am. Hosp. Ass'n*, 964 F.3d at 1245. Accordingly, we propose here to remove this differential for drug administration services delivered in excepted PBDs.

Many healthcare services can be performed in multiple settings. Even when there is little variation in the service provided across settings, the Medicare Trust Fund and Medicare beneficiaries typically pay more when that service is performed in an OPD than when the same service is performed in a physician office. That payment differential creates an incentive for

providers to shift the care of beneficiaries to an OPD rather than a physician office or ASC, even if the services can be safely performed in the physician office or an ASC. Generally, 20 percent of any increased payment is the responsibility of the beneficiary in the form of coinsurance. Taking into account that any payment differential occurs across millions of claims for drug administration and other services each year, this threatens to create a significant source of unnecessary spending by Medicare beneficiaries directly (in the form of unnecessarily high copayments) and on behalf of Medicare (in the form of unnecessarily high Medicare payments for services that can be performed safely in a different setting).

In the CY 2019 OPPS/ASC final rule with comment period we discussed vertical consolidation and the practice of hospitals purchasing freestanding physician practices and converting the billing from the PFS to higher paying OPD visits. These conversions shift market share from freestanding physician offices to OPDs. We stated that we believed there was a correlation among the increasing volume of OPD clinic visits, vertical integration, and the higher OPPS payment rates for clinic visits. Favorable reimbursement for hospital-owned sites has been shown to encourage hospitals' acquisition of physician practices.[100][101] Once a practice is acquired and designated as an outpatient department, physician services can be billed at higher, hospital-based rates. This type of consolidation has been associated with higher Medicare spending and more intense treatment patterns.[102][103][104] We believe that the impact of vertical integration and the increases in volume of outpatient services extends beyond just the clinic visit. In the CY 2019 OPPS/ASC final rule with comment period we cited our concern that beneficiaries receiving chemotherapy administration, a high-volume service within the drug administration APC family, receive more sessions on average when treated in the OPD. Chemotherapy days per beneficiary were an estimated 9 to 12 percent higher in the hospital

[100] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830.*
[101] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.13613.*
[102] *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2463591.*
[103] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01183.*
[104] *https://onlinelibrary.wiley.com/doi/10.1111/1475-6773.14172.*

outpatient department than the physician office setting.[105] From 2003-2015 the rate of hospital or health system ownership of cancer care practices doubled from about 30 percent to about 60 percent.[106] For some drug administration services for cancer care, provider consolidation increases the cost of outpatient chemotherapy treatment.[107]

Our policy in the CY 2019 OPPS/ASC final rule with comment period to pay for clinic visits in excepted off-campus PBDs at the PFS-equivalent rate addressed the financial incentive for only one type of service in one outpatient setting. However, the share of other ambulatory services billed under the OPPS has continued to increase. For example, in its 2023 report, MedPAC stated that the share of chemotherapy services furnished in OPDs has grown from 35.2 percent in 2012 to 51.9 percent in 2021. HCPCS code 96413 – which describes chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug -- is one of the most frequently billed drug administration codes in the OPPS. In 2025 this service has a physician office payment rate of around $119 dollars and an OPPS payment rate of approximately $341, making the same chemotherapy infusion service 186 percent more expensive in the OPD than in the physician office. Similarly, between 2012 and 2021, the OPD share of nuclear cardiography services has grown from 33.9 percent to 47.6 percent, and the OPD share of echocardiography services has grown from 31.6 percent to 43.1 percent.[108]

We are not aware of any clinical or other substantive change in the services provided that would have led to the increases in the share of these services furnished in OPDs, as opposed to in other settings. The natural inference is that these changes result from financial incentives, and therefore are unnecessary increases in the volume of OPD services.

We believe that financial incentives have driven volume from the office setting to the higher paying OPD setting, creating unnecessary increases in the volume of OPD services. We

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[105] *https://www.siteneutral.org/wp-content/uploads/2016/06/14_USON-Moran-Report-08272013.pdf.*
[106] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830.*
[107] *https://www.healthaffairs.org/doi/10.1377/hlthaff.2016.0830.*
[108] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

believe that this problem is pervasive and exists across service families. Any time a service is provided in the higher cost OPD when it could be provided safely in the physician office, but it is not because of financial incentives, that represents unnecessary utilization of the OPD setting. In CY 2019, we chose to start tackling this problem by addressing the clinic visit when provided in excepted PBDs. In that case, it was practical to address only a single code, G0463, the clinic visit. For CY 2026, we are proposing to address drug administration services provided at excepted PBDs. We propose to address payment for these services across the APC family, as we believe this volume control method should apply to all drug administration services at excepted PBDs. As discussed later in this section, in future years we plan to examine other APC families of services, such as imaging without contrast, and other settings, specifically on-campus outpatient clinic visits.

Our authority under section 1833(t)(2)(F) of the Act to adopt a method to control unnecessary increases in the volume of covered outpatient department services authorizes us to address the consequences of these payment inequalities. Given these continued disparities, we believe it is necessary to further examine and refine our volume control method by identifying additional covered OPD services at high risk of unnecessarily shifting to the hospital setting based on financial incentives rather than medical necessity. We conducted analyses of several families of services paid under the OPPS and present our findings on the utilization and payment of drug administration services in the sections below.

3. Utilization of Drug Administration Services

The high volume of drug administration services and the magnitude of rate differences between the physician office and OPD settings make it a family of services likely to migrate to a higher paying setting of care. Drug administration includes the intravenous or intramuscular administration of a range of medicines. Drug administration can be performed in either physician offices or OPDs. The effort to administer a drug does not meaningfully differ between a physician office or OPD. In the OPPS, drug administration is categorized into four levels of

complexity. Payments are set at a category level, called an Ambulatory Payment Classification (APC). The APCs for drug administration are 5691, 5692, 5693, and 5694. Currently, 61 Healthcare Common Procedure Coding System (HCPCS) codes make up the four drug administration APCs. HCPCS codes that are similar in terms of cost and clinical attributes are placed in the same APC. All HCPCS codes in the same APC have the same OPPS payment rate. The individual HCPCS and APC assignments are available in Addendum B to this proposed rule.

We evaluated the growth in volume and spending for multiple families of Ambulatory Payment Classifications (APCs) in OPDs across multiple years of claims data. Should commenters wish to replicate any of our analyses, the CMS website includes information about obtaining the ‘‘Limited Data Set,’’ *https://www.cms.gov/data-research/files-for-order/data-disclosures-and-data-use-agreements-duas/limited-data-set-lds* through which OPPS claims data is available for purchase. We found that there has been an increase in volume of services paid through the drug administration APCs (5691-5694) over time, which would indicate that there has been migration of these services to the OPD setting. From 2011 to 2019 the volume of drug administration services paid under these APCs grew by almost 35 percent. This growth persisted even with the introduction of the PFS-equivalent rate for PBDs subject to section 603 of the Bipartisan Budget Act of 2015 starting in 2017. The COVID-19 Public Health Emergency (PHE) did impact utilization across the OPPS, but we have seen the volume of drug administration services rebound and return to this pattern of growth. Between 2018 and 2024 the number of beneficiaries enrolled in fee-for-service Medicare decreased by over 14 percent.[109] Since 2022, we have simultaneously seen increases in the volume of drug administration services provided in OPDs utilized per beneficiary[110]. Meaning that while there are now fewer Medicare fee-for-service beneficiaries than there were prior to the COVID-19 PHE, each beneficiary on average is

[109] *https://data.cms.gov/summary-statistics-on-beneficiary-enrollment/medicare-and-medicaid-reports/medicare-monthly-enrollment.*
[110] Based on our analysis of claims data and Medicare FFS enrollment.

receiving more drug administration services in the OPD setting than they were prior to the COVID-19 PHE.

In addition to looking at the growth in volume and spending at the APC level, we looked at the growth in volume at the HCPCS code level and found that some HCPCS codes within the drug administration APCs have experienced significant growth. HCPCS code 96413 – which describes chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug – is the most frequently billed HCPCS code within any of the drug administration APCs at excepted PBDs. This code has seen an almost 70 percent increase in volume from 2011 to 2023.[111] In 2025, this service has a physician office payment rate of around $119 dollars and an OPPS payment rate of approximately $341. That makes the same chemotherapy infusion service 184 percent more expensive in the OPD than in the physician office. We conclude that this 70 percent increase in excepted hospital outpatient department volume over a 10-year period was at least partially driven by the payment differential between the physician office and OPD setting. The HCPCS codes representing chemotherapy administration grew in volume by 64 percent in the OPPS between 2011 and 2023.[112] The chemotherapy administration codes represent some of the highest cost and most frequently billed services within the drug administration APCs. MedPAC found that from 2015 to 2021, the volume of chemotherapy administration in freestanding clinician offices, the ambulatory setting for which payment rates are usually lowest, fell 14.2 percent.[113] We conclude that if there was not a difference in payment rates, fewer of these services would have shifted to the hospital outpatient setting and the corresponding increase in Medicare payments and beneficiary cost-sharing would not have occurred.

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[111] Based on our analysis of claims data.
[112] HCPCS included in the chemotherapy administration category are:96423, 96549, 96401, 96402, 96405, 96411, 96415, 96417, 96406, 96409, 96422, 96542, 96413, 96416, 96420, 96425, 96440, 96446, 96450, G0498
[113] *https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.*

We are also concerned about beneficiaries who pay higher cost sharing because of the payment incentives driving them to OPDs. Drug administration services are skewed toward a small portion of the population with high utilization. Cancer patients receiving chemotherapy are among the highest utilizers of these services. The administration of chemotherapy highlights that a small portion of the population is disproportionately harmed by the current state of drug administration payment in the OPPS. A meaningful number of beneficiaries in this cohort are paying substantially more per year in cost sharing than they would had they received the same treatments at freestanding facilities or non-excepted off-campus PBDs.[114] Focusing on the cost sharing of chemotherapy patients demonstrates how this cohort is disproportionately impacted by the current payment structure and is uniquely positioned to benefit from an appropriate application of our authority to control for unnecessary increases in the volume of OPD services. Indeed, one study found that "in 2021, approximately 74,000 Medicare FFS chemotherapy patients utilized excepted off-campus OPDs and would have had cost sharing expenses that were $292 lower per patient had site neutrality applied. For the highest utilizing 5,000 patients who received chemotherapy most frequently at excepted off-campus OPDs, cost sharing would have been $1,055 lower per patient if payments had been site neutral."[115]

While there have been increases in the volume of drug administration services in the hospital outpatient setting in recent years, drug administration services are still frequently provided in freestanding facilities. One study found that 68 percent of drug administration services currently take place in physician offices, indicating that they are safely performed in multiple settings.[116] In its 2023 report, MedPAC examined APCs for which it might be appropriate to make a site neutral payment. To identify appropriate APCs they compared the volume of services in each APC that was provided in OPDs, ASCs, and freestanding offices over the period of 2016 through 2021, but omitted 2020 because the coronavirus pandemic affected

[114] *https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf.*
[115] *https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf.*
[116] *https://craftmediabucket.s3.amazonaws.com/uploads/Drug-Admin-Off-Campus-Site-Neutrality-2023.10.18.pdf.*

the volume of care in ambulatory settings. If freestanding offices had the highest volume for an APC, they concluded that the services in that APC could be provided safely in freestanding offices for most beneficiaries and that beneficiaries would be able to access the services in that APC. Therefore, for those services, it would be reasonable to align the OPPS payment rates with the PFS payment rates. MedPAC found that all four of the drug administration APCs had higher volume in freestanding facilities than in OPDs, indicating that these services can be safely provided to beneficiaries in a lower cost setting of care. We believe MedPAC's analysis aligns well with the rationale CMS adopted in the CY 2019 OPPS/ASC final rule with comment period: we consider OPPS utilization unnecessary if the beneficiary can safely receive the same services in a lower cost setting but instead receives care in the hospital outpatient setting because of site-of-service payment differentials.

In our review of the utilization of drug administration services in excepted PBDs we found increases in the volume of services over time, increases in the volume of services provided per beneficiary, and cases of significant volume growth for some individual HCPCS codes within the drug administration APC family. We believe that these changes represent unnecessary increases in the volume of covered outpatient department drug administration services and that it would be appropriate to apply our volume control method to these services.

4. Payment for Drug Administration Services at PBDs

As discussed in the CY 2017 OPPS/ASC final rule with comment period (81 FR 33648), we established a PFS relativity adjuster that is applied to the OPPS rate for the billed non-excepted items and services furnished in a non-excepted off-campus PBD in order to calculate payment rates under the PFS. The PFS relativity adjuster reflects the estimated overall difference between the payment that would otherwise be made to a hospital under the OPPS for the non-excepted items and services furnished in non-excepted off-campus PBDs and the resource-based payment under the PFS for the technical aspect of those services with reference to the difference between the facility and nonfacility (office) rates and policies under the PFS. The current PFS

relativity adjuster is set at 40 percent of the amount that would have been paid under the OPPS (82 FR 53028). Non-excepted PBDs are required to use the modifier "PN" so that the PFS relativity adjuster is applied to the payment of their claim. Excepted PBDs use the modifier "PO" on their claims to indicate that the service was provided at an excepted off-campus PBD and that payment should generally be made at the OPPS rate.

In the CY 2019 OPPS/ASC final rule with comment period, we stated that we consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives.[117] In order to better understand the migration of services in OPDs we analyzed claims data for drug administration services to assess whether increases in volume and spending could be driven by payment incentives. We examined the top twenty most frequently billed HCPCS codes in the drug administration APC family at both excepted and non-excepted off-campus PBDs. Twenty HCPCS codes account for over 98 percent of the volume of drug administration services in off-campus PBDs. We found that the top twenty most frequently billed HCPCS codes in the drug administration APCs when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines) and off-campus PBDs that are not excepted from section 603 (departments that bill the modifier "PN"), are the same with slight variations in the order based on volume. We know that there is claims volume for the overwhelming majority of HCPCS codes in the drug administration APCs with both the "PO" and "PN" modifiers. That indicates that the payment rate in non-excepted PBDs is sufficient and can support of the provision of these services in an off-campus PBD. We further used the PFS payment rates for the top twenty most frequently billed drug administration HCPCS codes by excepted PBDs (departments that bill the modifier "PO" on claim lines) and volume weighted

[117] *https://www.federalregister.gov/documents/2018/11/21/2018-24243/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center.*

them to create a PFS proxy APC payment rate for each of the four drug administration APCs. We found that for each of the four APC payment levels, the same services were paid 200-300 percent higher under the OPPS than under the PFS. The volume-weighted PFS payment for the drug administration APCs ranged from 24 percent to 33 percent of the OPPS payment.

We conclude that the differential in our payment rates has created a payment incentive that has led to unnecessary growth for the services in the drug administration APCs. If the PFS payment rate for drug administration APCs ranges from 24 percent to 33 percent of the OPPS payment, then payment using the PFS relativity adjuster of 40 percent should sufficiently cover the cost of these services. We consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We believe the OPPS payment rate for drug administration APCs being several times greater than the PFS rate provides this payment incentive and that the growth in drug administration services paid under the OPPS over time is unnecessary.

5. Patient Severity and Cost of Care

In comments to the CY 2019 OPPS/ASC proposed rule and subsequent rulemaking, we heard from commenters that the higher payments for services in hospital outpatient settings are justified by the level of care patients need, the higher costs of providing care in hospitals, and the costs of maintaining emergency care and standby capacity. We recognize that OPDs serve unique patient populations and provide services to medically complex beneficiaries; however, there is no evidence to demonstrate the need for higher payment for services provided in OPDs that could also be provided in lower-cost settings. In general, despite marked differences in payment rates for a range of services, identical services are being delivered to very similar patients across physicians' offices, hospital outpatient departments, and ASCs.[118][119] Moreover, a

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[118] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*

[119] https://www.medpac.gov/wp-content/uploads/2023/06/Jun23_Ch8_MedPAC_Report_To_Congress_SEC.pdf.

2023 literature review found no peer-reviewed evidence that shows differences in the quality of services delivered across hospital outpatient departments and physicians' offices.[120] In their 2023 report, MedPAC evaluated risk scores from the CMS hierarchical condition category (CMS–HCC) risk-adjustment model to compare the medical complexity of OPD patients with patients in freestanding offices. They found that, on average, OPD patients have higher risk scores, which suggests that OPD patients are potentially more medically complex than those in physician offices. However, they also found substantial overlap in the CMS–HCC risk scores of patients in these two settings, which suggests that the difference in patient severity between settings is small. Their analysis showed that the effects of patient severity on cost of care for the aligned services is not statistically significant as the services, like drug administration, are generally of low complexity. In addition, if there is a need to bill for more complex cases, under the OPPS providers can often bill separately for additional services that a patient might need.

6. Impact of Unnecessary Increases in Volume on the OPPS

Our concern with unnecessary increases in the volume of drug administration services is tied to the health and sustainability of the OPPS. In the CY 2019 OPPS/ASC final rule with comment period, we found that the mean and median annual increase in the volume and intensity of hospital outpatient services was about 5.5 percent and 5.4 percent, respectively, from 2011 to 2019. During this time period, the estimated increase in aggregate annual hospital reimbursements incurred through Medicare Fee for Service (FFS) Part B was $28.2 billion.[121] As Table 70 shows, we projected that between 2019 and 2027, the cost of outpatient hospital services per FFS enrollee would grow at a mean of about 7.3 percent per year and a median of 8.1 percent per year. This accounts for a $27.2 billion increase in aggregate annual incurred

[120] *https://tobin.yale.edu/sites/default/files/2023-10/Site-Neutral%20Payment%20Literature%20Review%2010302023.pdf.*
[121] Available in Table IV.B6 at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2019.pdf.*

reimbursements for hospitals in FFS Part B during that time, far exceeding the growth of other categories of Part B services in FFS in dollar terms.[122]

TABLE 70: GROWTH IN HOSPITAL OUTPATIENT COSTS PER FEE-FOR-SERVICE ENROLLEE[123]

Calendar Year	Percent Increase
2019	5.2
2020	-5.6
2021	19.8
2022	4.3
2023	9.1
2024	8.3
2025 (Estimated)	7.9
2026 (Estimated)	8.1
2027 (Estimated)	8.4

As we stated in the CY 2019 OPPS/ASC final rule with comment period, there is evidence that increased volume and intensity of certain covered OPD services is likely driven by financial incentives to furnish services in hospitals in order to receive higher reimbursement, rather than making site-of-service decisions based on medical necessity. We continue to be concerned with the rate of increase in program expenditures under the OPPS for several reasons. The OPPS was originally designed to manage Medicare spending growth by replacing a cost-based system with a prospective payment system. Contrary to this Congressional purpose, the OPPS has continued to be the one of the fastest growing sectors of Medicare payments out of all payment systems under Medicare Parts A and B.[124] Furthermore, we are concerned that the persisting rate of growth relative to other payment systems suggests that payment incentives, rather than patient acuity or medical necessity, continue to affect site-of-service decision-making. This site-of-service selection has an impact on not only the Medicare program, but also on Medicare beneficiary out-of-pocket spending. Therefore, to the extent that there are lower-cost sites-of-service available, we continue to believe that beneficiaries and the physicians treating them

[122] Available in Tables IV.B3 and B6 at *https://www.cms.gov/oact/tr/2024.*
[123] Available in Table IV.B3 at *https://www.cms.gov/oact/tr/2024*.
[124] *https://www.gpo.gov/fdsys/pkg/FR-2018-11-21/pdf/2018-24243.pdf.*

should have that choice and not be encouraged to receive or provide care in higher paid settings solely for financial reasons. Our authority to implement volume control methods is an important tool in combating unnecessary OPPS utilization. We have seen success in stemming the unnecessary growth in the volume of off-campus clinic visits and believe off-campus drug administration services are in need of similar examination.

As we stated in the CY 2019 OPPS/ASC final rule with comment period, we consider the shift of services from the physician office to the hospital outpatient department unnecessary if the beneficiary can safely receive the same services in a lower cost setting but is instead receiving services in the higher paid setting due to payment incentives. We believe the increase in the volume of drug administration services is due to the payment incentive that exists to provide this service in the higher cost setting. Because these services could generally be safely provided in a lower cost setting, we believe that the growth in drug administration services paid under the OPPS is unnecessary. Further, we believe that paying for drug administration services provided at excepted off-campus departments at the PFS-equivalent rate would be an effective method to control the volume of these unnecessary services because the payment differential that is driving the site-of-service decision will be removed. In particular, we believe this method will control unnecessary volume increases both in terms of the number of covered outpatient department services furnished and costs associated with those services.

Therefore, given the unnecessary increases in the volume of drug administration services in hospital outpatient departments, for the CY 2026 OPPS, we propose to use our authority under section 1833(t)(2)(F) of the Act to apply an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a non-excepted off-campus PBD (the PFS payment rate) for any HPCPCs codes assigned to the drug administration services APCs, when provided at an off-campus PBD excepted from section 1833(t)(21) of the Act (departments that bill the modifier "PO" on claim lines). Table 71 shows the specific APCs that we would identify for this proposal, which are APCs 5691-5694. Off-campus PBDs that are not excepted from

section 603 (departments that bill the modifier "PN") already receive a PFS-equivalent payment rate for any HCPCS codes assigned to the drug administration services APCs. Additionally, this proposal aligns with President Trump's Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First."[125] Section 11 of the E.O., "Reducing Costly Care for Seniors," directs the Secretary to "evaluate and, if appropriate and consistent with applicable law, propose regulations to ensure that payment within the Medicare program is not encouraging a shift in drug administration volume away from less costly physician office settings to more expensive hospital outpatient departments."

TABLE 71: PROPOSED NEW APCS PAID THE PFS-EQUIVALENT RATE FOR SERVICES PROVIDED AT EXCEPTED OFF-CAMPUS PBDS

APC	APC Description
5691	Level 1 Drug Administration
5692	Level 2 Drug Administration
5693	Level 3 Drug Administration
5694	Level 4 Drug Administration

In the CY 2019 OPPS/ASC proposed rule (83 FR 37142), we finalized our method to address the unnecessary increases in utilization of clinic visits in the OPD setting in a nonbudget neutral manner. For CY 2026, we likewise propose to implement this proposed method to address the unnecessary increases in utilization of drug administration services in the OPD setting in a non-budget neutral manner. We continue to believe that, while section 1833(t)(9)(B) of the Act requires that certain changes made under the OPPS be made in a budget neutral manner, this section does not apply to the volume control method under section 1833(t)(2)(F) of the Act. In particular, section 1833(t)(9)(A) of the Act, titled "Periodic review," provides, in part, that the Secretary must annually review and revise the groups, the relative payment weights, and *the wage and other adjustments* described in paragraph (2) to take into account changes in medical practice, changes in technology, the addition of new services, new cost data, and other relevant information and factors" (emphasis added). Section 1833(t)(9)(B) of the Act, titled

[125] *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

"Budget neutrality adjustment" provides that if "the Secretary makes *adjustments* under paragraph (A), then the *adjustments* for a year may not cause the estimated amount of expenditures under this part for the year to increase or decrease from the estimated amount of expenditures under this part that would have been made if the adjustments had not been made" (emphasis added). However, a volume-control method under section 1833(t)(2)(F) of the Act is not an "adjustment" under paragraph (2). Unlike the wage adjustment under section 1833(t)(2)(D) of the Act and the outlier, transitional pass-through, and equitable adjustments under section 1833(t)(2)(E) of the Act, section 1833(t)(2)(F) of the Act refers to a "method" for controlling unnecessary increases in the volume of covered OPD services, not an adjustment. Likewise, sections 1833(t)(2)(D) and (E) of the Act also explicitly require the adjustments authorized by those paragraphs to be budget neutral, while the volume control method authority at section 1833(t)(2)(F) of the Act does not. Therefore, the volume control method proposed under section 1833(t)(2)(F) of the Act is not one of the adjustments under section 1833(t)(2) of the Act that is referenced under section 1833(t)(9)(A) of the Act that must be included in the budget neutrality adjustment under section 1833(t)(9)(B) of the Act. Moreover, section 1833(t)(9)(C) of the Act specifies that if the Secretary determines under methodologies described in paragraph (2)(F) that the volume of services paid for under this subsection increased *beyond* amounts established through those methodologies, the Secretary *may* appropriately adjust the update to the conversion factor otherwise applicable in a *subsequent* year. We interpret this provision to mean that the Secretary can implement a volume control method under section 1833(t)(2)(F) of the Act in a nonbudget neutral manner in the year in which the method is implemented, and that the Secretary may then make further adjustments to the conversion factor in a subsequent year to account for volume increases that are *beyond* the amounts estimated by the Secretary under the volume control method.

We stated in the CY 2019 OPPS/ASC proposed rule (83 FR 37143) that we believe implementing a volume control method in a budget neutral manner would not appropriately

reduce the overall unnecessary volume of covered OPD services, and instead would simply shift the movement of the volume within the OPPS system in the aggregate, a concern similar to the one we discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66613). We believe that concern applies to drug administration services just the same. The estimated payment impact for various provider classifications is displayed in Table 113: Estimated Impact of the Proposed Changes for the Hospital Outpatient Prospective Payment System of this proposed rule. For CY 2026, the estimated savings are $280 million, with $210 million of the savings accruing to Medicare, and $70 million saved by Medicare beneficiaries in the form of reduced beneficiary coinsurance. To effectively establish a method for controlling the unnecessary growth in the volume of drug administration services furnished by excepted off-campus PBDs that does not simply reallocate expenditures that are unnecessary within the OPPS, we believe that this method must be adopted in a nonbudget neutral manner. The impact associated with this proposal is further described in section XXV. of this proposed.

While we are refining our method to control for unnecessary increases in the volume of hospital outpatient department services, we continue to recognize the importance of not impeding development or beneficiary access to new innovations. We are soliciting public comments on other ways to exercise the Secretary's statutory authority under section 1833(t)(2)(F) of the Act:

● Are there other services for which CMS should develop a method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent rate for services provided at excepted off-campus PBDs? Of particular concern for us are the services within the imaging without contrast APCs (APCs 5521-5524). Imaging without contrast services are some the most costly and frequently provided services at excepted PBDs. We believe that there is a high likelihood that there has been unnecessary growth in this space and that a volume control method would be appropriate to apply here in the future. Would it be appropriate to apply this method to the Imaging Without Contrast APCs?

7. Request for Information: Expanding the Method to Control for Unnecessary Increases in the Volume of Covered OPD Services to On-Campus Clinic Visits

As discussed above, we finalized a method to control unnecessary increases in the volume of covered OPD services under section 1833(t)(2)(F) of the Act in the CY 2019 OPPS/ASC final rule with comment period. This method was to pay the PFS-equivalent payment rate for clinic visit services furnished by excepted off-campus PBDs, removing the payment incentive to furnish clinic visit services in these PBDs. In the above discussion, we note that the volume of covered OPD services is still unnecessarily high for other services, and we propose a similar policy for drug administration services furnished by excepted off-campus PBDs. For the reasons explained above, we believe that drug administration is the next most appropriate service to include in our method for volume at excepted off-campus PBDs. However, we recognize that the clinic visit is still the most utilized service across the OPPS and over 60 percent of clinic visits furnished under the OPPS are furnished on-campus. These on-campus clinic visits are not impacted by the existing volume control policy. Given the volume for clinic visits is so significant, we are requesting information on whether it would be appropriate to address unnecessary increases in the volume of covered OPD services by expanding the method to control unnecessary increases in volume to on-campus clinic visits. We are requesting information on the potential impact of a policy to pay the PFS-equivalent rate of 40 percent of the OPPS rate for clinic visit services furnished in on-campus OPDs. We intend to use the responses to this request to inform future rulemaking. Specifically, we are requesting feedback on to the following topics:

● Given clinic visits can safely be performed in other, lower cost settings, to what extend are clinic visits performed at OPDs “necessary” or “unnecessary”? Is it appropriate to include on-campus clinic visits when considering how to address unnecessary volume increases at OPDs? How would commenters suggest that CMS could identify which clinic visits may be necessary to be provided on-campus at an OPD? Are there such clinic visits?

● What would be the impact on providers of such a policy? Would any category of hospital be impacted more than others, for example, those in rural areas? Would such a policy result in lower on-campus OPD volume for clinic visits?

● What would be the impact on beneficiaries of such a policy? To what extent would removing any payment incentive from site-of-service determination provide beneficiaries with greater access at sites other than on-campus? To what extent would lower payments for on-campus clinic visits reduce beneficiary access at on-campus OPDs? To what extent would lower co-payments for on-campus clinic visits improve beneficiary access by reducing cost as a potential barrier to care?

● Are there additional costs associated with on-campus clinic visits? If there are additional costs associated with on-campus clinic visits, to what extent could these clinic visits be furnished in a lower-cost setting, for example an off-campus PBD or a physician's office?

● Rural SCHs are excluded from the off-campus clinic visit policy. Should rural SCHs be excluded from any similar on-campus policy? Should any other type of hospital be excluded? Are there any types of hospitals where clinic visits would be more likely to represent "necessary" volume despite being able to be furnished in a lower-cost setting?

8. Exemptions for Rural Sole Community Hospitals

We propose to expand our method to control unnecessary increases in the volume of covered OPD services by paying a PFS-equivalent payment rate for drug administration services furnished in excepted off-campus PBDs. As discussed earlier in this section, we believe that this policy is an appropriate method for controlling unnecessary volume of these drug administration services in excepted off-campus PBDs because beneficiaries can generally safely receive these same services in a lower cost setting but instead receive care in a higher cost setting due to payment incentives. In these cases, we explained that, similar to the clinic visit policy established in the CY 2019 OPPS/ASC final rule with comment period (83 FR 37142), to the extent similar services can be safely provided in more than one setting, we do not believe it is prudent for the

Medicare program to pay more for these services in one setting than another. We continue to believe the difference in payment for these services is a significant factor in the shift in services from the physician's office setting to the hospital outpatient department.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72047 through 72051), we stated that we believe that the volume of the clinic visit service in PBDs of rural Sole Community Hospitals (SCHs) has been driven by factors other than the payment differential for that service. In that rule, we finalized an exemption to our clinic visit volume control method and to instead pay the full OPPS payment rate, rather than the PFS-equivalent rate, when the clinic visit is furnished in excepted PBDs. In that rule, we explained that rural SCHs have historically received special payment treatment to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. Because we propose a site-neutral payment policy for drug administration services, we have additionally considered whether a similar policy for rural SCHs or other provider types would be appropriate.

a. Special Payment Treatment for Rural SCHs

Across the various Medicare payment systems, CMS has established a number of special payment provisions for rural providers to ensure access to high quality care for beneficiaries in rural areas. CMS administers five statutory hospital payment designations in which rural or isolated hospitals that meet specified eligibility criteria receive higher reimbursement for hospital services than they otherwise would receive under Medicare's standard payment methodologies. A rural hospital may qualify as a Critical Access Hospital, [126] Sole Community Hospital[127] (SCH), Rural Emergency Hospital[128] (REH), or Medicare Dependent Hospital[129]—each of which has different eligibility criteria and payment methodologies. With the exception of Critical Access Hospitals, rural hospitals may also qualify as Low Volume Hospitals[130] and Rural

[126] 42 CFR 485.601 through 485.647.
[127] 42 CFR 412.92
[128] 42 CFR 419.91
[129] 42 CFR 412.108.
[130] 42 CFR 412.101.

Referral Centers (RRCs),[131] which qualify these hospitals for additional payments or exemptions. Not all rural or isolated hospitals receive special payment treatment under the OPPS. For instance, CAHs are not paid under the OPPS and are reimbursed at 101 percent of reasonable costs for outpatient services. PBDs of CAHs are not subject to Section 603 of the Bipartisan Budget Act of 2015.

Rural SCHs are a hospital type that has received special payment treatment under the OPPS to account for their higher costs and the disproportionately harmful impact that payment reductions could have on them. In the CY 2006 OPPS final rule with comment period (70 FR 68556 through 68561), we finalized a payment increase for rural SCHs of 7.1 percent for all services and procedures paid under the OPPS, excluding separately payable drugs and biologicals, items paid at charges reduced to costs, and devices paid under the pass-through payment policy. This policy was adopted under section 1833(t)(13)(B) of the Act, which required the Secretary, by January 1, 2006, to provide for an appropriate adjustment under paragraph (t)(2)(E) to reflect the higher costs of hospitals in rural areas if the Secretary determined, pursuant to a study required by section 1833(t)(13)(A), that the costs to rural hospitals by APC exceeded those costs for hospitals in urban areas. Our analysis revealed that rural SCHs had significantly higher costs per unit than urban hospitals. We have continued to adjust payments for rural SCHs by 7.1 percent each year since 2006. As discussed in section II.E. of this proposed rule, for CY 2026 we propose to continue the current policy of utilizing a 7.1 percent payment adjustment for rural SCHs.

As noted above, in the CY 2023 OPPS/ASC final rule with comment period we finalized an exemption to our policy to pay the PFS-equivalent rate for the clinic visit service at excepted off-campus PBDs to control unnecessary increases in the volume of covered OPD services. Commenters were generally supportive of this proposal and noted that rural SCHs are typically the chief, if not sole, source of community outpatient care for rural residents and opined that this

[131] 42 CFR 412.96.

exemption would be vital to ensuring continued access to the care they need. Some commenters stated that the exemption should be extended to other types of hospitals, including urban SCHs. In that rule, we explained that our analysis did not find that urban SCHs had the additional resource costs for covered outpatient department services that rural SCHs have, and only finalized applying the clinic visit policy exemption to rural SCHs.

b. Utilization of Drug Administration Services in Off-Campus Provider-Based Departments of Rurals SCHs

Earlier in this section, where we propose the volume control method policy for drug administration services, we state that to the extent there are lower-cost sites of service available, beneficiaries and the physicians treating them should be able to choose the appropriate care setting and not be encouraged to receive or provide care in settings for which payment rates are higher solely for financial reasons. However, many rural providers, and rural SCHs in particular, are often the only source of care in their communities,[132] which means beneficiaries and providers are not choosing between a higher paying off-campus PBD of a hospital and a lower paying physicians' office setting. The closure of inpatient departments of hospitals and the shortage of primary care providers in rural areas likely further drives utilization to off-campus PBDs in areas where rural SCHs are located.

We have reviewed utilization data for drug administration services at rural SCHs and have not found strong evidence that drug administration services are being utilized at an unnecessary volume at excepted off-campus PBDs of rural SCHs. As with clinic visits, we do not believe that rural SCH site-of-service decisions for drug administration are being made solely based on payment rates. Rural areas often experience lower availability of health care professionals and hospitals than urban areas. [133] Hospital closures in rural communities are

[132] *https://www.shepscenter.unc.edu/wp-content/uploads/dlm_uploads/2017/11/SCHs_Differences_in_Community_Characteristics.pdf.*
[133] *https://www.gao.gov/assets/gao-21-93.pdf.*

associated with lower access to health care and worse health outcomes. [134] Access to outpatient services, particularly in rural areas, is vital to keeping beneficiaries healthy and out of the hospital because beneficiaries in rural settings face unique challenges that impact their health. In the CY 2023 OPPS/ASC final rule, we explained that we believe that exempting rural SCHs from the clinic visit policy would help to maintain access to care in rural areas by ensuring rural providers are paid for clinic visit services provided at off-campus PBDs at rates comparable to those paid at on-campus departments (87 FR 72049). We believe that a similar exemption would be warranted for the drug administration policy for similar reasons. Specifically, we are proposing to exempt rural SCHs from payment of the site-specific PFS-equivalent payment for drug administration services, as described by APC family 569X, when furnished at an off-campus PBD exempted from section 1833(t)(21) of the Act (departments that bill the modifier ‘‘PO’’ on claim lines). Under this proposed policy, a rural SCH would continue to bill services in APC family 569X with the "PO" modifier for CY 2026 and the payment rate for such services would continue be the full OPPS payment without the PFS relativity adjustment.

This exemption, should it be finalized, would result in higher payments to excepted off-campus PBDs of rural SCHs compared to if it were not finalized and rural SCHs were subject to the proposed volume control method. The proposed CY 2026 OPPS full payment rates for drug administration APCs 5691, 5692, 5693, and 5694 are $47.83, $74.57, $216.49, $341.52, respectively. The PFS-equivalent rates for these APCs, calculated by applying the 40 percent relativity adjuster to the OPPS payment rates for rural SCHs, would be $19.13, $29.83, $86.60, $136.61, respectively. By exempting rural SCHs, the Medicare payments for these services would remain at the OPPS level. We estimate that exempting rural SCHs from the method to control unnecessary volume of drug administration services reduces the savings from this provision by approximately $16 million for CY 2026. Per treatment, exempting rural SCHs from

[134] Mills CA, Yeager VA, Unroe KT, Holmes A, Blackburn J. The impact of rural general hospital closures on communities—A systematic review of the literature. *J Rural Health*. 2024;40:238–248. *https://doi.org/10.1111/jrh.12810.*

this policy results in beneficiary cost sharing remaining between $5.74 and $40.98 higher than it would be should we not finalize this exemption, depending on the service. We note, however, that these figures do not represent increases in costs to Medicare or the beneficiaries above the current policy, as our proposed exemption would maintain current payment rates at excepted off-campus PBDs of rural SCHs of 107.1 percent of the OPPS payment rate for these services. These figures are solely for the purpose of comparing potential savings should we implement a method to control unnecessary volume in drug administration services without such an exemption.

We invite comments on all aspects of the proposed exemption for rural SCHs from the method to control unnecessary volume of drug administration services. Specifically, we are requesting comments on whether such an exemption is appropriate for rural SCHs, what the impact on SCHs would be should we finalize the method without an exemption for rural SCHs, and whether we should consider any other hospital types for an exemption to either of the policies to control unnecessary volume of outpatient services at off-campus PBDs. Additionally, we are requesting comments on whether the current exemption for rural SCHs from the method to control unnecessary volume of clinic visit services remains appropriate.

B. Request for Information: Adjusting Payment under the OPPS for Services Predominately Performed in the Ambulatory Surgical Center or Physician Office Settings

In general, Medicare payments to hospital outpatient departments under the Outpatient Prospective Payment System (OPPS) are higher than payments made to ASCs under the ASC payment system or to physician offices under the Physician Fee Schedule (PFS) for the same services. As discussed in section X.A. of this proposed rule, CMS has taken steps to address payment disparities between hospital outpatient departments and the physician office setting. While we believe that our regulatory and the related legislative efforts to control for unnecessary utilization and promote site neutrality in Medicare payments for OPD services has had a positive impact, there is evidence of continued growth in the volume of OPD services driven by site-of-service payment differentials. Building on the CY 2019 OPPS/ASC final rule with comment

period policy for clinic visits, section X.A. of this proposed rule includes a proposal to pay off-campus PBDs otherwise excepted under section 603 of the BBA at the equivalent of the site-specific PFS rate for drug administration services.

While we have implemented site-neutral policies to pay for certain hospital outpatient clinic visits at a rate closer to that under the PFS and propose to expand this policy to drug administration services, we are seeking feedback for future rulemaking on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity and adjusting payments according. Specifically, we seek feedback on the following questions:

1. What items and services paid under the OPPS may have experienced unnecessary increases in volume? Should any policies that address those increases be more targeted to those services that have the most notable increases in volume indicative of shifting care from the ASC or physician office setting to the hospital OPD setting?

2. Should we limit OPPS payment for certain services to the payment made for that service under the ASC payment system or the PFS – depending on the setting where the service is performed most frequently? We note that the OPPS currently does not have a payment policy to limit OPPS payment rates to the rate under ASC payment system for procedures that are predominantly performed in an ASC. For example, while a simple cataract removal with insertion of an intraocular lens is a commonly-performed hospital outpatient surgical procedure, 82 percent of all such procedures that Medicare beneficiaries receive are performed in an ASC setting. In general, ASC payment rates are roughly 55 percent of the payment rate under the OPPS (86 FR 63485).

3. If we were to adjust payment based on the setting-specific volume of ambulatory services, should we pay the ASC payment amount if the service is predominantly performed in the ASC setting; and if the service is predominantly performed in the physician office setting,

should we continue to calculate the PFS-equivalent rate using a PFS relativity adjuster that we would periodically update?

4. In determining the setting in which a service is performed most frequently, should we use the most recent data available or should we use data that is 5 or even 10 years prior to the rate-setting year? For example, as noted above, the share of chemotherapy administration services billed under the OPPS increased from 35.2 percent to 51.9 percent between 2012 and 2021, so using only more recent data may lead to the conclusion that most of these services take place in the hospital OPD setting, even if that was not historically true. For services that experienced this type of migration, we believe it may be prudent to attempt to address the accumulation of past unnecessary increases in volume rather than allow that shift and the underlying financial incentive that caused it to remain permanent. Should we use solely Medicare FFS data for our analysis or should we explore and potentially incorporate Medicare Advantage data into our work (to the extent feasible and practicable)?

5. How could we account for the availability of OPDs, ASCs, and physician offices in a geographic area when determining the setting in which a service is most frequently performed? If there is a shortage of one of these settings of care in a geographic area, would it be appropriate to tie payment for a service to a setting of care that may not be readily available to a beneficiary?

6. What are the best ways to address different packaging and bundling policies across ambulatory payment systems? The PFS has less packaging of ancillary items than the OPPS and ASC payment system and tends to provide separate payment more frequently. Conversely, certain surgical procedures that have a global code in the PFS may not be packaged in the OPPS or ASC payment systems and the packaging policies of the OPPS and ASC payment system are not based on the period of time elapsed before or after the procedure or service. We could consider retaining the original payment rate that would apply absent any expanded site neutral policies, or we could apply a payment adjustment that approximates the impact of the packaging

policies in the payment system whose rate would apply to the item or service under the proposed ambulatory payment adjustment.

7. Should we exempt certain services from a larger site neutral policy if such services are delivered in relation to emergent care, trauma-related care, or other care where the hospital is the most appropriate setting regardless of whether the item or service is typically furnished in a different setting? We note that physicians are appropriately responsible for making site-of-service decisions based on their clinical expertise and may determine that the hospital OPD setting is most appropriate for their patient's circumstances regardless of the level of Medicare payment. We solicit comment on the best way to designate items and services as being emergent or trauma-related and whether to include other categories of care or circumstances where certain items or services would be most appropriately paid at the OPPS rate regardless of the typical setting of care where they are furnished.

8. Should we apply OPPS site neutral policies more broadly to all hospital OPDs or should we instead consider applying this payment adjustment to only certain hospital OPDs, such as excepted off-campus hospital PBDs?

9. Should we exempt certain types of hospitals from a larger site neutral policy, such as rural Sole Community Hospitals, Medicare Dependent Hospitals, or Rural Emergency Hospitals? Currently, rural Sole Community Hospitals are exempted from the clinic visit site neutrality policy and instead are paid the full OPPS rate when such visits are furnished in excepted off-campus PBDs of these hospitals.

10. What other methods may be warranted to control unnecessary increases in the volume of outpatient services besides changes to payment rates, including prior authorization or other utilization management policies?

11. What impact would the proposed ambulatory payment adjustment have on beneficiaries and the health care market, including the development of or beneficiary access to new health care innovations?

C. Virtual Direct Supervision of Cardiac Rehabilitation (CR), Intensive Cardiac Rehabilitation (ICR), Pulmonary Rehabilitation (PR) Services and Diagnostic Services Furnished to Hospital Outpatients

1. Background

a. Virtual Direct Supervision of CR, ICR and PR Services Furnished to Hospital Outpatients (42 CFR 410.27(a)(1)(iv)(B)(*1*))

In the interim final rule with comment period titled "Policy and Regulatory Provisions in Response to the COVID–19 Public Health Emergency," published on April 6, 2020 (the April 6th COVID–19 IFC) (85 FR 19230, 19246, 19286), we changed the regulation at 42 CFR 410.27(a)(1)(iv)(D)[135] to provide that, during a Public Health Emergency (PHE) as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for PR, CR, and ICR services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider. Specifically, the required direct physician supervision can be provided through virtual presence using audio/video real-time communications technology (excluding audio-only) subject to the clinical judgment of the supervising practitioner. We further amended § 410.27(a)(1)(iv)(B)[136] in the CY 2021 OPPS/ASC final rule with comment period to provide that this flexibility continues until the later of the end of the calendar year in which the PHE as defined in § 400.200 ends or December 31, 2021 (85 FR 86113 and 86299). In the CY 2021 OPPS/ASC final rule with comment period we also clarified that this flexibility excluded the presence of the supervising practitioner via audio-only telecommunications technology (85 FR 86113).

[135] In the CY 2023 OPPS/ASC final rule with comment period, we removed § 410.27(a)(1)(iv)(D) in its entirety and added its language regarding pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services and the virtual presence of a physician through audio/video real-time communications technology during the PHE to the newly designated § 410.27(a)(1)(iv)(B)(*1*) (87 FR 72024).

[136] Ibid.

In the CY 2023 OPPS/ASC final rule with comment period, we finalized a policy to extend the revised definition of direct supervision of CR, ICR, and PR services to include the presence of the supervising physician through two-way, audio/video telecommunications technology (excluding audio-only) until December 31, 2023 (87 FR 72019 and 72020).

In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to further revise § 410.27(a)(1)(iv)(B)(*1*) to continue to allow for the direct supervision requirement for CR, ICR, and PR services to include the virtual presence of the physician through audio-video real-time communications technology (excluding audio-only) through December 31, 2024 and to extend this policy to the nonphysician practitioners, that is NPs, PAs, and CNSs, who were eligible to supervise these services beginning in CY 2024 (88 FR 81863 through 81867).

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a policy to continue to allow for the direct supervision of CR, ICR, PR services to include the virtual presence of the physician (or other nonphysician practitioner) through audio-video real-time communications technology (excluding audio-only) through December 31, 2025 (89 FR 94280).

b. Virtual Direct Supervision of Diagnostic Services Furnished to Hospital Outpatients (42 CFR 410.28(e)(2)(iii))

In the April 6th, 2020 COVID–19 IFC, for consistency with the revisions made to 42 CFR 410.27(a)(1)(iv)(D)[137] described above and 410.32(b)(3)(ii) (revising the definition of direct supervision of diagnostic services furnished in a physician's office to include virtual supervision for the duration of the PHE), we changed the regulation at 42 CFR 410.28(e) to provide that, during a PHE as defined in 42 CFR 400.200, the presence of the physician for purposes of the direct supervision requirement for diagnostic services includes virtual presence through audio/video real-time communications technology when use of such technology is indicated to reduce exposure risks for the beneficiary or health care provider (85 FR 19245 and 19246).

To ensure consistency with additional revisions made to 42 CFR 410.27(a)(1)(iv)(B)(*1*) and 410.32(b)(3)(ii) extending the end date of the flexibility allowing for the virtual supervision of the services governed by those regulations, the CY 2023 OPPS final rule with comment period (87 FR 72024 through 72026), CY 2024 OPPS final rule with comment period (88 FR 81866 and 81867), and CY 2025 OPPS final rule with comment period (89 FR 94278 and 94280) subsequently extended the end date of the flexibility allowing for direct supervision to include the virtual supervision of outpatient diagnostic services through audio/video real-time communications technology (excluding audio-only) through December 31, 2025.

2. CY 2026 Virtual Direct Supervision of CR, ICR, PR Services and Diagnostic Services Furnished to Hospital Outpatients.

In the CY 2026 Physician Fee Schedule (PFS) proposed rule, published elsewhere in the **Federal Register**, we propose to revise the definition of direct supervision at § 410.26(a)(2) and § 410.32(b)(3)(ii) to make permanent the availability of virtual direct supervision of therapeutic and diagnostic services under the PFS, except for services that have a global surgery indicator of 010 or 090. This information can be found in the PFS PPRVU public use file (*https://www.cms.gov/medicare/payment/fee-schedules/physician/pfs-relative-value-files*). These global surgery indicators are defined in IOM Pub. 100-04, chapter 23, section 50.6 as 010 "Minor procedure with preoperative relative values on the day of the procedure and postoperative relative values during a 10-day postoperative period included in the fee schedule amount; evaluation and management services on the day of the procedure and during this 10-day postoperative period generally not payable" and 090 "Major surgery with a 1-day preoperative period and 90-day postoperative period included in the fee schedule payment amount" As explained in that rule, this proposal is made in response to overwhelming support and requests to extend this policy permanently for a wider set of services than the ones that were finalized in the CY 2025 PFS Final Rule and would build on the incremental approach of making the virtual supervision of certain services permanent which we began in the CY 2025 PFS rule. As noted in

the CY 2026 PFS proposed rule, this approach would recognize that virtual supervision has been available and widely utilized since the beginning of the PHE while excluding certain services to ensure quality of care and patient safety, and in particular, the ability of the supervising practitioner to intervene if complications arise, particularly in complex, high-risk instances where unexpected or adverse events may occur or for procedures that may be riskier or more intense since a patient's clinical status can quickly change. For the complete discussion of the proposed revisions to § 410.26(a)(2) and § 410.32(b)(3)(ii), we refer readers to the CY 2026 PFS proposed rule published elsewhere in the **Federal Register**.

In addition to desiring uniformity under the PFS and OPPS in how regulations are applied to similarly situated clinicians and providers, we agree that the approach proposed in the PFS proposed rule strikes the appropriate balance between recognizing that the virtual supervision of diagnostic services has been available and widely utilized since the beginning of the PHE and ensuring quality of care and patient safety. Consequently, we propose to revise § 410.27(a)(1)(iv)(B)(*1*) and § 410.28(e)(2)(iii) to make the availability of the direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only) permanent, except for diagnostic services that have a global surgery indicator of 010 or 090. We would like to note that permanently adopting a definition of direct supervision that allows "immediate availability" of the supervising practitioner using audio/video real-time communications technology (excluding audio-only), for CR, ICR, PR and diagnostic services described under § 410.28, except for diagnostic services that have a global surgery indicator of 010 or 090 does not mean that it is appropriate to allow virtual presence for every service for every Medicare beneficiary in every clinical scenario. As always, the physician or nonphysician practitioner should use his or her complex professional judgment to determine the appropriate supervision modality on a case-by-case basis.

D. Medical Review of Certain Inpatient Hospital Admissions Under Medicare Part A for CY 2026 and Subsequent Years

1. Background on the 2-Midnight Rule

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50944 through 50952), we clarified our policy regarding when an inpatient admission is considered reasonable and necessary for purposes of Medicare Part A payment. Under this policy, we established a benchmark providing that surgical procedures, diagnostic tests, and other treatments would be generally considered appropriate for payment under Medicare Part A when the physician expects the patient to require a stay that crosses at least 2 midnights and admits the patient as an inpatient based upon that expectation. Conversely, when a beneficiary enters a hospital for a surgical procedure not designated as an inpatient-only (IPO) procedure as described in 42 CFR 419.22(n), a diagnostic test, or any other treatment, and the physician expects to keep the beneficiary in the hospital for only a limited period of time that does not cross 2 midnights, the services would be generally inappropriate for payment under Medicare Part A, regardless of the hour that the beneficiary came to the hospital or whether the beneficiary used a bed. With respect to services designated under the OPPS as IPO procedures, we explained that because of the intrinsic risks, recovery impacts, or complexities associated with such services, these procedures would continue to be appropriate for payment under Medicare Part A regardless of the expected length of stay. We also indicated that there might be further "rare and unusual" exceptions to the application of the benchmark, which would be detailed in subregulatory guidance.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50944 through 50952), we also finalized the 2-midnight presumption, which is related to the 2-midnight benchmark but is a separate medical review policy. The 2-midnight benchmark represents guidance to reviewers to identify when an inpatient admission is generally reasonable and necessary for purposes of Medicare Part A payment, while the 2-midnight presumption relates to instructions to medical reviewers regarding the selection of claims for medical review. Specifically, under the 2-midnight presumption, inpatient hospital claims with lengths of stay greater than 2 midnights after the formal admission following the order are presumed to be appropriate for Medicare Part

A payment and are not the focus of medical review efforts, absent evidence of systematic gaming, abuse, or delays in the provision of care in an attempt to qualify for the 2-midnight presumption. We refer readers to the CY 2021 OPPS/ASC final rule with comment period for additional discussion about the distinction between the 2-midnight presumption and benchmark (85 FR 86113 through 86114).

In the CY 2016 OPPS/ASC final rule with comment period (80 FR 70538 through 70545), we revisited the previous rare and unusual exceptions policy and finalized a proposal to allow for case-by-case exceptions to the 2-midnight benchmark, whereby Medicare Part A payment may be made for inpatient admissions where the admitting physician does not expect the patient to require hospital care spanning 2 midnights, if the documentation in the medical record supports the physician's determination that the patient nonetheless requires inpatient hospital care. We stated that the following criteria would be relevant to determining whether an inpatient admission with an expected length of stay of less than 2 midnights is nonetheless appropriate for Medicare Part A payment:

- Complex medical factors such as history and comorbidities;
- The severity of signs and symptoms;
- Current medical needs; and
- The risk of an adverse event.

In other words, for purposes of Medicare payment, an inpatient admission is payable under Part A if the documentation in the medical record supports either the admitting physician’s reasonable expectation that the patient will require hospital care spanning at least 2 midnights, or the physician’s determination based on factors such as those identified previously that the patient nonetheless requires care on an inpatient basis. The exceptions for procedures on the IPO list and for “rare and unusual” circumstances designated by CMS as national exceptions were unchanged by the CY 2016 OPPS/ASC final rule with comment period.

As we stated in the CY 2016 OPPS/ASC final rule with comment period, the decision to formally admit a patient to the hospital is subject to medical review. Specifically, for inpatient admissions not related to a surgical procedure specified by Medicare as an IPO procedure under § 419.22(n) and for which there is not a national exception, payment of the claim under Medicare Part A is subject to the clinical judgment of the medical reviewer to determine whether the medical record supports a reasonable expectation of the need for hospital care crossing at least 2 midnights or otherwise supports a need for inpatient care. The medical reviewer's clinical judgment involves the synthesis of all submitted medical record information (for example, progress notes, diagnostic findings, medications, nursing notes, and other supporting documentation) to make a medical review determination on whether the clinical requirements in the relevant policy have been met. In addition, Medicare review contractors must abide by CMS' policies in making payment determinations. While Medicare review contractors may continue to use commercial screening tools to help evaluate the inpatient admission decision for purposes of payment under Medicare Part A, such tools are not binding on the hospital, CMS, or its review contractors. This type of information also may be appropriately considered by the physician as part of the complex medical judgment that guides his or her decision to keep a beneficiary in the hospital and formulation of the expected length of stay.

2. Current Policy for Medical Review of Inpatient Hospital Admissions for Procedures Removed from the Inpatient Only List

In the CY 2020 OPPS/ASC final rule with comment period, we finalized a policy to exempt procedures that have been removed from the IPO list from certain medical review activities to assess compliance with the 2-midnight rule within the 2 calendar years following their removal from the IPO list. We stated that these procedures would be exempted from site-of-service claim denials under Medicare Part A, eligibility for Beneficiary and Family-Centered Care Quality Improvement Organizations (BFCC–QIOs) referrals to Recovery Audit Contractors (RACs) for noncompliance with the 2-midnight rule, and RAC reviews for “patient

status" (that is, site-of-service). We explained that during this 2-year period, BFCC–QIOs would have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant would not be denied with respect to the site-of-service under Medicare Part A.

For CY 2021, in conjunction with our proposal to eliminate the IPO list, we modified our proposal to continue the 2-year exemption, and instead finalized a policy under which procedures removed from the IPO list on or after January 1, 2021, would be indefinitely exempted from the above described medical review activities. We explained that the elimination of the IPO list was a large-scale change that created brand new considerations for providers regarding site-of-service determinations. We believed a change of this significance required us to reevaluate our stance on the exemption period for procedures removed from the IPO list, resulting in our decision to finalize an indefinite exemption period rather than continuing the previous 2-year exemption period. We stated that this exemption would last with respect to each procedure removed from the IPO list until we had Medicare claims data indicating that the procedure was more commonly performed in the outpatient setting than the inpatient setting. Thus, for the exemption to end for a specific procedure, in a single calendar year we would need to have Medicare claims data indicating that the procedure was performed more than 50 percent of the time in the outpatient setting. We noted that the end of the exemption period for each procedure removed from the IPO list on or after January 1, 2021 would be announced via rulemaking.

Consequently, in the CY 2021 OPPS/ASC final rule with comment period, we amended 42 CFR 412.3(d)(2) to clarify when a procedure removed from the IPO list is exempt from the identified medical review activities. To account for the previous exemption policy that was in effect for CY 2020, we added § 412.3(d)(2)(i) which stated that for "those services and procedures removed between January 1 and December 31, 2020, this exemption will last for 2 years from the date of such removal." To implement the change to an indefinite exemption period that we finalized in CY 2021, we added § 412.3(d)(2)(ii) which stated that for "those

services and procedures removed on or after January 1, 2021, this exemption will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting."

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63736 through 63740), given our decision in that rule to halt the elimination of the IPO list, and the fact that we were accordingly no longer removing an unprecedented number of procedures from the list at one time, we proposed to return to the 2-year exemption period from the specified medical review activities for procedures removed from the IPO list. Under the circumstances of that final rule with comment period, we believed that a 2-year exemption period was adequate to enable providers to gain experience with the application of the 2-midnight rule to those procedures that have been newly removed from the IPO list. We also stated that we believed that a 2-year exemption from the medical review activities was also sufficient time for providers and BFCC-QIOs to understand the documentation necessary to support Part A payment for those patients for which the admitting physician determines that the procedures should be furnished in an inpatient setting.

In the preamble to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63739), we stated that we were amending § 412.3(d)(2) to clarify "that for all services and procedures removed after January 1, 2020, this exemption would last for 2 years from the date of such removal. This would include those services and procedures removed on or after January 1, 2021, for which this exemption would also be for 2 years from the date of such removal." Accordingly, § 412.3(d)(2)(i) was revised to read "for those services and procedures removed on or after January 1, 2020, the exemption in this paragraph (d)(2) will last for 2 years from the date of such removal." However, due to a drafting oversight, we failed to correspondingly remove § 412.3(d)(2)(ii): "For those services and procedures removed on or after January 1, 2021, the exemption in this paragraph (d)(2) will last until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting." As a result of this error, the

exemption period was not changed to two years as we intended and instead remained the indefinite exemption period that was finalized in the CY 2021 OPPS/ASC final rule with comment period.

3. Medical Review of Inpatient Hospital Admissions for Procedures Removed from the Inpatient Only List for CY 2026 and Subsequent Years

As stated earlier in this section, services on the IPO list are not subject to the 2-midnight rule for purposes of determining whether payment is appropriate under Medicare Part A. However, the 2-midnight rule is applicable once services have been removed from the IPO list. Outside of the exemption periods discussed above, services that have been removed from the IPO list are currently subject to initial medical reviews of claims for short-stay inpatient admissions conducted by BFCC-QIOs.

BFCC-QIOs may also refer providers to the RACs for further medical review due to exhibiting persistent noncompliance with Medicare payment policies, including, but not limited to:

- Having high denial rates;
- Consistently failing to adhere to the 2-midnight rule; or
- Failing to improve their performance after QIO educational intervention.

However, as finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures that have been removed from the IPO list on January 1, 2021 or later were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC-QIO referrals to RACs for noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service). We stated that this exemption would last for each procedure until we have Medicare claims data indicating that the procedure is more commonly performed in the outpatient setting than the inpatient setting.

As stated in section IX., we propose to eliminate the IPO list in CY 2026 with a transitional period of 3 years. For CY 2026, we propose to remove all musculoskeletal

procedures from the IPO list. Prior to the CY 2020 exemption for services removed from the IPO list, the elimination of the IPO list would have meant that procedures currently on the IPO list would be subject to the 2-midnight rule (both the 2-midnight benchmark and 2-midnight presumption) upon removal from the IPO list.

We believe that with the proposed elimination of the IPO list, the 2-midnight benchmark remains an important metric to help guide when Part A payment for inpatient hospital admissions is appropriate. As technology advances and more services may be safely performed in the hospital outpatient setting and paid under the OPPS, it is increasingly important for physicians to exercise their clinical judgment in determining the appropriate clinical setting for their patient to receive a procedure, whether that be as an inpatient or on an outpatient basis. Importantly, removal of a service from the IPO list has never meant that a beneficiary cannot receive the service as a hospital inpatient—as always, the physician should use his or her complex medical judgment to determine the appropriate setting on a case-by-case basis.

As finalized in the CY 2021 OPPS/ASC final rule with comment period, procedures removed from the IPO list after January 1, 2021, were indefinitely exempted from site-of-service claim denials under Medicare Part A, eligibility for BFCC-QIO referrals to RACs for noncompliance with the 2-midnight rule, and RAC reviews for "patient status" (that is, site-of-service). These procedures are not considered by the BFCC-QIOs in determining whether a provider exhibits persistent noncompliance with the 2-midnight rule for purposes of referral to the RAC nor will claims for these procedures be reviewed by RACs for "patient status." During the exemption period, BFCC-QIOs have the opportunity to review such claims in order to provide education for practitioners and providers regarding compliance with the 2-midnight rule, but claims identified as noncompliant are not denied with respect to the site-of-service under Medicare Part A. Again, information gathered by the BFCC-QIO when reviewing procedures as they are newly removed from the IPO list can be used for educational purposes but will not result in a claim denial during the exemption period.

When we previously finalized elimination of the IPO list in the CY 2021 OPPS/ASC final rule with comment period, we received numerous comments that suggested a longer exemption period would be appropriate, due to the unprecedented volume of procedures becoming subject to the 2-midnight rule. Therefore, we finalized an indefinite exemption period for procedures removed from the IPO list during the 3-year transition from the list to allow providers to become more familiar with how to comply with the 2-midnight rule and with the availability of payment under both the hospital inpatient and outpatient payment systems for procedures removed from the IPO list. Our current proposal to eliminate the IPO list over a 3-year period warrants similar considerations. Accordingly, we propose to maintain the indefinite exemption period under 42 CFR 412.3(d)(2)(ii) for procedures that are removed from the IPO list that is currently in effect. In the interest of clarity, we propose to delete § 412.3(d)(2)(i) and (ii) and revise § 412.3(d)(2) to read "An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2021 are exempt from certain medical review activities until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting." As indicated in the CY 2021 OPPS/ASC final rule with comment period, the determination of the Secretary that a service or procedure is more commonly performed in the outpatient setting is based on claims data that demonstrates that the service or procedure is being performed more than 50 percent of the time in the outpatient setting in a single calendar year (85 FR 86117 and 86119). We note that this would be an exemption from certain medical review activities, not an exception to the 2-midnight rule. Providers are still required to comply with the 2-midnight rule during the exemption period, and CMS or its contractors may still conduct

patient status medical review in cases in which there is evidence of systemic fraud or abuse occurring. Additionally, we note that other types of medical review, unrelated to patient status, would not be impacted by the proposed exemption. We will announce in subregulatory guidance when the exemption is ending for a particular service or procedure prior to the effective date of the end of the exemption for the particular service or procedure. We invite commenters to indicate whether and why they believe an indefinite exemption period, or another time period, would be most appropriate.

In summary, for CY 2026 and subsequent years, we propose to continue the indefinite exemption from site-of-service claim denials, initial medical review contractor[138] referrals to RACs, and RAC reviews for "patient status" (that is, site-of-service) finalized in the CY 2021 OPPS/ASC final rule with comment period for procedures that are removed from the IPO list in CY 2021 or later under the OPPS. We also propose to remove § 412.3(d)(2)(i) and (ii) and revise § 412.3(d)(2) to clarify that claims for services and procedures removed from the IPO list on or after January 1, 2021 are exempt from certain medical review activities until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting. Finally, we are seeking comment on whether other exemption periods may be warranted.

E. Coding and Payment for Category B IDE Devices and Studies

We propose to revise the section heading and paragraph (a) introductory text at § 419.47 to correct two errors that occurred when this regulation was revised in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94304 through 94307).

In the CY 2025 OPPS/ASC final rule with comment period, we finalized our proposal to codify our coding and payment policy for Category B Investigational Device Exemption (IDE) clinical trials with control arms through revisions to § 419.47. Specifically, we revised

[138] On May 22, 2025, CMS announced that responsibility for short-stay reviews will be transitioned from the BFCC-QIOs to the MACs, as of September 1, 2025. *https://www.cms.gov/data-research/monitoring-programs/medicare-fee-service-compliance-programs/medical-review-and-education/hospital-patient-status-reviews*.

§ 419.47's paragraph (a) introductory text to specify that our policy only applies to IDE studies with a placebo control arm and where a payment adjustment is necessary to preserve the scientific validity of such a study. However, in making these revisions, we inadvertently deleted existing regulatory text that was not changed in the CY 2025 OPPS/ASC final rule with comment period. Specifically, we inadvertently deleted § 419.47(a)(1) "The Medicare coverage IDE study criteria in § 405.212 of this chapter are met" and paragraph (2) "A new or revised code is necessary to preserve the scientific validity of such a study, such as by preventing the unblinding of the study." Therefore, effective January 1, 2026, we propose to amend the regulatory text at § 419.47(a) to restore these two inadvertently removed paragraphs.

Additionally, in the CY 2025 OPPS/ASC final rule with comment period, we decided not to finalize our CY 2025 OPPS/ASC proposal to extend our coding and payment policy to drugs and devices that are being studied in clinical trials under a Coverage with Evidence Development (CED) National Coverage Determination (NCD)[139] for which the trial includes a treatment and control arm for CY 2025. However, despite our intent to remove all proposed revisions relating to this extension of the policy in the final rule, we inadvertently revised the section heading at § 419.47 to state that the policy applied to "devices/drugs studies." Since we did not finalize the policy for CY 2025, we propose, effective January 1, 2026, to delete "and devices/drugs studies" from the section heading at § 419.47.

XI. Proposed CY 2026 OPPS Payment Status and Comment Indicators

A. Proposed CY 2026 OPPS Payment Status Indicator Definitions

Payment status indicators (SIs) that we assign to HCPCS codes and APCs serve an important role in determining payment for services under the OPPS. They indicate whether a service represented by a HCPCS code is payable under the OPPS or another payment system and whether particular OPPS policies apply to the code.

[139] *https://www.cms.gov/medicare/coverage/evidence* .

For CY 2026 and subsequent years, we propose to create a new status indicator "S1". We propose this new status indicator to indicate that the skin substitute product is paid separately from other procedure codes under the OPPS. We propose to assign all existing HCPCS codes describing skin substitute products to status indicator "S1" for CY 2026. This policy is further discussed in section V.B.10. of this proposed rule. The proposed definition and payment status of proposed status indicator "S1" can be found in Table 72.

TABLE 72: Proposed Definition and Payment Status of Proposed Status Indicator S1

Proposed Status Indicator	Proposed Descriptor	Proposed OPPS Payment Status
S1	Skin substitute product paid separately	Paid under OPPS; separate APC payment. Subject to payment based on FDA regulatory pathway.

We are not proposing to make any additional changes to the existing definitions of status indicators that were listed in Addendum D1 to the CY 2025 OPPS/ASC final rule with comment period, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices.*

The complete list of proposed CY 2026 payment status indicators and their definitions is displayed in Addendum D1 to this proposed rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. The proposed CY 2026 payment status indicator assignments for APCs and HCPCS codes are shown in Addendum A and Addendum B, respectively, to this proposed rule, which are available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. We solicit public comments on the proposed definitions of the OPPS payment status indicators for CY 2026.

B. Proposed CY 2026 Comment Indicator Definitions

We propose to use four comment indicators for the CY 2026 OPPS. These comment indicators, "CH," "NC," "NI," and "NP," are in effect for CY 2025; and we propose to continue their use in CY 2026. The proposed CY 2026 OPPS comment indicators are as follows:

- "CH"—Active HCPCS code in current and next calendar year, status indicator and/or APC assignment has changed; or active HCPCS code that will be discontinued at the end of the current calendar year.
- "NC"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year for which we requested comments in the proposed rule; final APC assignment; comments will not be accepted on the final APC assignment for the new code.
- "NI"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, interim APC assignment; comments will be accepted on the interim APC assignment for the new code.
- "NP"—New code for the next calendar year or existing code with substantial revision to its code descriptor in the next calendar year, as compared to current calendar year, proposed APC assignment; comments will be accepted on the proposed APC assignment for the new code.

The definitions of the proposed OPPS comment indicators for CY 2026 are listed in Addendum D2 to this proposed rule, which is available on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*. We solicit public comments on our proposed definitions of the OPPS comment indicators for CY 2026.

XII. MedPAC Recommendations

The Medicare Payment Advisory Commission (MedPAC) was established under section 1805 of the Act in large part to advise the U.S. Congress on issues affecting the Medicare program. As required under the statute, MedPAC submits reports to the Congress no later than

March and June of each year that present its Medicare payment policy recommendations. The March report typically provides discussion of Medicare payment policy across different payment systems and the June report typically discusses selected Medicare issues. We are including this section to make interested parties aware of certain MedPAC recommendations for the OPPS and ASC payment systems as discussed in its March 2025 report.

A. OPPS Payment Rates Update

The March 2025 MedPAC "Report to the Congress: Medicare Payment Policy," recommended that Congress update Medicare OPPS payment rates by the amount specified in current law plus one percent. We refer readers to the March 2025 report for a complete discussion of this recommendation.[140] We appreciate MedPAC's recommendation and, as discussed further in section II.B. of this proposed rule, we propose to increase the OPPS payment rates by the amount specified in current law.

B. Medicare Safety Net Index

In the March 2025 MedPAC "Report to the Congress: Medicare Payment Policy," MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1 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 the Congress transitional approaches for an MSNI policy. The FY 2026 IPPS/LTCH proposed rule provides additional information regarding statutory requirements for disproportionate share hospital and uncompensated care payments. We look forward to working with Congress on these matters.

[140] Medicare Payment Advisory Committee. March 2025 Report to the Congress. Chapter 3: Hospital inpatient and outpatient services, pp.61-94. Available at: *https://www.medpac.gov*.

XIII. Proposed Updates to the Ambulatory Surgical Center (ASC) Payment System

A. Background, Legislative History, Statutory Authority, and Prior Rulemaking for the ASC Payment System

For a detailed discussion of the legislative history and statutory authority related to payments to ASCs under Medicare, we refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74377 through 74378) and the June 12, 1998 proposed rule (63 FR 32291 through 32292). For a discussion of prior rulemaking on the ASC payment system, we refer readers to the CYs 2012 to 2025 OPPS/ASC final rules with comment period (76 FR 74378 through 74379; 77 FR 68434 through 68467; 78 FR 75064 through 75090; 79 FR 66915 through 66940; 80 FR 70474 through 70502; 81 FR 79732 through 79753; 82 FR 59401 through 59424; 83 FR 59028 through 59080; 84 FR 61370 through 61410; 85 FR 86121 through 86179; 86 FR 63761 through 63815; 87 FR 72054 through 72096; 88 FR 81900 through 81961; and 89 FR 94309 through 94367).

B. Proposed ASC Treatment of New and Revised Codes

1. Background on Process for New and Revised HCPCS Codes

We update the lists and payment rates for covered surgical procedures and covered ancillary services in ASCs in conjunction with the annual proposed and final rulemaking process to update the OPPS and the ASC payment systems (§ 416.173; 72 FR 42535). We base ASC payment and policies for most covered surgical procedures, drugs, biologicals, and certain other covered ancillary services on the OPPS payment policies and we use quarterly change requests (CRs) to update services paid for under the OPPS. We also provide quarterly update CRs for ASC covered surgical procedures and covered ancillary services throughout the year (January, April, July, and October). We release new and revised Level II HCPCS codes and recognize the release of new and revised CPT codes by the American Medical Association (AMA) and make these codes effective (that is, the codes are recognized on Medicare claims) via these ASC quarterly update CRs. We recognize the release of new and revised Category III CPT codes in

the July and January CRs. These updates implement newly created and revised Level II HCPCS and Category III CPT codes for ASC payments and update the payment rates for separately paid drugs and biologicals based on the most recently submitted ASP data. New and revised Category I CPT codes, except vaccine codes, are released only once a year, and are implemented only through the January quarterly CR update. New and revised Category I CPT vaccine codes are released twice a year and are implemented through the January and July quarterly CR updates. We refer readers to Table 41 in the CY 2012 OPPS/ASC proposed rule for an example of how this process is used to update HCPCS and CPT codes, which we finalized in the CY 2012 OPPS/ASC final rule with comment period (76 FR 42291; 76 FR 74380 through 74384).

In our annual updates to the ASC list of covered surgical procedures and covered ancillary services, we undertake a review of excluded surgical procedures, new codes, and codes with revised descriptors, to identify any that we believe meet the criteria for designation as ASC covered surgical procedures or covered ancillary services. Updating the lists of ASC covered surgical procedures and covered ancillary services, as well as their payment rates, in association with the annual OPPS rulemaking cycle, is particularly important because the OPPS relative payment weights and, in some cases, payment rates, are used as the basis for the payment of many covered surgical procedures and covered ancillary services under the revised ASC payment system. This joint update process ensures that the ASC updates occur in a regular, predictable, and timely manner.

Payment for ASC procedures, services, and items are generally based on medical billing codes, specifically, HCPCS codes, that are reported on ASC claims. The HCPCS is divided into two principal subsystems, referred to as Level I and Level II. Level I is comprised of CPT (Current Procedural Terminology) codes, a numeric and alphanumeric coding system maintained by the AMA, and includes Category I, II, and III CPT codes. Level II of the HCPCS, which is maintained by CMS, is a standardized coding system that is used primarily to identify products, supplies, and services not included in the CPT codes. Together, Level I and II HCPCS codes are

used to report procedures, services, items, and supplies under the ASC payment system. Specifically, we recognize the following codes on ASC claims:

● Category I CPT codes, which describe surgical procedures, diagnostic and therapeutic services, and vaccine codes;

● Category III CPT codes, which describe new and emerging technologies, services, and procedures; and

● Level II HCPCS codes (also known as alpha-numeric codes), which are used primarily to identify drugs, devices, supplies, temporary procedures, and services not described by CPT codes.

We finalized a policy in the August 2, 2007 final rule (72 FR 42533 through 42535) to evaluate each year all new and revised Category I and Category III CPT codes and Level II HCPCS codes that describe surgical procedures, and to make preliminary determinations during the annual OPPS/ASC rulemaking process regarding whether or not they meet the criteria for payment in the ASC setting as covered surgical procedures and, if so, whether or not they are office-based procedures. In addition, we identify new and revised codes as ASC covered ancillary services based upon the final payment policies of the revised ASC payment system. In prior rulemakings, we refer to this process as recognizing new codes. However, this process has always involved the recognition of new and revised codes. We consider revised codes to be new when they have substantial revision to their code descriptors that necessitate a change in the current ASC payment indicator. To clarify, we refer to these codes as new and revised in this CY 2026 OPPS/ASC proposed rule.

We have separated our discussion below based on when the codes are released and whether we propose to solicit public comments in the proposed rule (and respond to those comments in the CY 2026 OPPS/ASC final rule with comment period) or whether we will be soliciting public comments in the CY 2026 OPPS/ASC final rule with comment period (and responding to those comments in the CY 2027 OPPS/ASC final rule with comment period).

2. April 2025 HCPCS Codes Proposed Rule Comment Solicitation

For the April 2025 update, there were no new CPT codes; however, there were several new Level II HCPCS codes. In the April 2025 ASC quarterly update (Transmittal 13152, dated April 10, 2025, CR 14017), we added several new Level II HCPCS codes to the list of covered ancillary services. Table 73 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2025) of this proposed rule lists the new Level II HCPCS codes that were implemented April 1, 2025. The proposed comment indicators, payment indicators and payment rates, where applicable, for these April codes can be found in Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective April 1, 2025 are assigned to comment indicator "NP" in Addendum BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that the following ASC addenda and OPPS Addendum O are available via the internet on the CMS website.

● *ASC Addendum AA:* Proposed ASC Covered Surgical Procedures for CY 2026 (Including Surgical Procedures for Which Payment is Packaged),

● *ASC Addendum BB:* Proposed ASC Covered Ancillary Services Integral to Covered Surgical Procedures for CY 2026 (Including Ancillary Services for Which Payment is Packaged),

● *ASC Addendum DD1:* Proposed ASC Payment Indicators (PI) for CY 2026,

● *ASC Addendum DD2:* Proposed ASC Comment Indicators (CI) for CY 2026,

● *ASC Addendum EE:* Proposed Surgical Procedures to be Excluded from Payment in ASC for CY 2026, and

● *ASC Addendum FF:* Proposed ASC Device Offset Percentages for CY 2026,

● *Addendum O:* Long Descriptors for New Category I CPT Codes, Category III CPT Codes, C-codes, and G-Codes Effective January 1, 2026.

We invite public comments on the proposed payment indicators for the new HCPCS codes that were recognized as ASC covered ancillary services in April 2025 through the quarterly update CRs, as listed in Table 73 (New Level II HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective April 1, 2025) of this proposed rule. We propose to finalize their payment indicators in the CY 2026 OPPS/ASC final rule with comment period.

TABLE 73: NEW LEVEL II HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND ANCILLARY SERVICES EFFECTIVE APRIL 1, 2025

CY 2025 HCPCS Code	CY 2025 Long Descriptor
A2030	Miro3d fibers, per milligram
A2031	Mirodry wound matrix, per square centimeter
A2032	Myriad matrix, per square centimeter
A2033	Myriad morcells, 4 milligrams
A2034	Foundation drs solo, per square centimeter
A2035	Corplex p or theracor p or allacor p, per milligram
C8004	Simulation angiogram with use of a pressure-generating catheter (e.g., one-way valve, intermittently occluding), inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the angiogram, for subsequent therapeutic radioembolization of tumors
C9302	Injection, zanidatamab-hrii, 2 mg
C9303	Injection, zolbetuximab-clzb, 1mg
C9304	Injection, marstacimab-hncq, subcutaneous, 0.5 mg
J0281	Injection, aminocaproic acid, 1 gram
J1072	Injection, testosterone cypionate (azmiro), 1 mg
J1271	Injection, doxycycline hyclate, 1 mg
J1299	Injection, eculizumab, 2 mg
J1308	Injection, famotidine, 0.25 mg
J1808	Injection, folic acid, 0.1 mg
J1938	Injection, furosemide, 1 mg
J2351	Injection, ocrelizumab, 1 mg and hyaluronidase-ocsq
J2428	Injection, paliperidone palmitate extended release (erzofri), 1 mg
J2804	Injection, rifampin, 1 mg
J2865	Injection, sulfamethoxazole 5 mg and trimethoprim 1 mg
J7521	Tacrolimus, granules, oral suspension, 0.1 mg
J9024	Injection, atezolizumab, 5 mg and hyaluronidase-tqjs
J9054	Injection, bortezomib (boruzu), 0.1 mg
Q4354	Palingen dual-layer membrane, per square centimeter
Q4355	Abiomend xplus membrane and abiomend xplus hydromembrane, per square centimeter
Q4356	Abiomend membrane and abiomend hydromembrane, per square centimeter
Q4357	Xwrap plus, per square centimeter
Q4358	Xwrap dual, per square centimeter
Q4359	Choriply, per square centimeter
Q4360	Amchoplast fd, per square centimeter
Q4361	Epixpress, per square centimeter

CY 2025 HCPCS Code	CY 2025 Long Descriptor
Q4362	Cygnus disk, per square centimeter
Q4363	Amnio burgeon membrane and hydromembrane, per square centimeter
Q4364	Amnio burgeon xplus membrane and xplus hydromembrane, per square centimeter
Q4365	Amnio burgeon dual-layer membrane, per square centimeter
Q4366	Dual layer amnio burgeon x-membrane, per square centimeter
Q4367	Amniocore sl, per square centimeter
Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg

3. July 2025 HCPCS Codes Proposed Rule Comment Solicitation

In the July 2025 ASC quarterly update (Transmittal 13259, Change Request 14101,June 6, 2025), we added several separately payable CPT and Level II HCPCS codes to the list of covered surgical procedures and covered ancillary services. Table 74(New HCPCS Codes for ASC Covered Surgical Procedures and Ancillary Services Effective July 1, 2025) of this proposed rule, lists the new HCPCS codes that are effective July 1, 2025. The proposed comment indicators, payment indicators, and payment rates for the codes can be found in Addendum AA and Addendum BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule. These new codes that are effective July 1, 2025, are assigned to comment indicator “NP” in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim APC assignment and that comments will be accepted on their interim APC assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.,

TABLE 74: NEW HCPCS CODES FOR ASC COVERED SURGICAL PROCEDURES AND COVERED ANCILLARY SERVICES EFFECTIVE JULY 1, 2025

CY 2025 HCPCS Code	CY 2025 Long Descriptor
0950T	Ablation of benign prostate tissue, transrectal, with high intensity–focused ultrasound (HIFU), including ultrasound guidance
0956T	Partial craniectomy, channel creation, and tunneling of electrode for sub-scalp implantation of an electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
0957T	Revision of sub-scalp implanted electrode array, receiver, and telemetry unit for electrode, when required, including imaging guidance

CY 2025 HCPCS Code	CY 2025 Long Descriptor
0958T	Removal of sub-scalp implanted electrode array, receiver, and telemetry unit for continuous bilateral electroencephalography monitoring system, including imaging guidance
0959T	Removal or replacement of magnet from coil assembly that is connected to continuous bilateral electroencephalography monitoring system, including imaging guidance
0960T	Replacement of sub-scalp implanted electrode array, receiver, and telemetry unit with tunneling of electrode for continuous bilateral electroencephalography monitoring system, including imaging guidance
0961T	Shortwave infrared radiation imaging, surgical pathology specimen, to assist gross examination for lymph node localization in fibroadipose tissue, per specimen (List separately in addition to code for primary procedure)
0963T	Anoscopy with directed submucosal injection of bulking agent into anal canal
0964T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; single arch, without mandibular advancement mechanism
0965T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, non-fixed hinge mechanism
0966T	Impression and custom preparation of jaw expansion oral prosthesis for obstructive sleep apnea, including initial adjustment; dual arch, with additional mandibular advancement, fixed hinge mechanism
0967T	Transanal insertion of endoluminal temporary colorectal anastomosis protection device, including vacuum anchoring component and flexible sheath connected to external vacuum source and monitoring system
0970T	Ablation, benign breast tumor (eg, fibroadenoma), percutaneous, laser, including imaging guidance when performed, each tumor
0971T	Ablation, malignant breast tumor(s), percutaneous, laser, including imaging guidance when performed, unilateral
0973T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs; first 100 sq cm
0974T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, trunk, arms, legs; each additional 100 sq cm (List separately in addition to code for primary procedure)
0975T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck, hands, feet, and/or multiple digits; first 100 sq cm
0976T	Selective enzymatic debridement, partial-thickness and/or full-thickness burn eschar, requiring anesthesia (ie, general anesthesia, moderate sedation), including patient monitoring, scalp, neck, hands, feet, and/or multiple digits;each additional 100 sq cm (List separately in addition to code for primary procedure)
0981T	Transcatheter implantation of wireless inferior vena cava sensor for long-term hemodynamic monitoring, including deployment of the sensor, radiological supervision and interpretation, right heart catheterization, and inferior vena cava venography, when performed
0984T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)
0985T	Intravascular imaging of extracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report;each additional vessel (List separately in addition to code for primary procedure)
0986T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report; initial vessel (List separately in addition to code for primary procedure)
0987T	Intravascular imaging of intracranial cerebral vessels using optical coherence tomography (OCT) during diagnostic evaluation and/or therapeutic intervention, including all associated radiological supervision, interpretation, and report;each additional vessel (List separately in addition to code for primary procedure)

CY 2025 HCPCS Code	CY 2025 Long Descriptor
C9174	Injection, datopotamab deruxtecan-dlnk, 1 mg
C9175	Injection, treosulfan, 50 mg
J0165	Injection, epinephrine, not otherwise specified, 0.1 mg
J0166	Injection, epinephrine (bpi), not therapeutically equivalent to j0165, 0.1 mg
J0167	Injection, epinephrine (hospira), not therapeutically equivalent to j0165, 0.1 mg
J0168	Injection, epinephrine (international medication systems), not therapeutically equivalent to j0165, 0.1 mg
J0169	Injection, epinephrine (adrenalin), not therapeutically equivalent to j0165, 0.1 mg
J0616	Injection, metoprolol tartrate, 1 mg
J0618	Injection, calcium chloride, 2 mg
J1163	Injection, diltiazem hydrochloride, 0.5 mg
J1326	Injection, zolbetuximab-clzb, 2 mg
J2312	Injection, naloxone hydrochloride, not otherwise specified, 0.01 mg
J2313	Injection, naloxone hydrochloride (zimhi), 0.01 mg
J3373	Injection, vancomycin hydrochloride, 10 mg
J3374	Injection, vancomycin hydrochloride (mylan) not therapeutically equivalent to j3373, 10 mg
J3375	Injection, vancomycin hydrochloride (xellia), not therapeutically equivalent to j3373, 10 mg
J7356	Injection, foscarbidopa 0.25 mg/foslevodopa 5 mg
J7172	Injection, marstacimab-hncq, 0.5 mg
J9174	Injection, docetaxel (beizray), 1 mg
J9220	Injection, indigotindisulfonate sodium, 1 mg
J9276	Injection, zanidatamab-hrii, 2 mg
J9289	Injection, nivolumab, 2 mg and hyaluronidase-nvhy
J9342	Injection, thiotepa, not otherwise specified, 1 mg
J9382	Injection, zenocutuzumab-zbco, 1 mg
Q4368	Amchothick, per square centimeter
Q4369	Amnioplast 3, per square centimeter
Q4370	Aeroguard, per square centimeter
Q4371	Neoguard, per square centimeter
Q4372	Amchoplast excel, per square centimeter
Q4373	Membrane wrap lite, per square centimeter
Q4375	Duograft ac, per square centimeter
Q4376	Duograft aa, per square centimeter
Q4377	Trigraft ft, per square centimeter
Q4378	Renew ft matrix, per square centimeter
Q4379	Amniodefend ft matrix, per square centimeter
Q4380	Advograft one, per square centimeter
Q4382	Advograft dual, per square centimeter
Q5099	Injection, ustekinumab-stba (steqeyma), biosimilar, 1 mg
Q5100	Injection, ustekinumab-kfce (yesintek), biosimilar, 1 mg

We invite public comments on the proposed payment indicators for the new HCPCS codes newly recognized as ASC covered surgical procedures and covered ancillary services effective April 1, 2025 and July 1, 2025, through the quarterly update CRs, as listed in Tables 73 and 74. We propose to finalize the payment indicators in the CY 2026 OPPS/ASC final rule with comment period.

4. October 2025 HCPCS Codes Final Rule Comment Solicitation

For CY 2026, consistent with our established policy, we propose that the Level II HCPCS codes that will be effective October 1, 2025, would be "NI" in Addendum BB to the CY 2026 OPPS/ASC final rule with comment period to indicate that we have assigned the codes an interim ASC payment status for CY 2025. We will invite public comments in the CY 2026 OPPS/ASC final rule with comment period on the interim payment indicators, which would then be finalized in the CY 2027 OPPS/ASC final rule with comment period.

5. January 2026 HCPCS Codes

a. Level II HCPCS Codes Final Rule Comment Solicitation

As has been our practice in the past, we incorporate those new Level II HCPCS codes that are effective January 1 in the final rule with comment period, thereby updating the ASC payment system for the calendar year. We note that unlike the CPT codes that are effective January 1 and are included in the OPPS/ASC proposed rules, and except for the G-codes listed in Addendum O to this proposed rule, most Level II HCPCS codes are not released until sometime around November to be effective January 1. Because these codes are not available until November, we are unable to include them in the OPPS/ASC proposed rules. Therefore, these Level II HCPCS codes will be released to the public through the CY 2026 OPPS/ASC final rule with comment period, January 2026 ASC Update CR, and the CMS HCPCS website.

In addition, for CY 2026, we propose to continue our established policy of assigning comment indicator "NI" in Addendum AA and Addendum BB to the OPPS/ASC final rule with comment period to the new Level II HCPCS codes that will be effective January 1, 2026, to indicate that we are assigning them an interim payment indicator, which is subject to public comment. We will be inviting public comments in the CY 2026 OPPS/ASC final rule with comment period on the payment indicator assignments, which would then be finalized in the CY 2027 OPPS/ASC final rule with comment period.

b. CPT Codes Proposed Rule Comment Solicitation

For the CY 2026 ASC update, we received the CPT codes that will be effective January 1, 2026, from the AMA in time to be included in this proposed rule. The new, revised, and deleted CPT codes can be found in ASC Addendum AA and Addendum BB to this proposed rule (which are available via the internet on the CMS website). We note that the new and revised CPT codes are assigned to comment indicator ‘‘NP’’ in ASC Addendum AA and Addendum BB of this proposed rule to indicate that the code is new for the next calendar year, or the code is an existing code with substantial revision to its code descriptor in the next calendar year as compared to the current calendar year with a proposed payment indicator assignment. We will accept comments and finalize the payment indicators in the CY 2026 OPPS/ASC final rule with comment period. Further, we remind readers that the CPT code descriptors that appeared in Addendum AA and Addendum BB are short descriptors and do not describe the complete procedure, service, or item described by the CPT code. Therefore, we included the 5-digit placeholder codes and their long descriptors for the new CY 2026 CPT codes in Addendum O to this proposed rule (which is available via the internet on the CMS website) so that the public can comment on our proposed payment indicator assignments. The 5-digit placeholder codes can be found in Addendum O to this proposed rule, specifically under the column labeled “CY 2026 OPPS/ASC Proposed Rule 5-Digit Placeholder Code.” We intend to include the final CPT code numbers in the CY 2026 OPPS/ASC final rule with comment period.

In summary, we solicit public comments on the proposed CY 2026 payment indicators for the new Category I and III CPT codes that will be effective January 1, 2026. Because these codes are listed in Addendum AA and Addendum BB with short descriptors only, we are listing them again in Addendum O with the long descriptors. We also propose to finalize the payment indicator for these codes (with their final CPT code numbers) in the CY 2026 OPPS/ASC final rule with comment period. The proposed payment indicators and comment indicators for these codes can be found in Addendum AA and BB to this proposed rule. The list of ASC payment indicators and corresponding definitions can be found in Addendum DD1 to this proposed rule.

The new CPT codes that will be effective January 1, 2026, are assigned to comment indicator "NP" in Addendum AA and BB to this proposed rule to indicate that the codes are assigned to an interim payment indicator and that comments will be accepted on their interim payment ASC payment assignments. The list of comment indicators and definitions used under the ASC payment system can be found in Addendum DD2 to this proposed rule. We note that ASC Addenda AA, BB, DD1, and DD2 are available via the internet on the CMS website.

Finally, in Table 75, we summarize our process for updating codes through our ASC quarterly update CRs, seeking public comments, and finalizing the treatment of these new codes under the ASC payment system.

TABLE 75: COMMENT AND FINALIZATION TIMEFRAMES FOR NEW AND REVISED ASC-RELATED HCPCS CODES

ASC Quarterly Update CR	Type of Code	Effective Date	Comments Sought	When Finalized
April 2025	HCPCS (CPT and Level II codes)	April 1, 2025	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
July 2025	HCPCS (CPT and Level II codes)	July 1, 2025	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
October 2025	HCPCS (CPT and Level II codes)	October 1, 2025	CY 2026 OPPS/ASC final rule with comment period	CY 2027 OPPS/ASC final rule with comment period
January 2026	CPT Codes	January 1, 2026	CY 2026 OPPS/ASC proposed rule	CY 2026 OPPS/ASC final rule with comment period
	Level II HCPCS Codes	January 1, 2026	CY 2026 OPPS/ASC final rule with comment period	CY 2027 OPPS/ASC final rule with comment period

6. Proposed ASC Payment and Comment Indicators

a. Background

In addition to the payment indicators that we introduced in the August 2, 2007 ASC final rule with comment period, we created final comment indicators for the ASC payment system in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66855). We created Addendum

DD1 to define ASC payment indicators that we use in Addenda AA and BB to provide payment information regarding covered surgical procedures and covered ancillary services, respectively, under the revised ASC payment system. The ASC payment indicators in Addendum DD1 are intended to capture policy-relevant characteristics of HCPCS codes that may receive packaged or separate payment in ASCs, such as whether they were on the ASC CPL prior to CY 2008; payment designation, such as device-intensive or office-based, and the corresponding ASC payment methodology; and their classification as separately payable ancillary services, including radiology services, brachytherapy sources, OPPS pass-through devices, corneal tissue acquisition services, drugs or biologicals, NTIOLs, or qualifying non-opioid devices.

We also created Addendum DD2 that lists the ASC comment indicators. The ASC comment indicators included in Addenda AA and BB to the proposed rules and final rules with comment period serve to identify, for the revised ASC payment system, the status of a specific HCPCS code and its payment indicator with respect to the timeframe when comments will be accepted. The comment indicator "NI" is used in the OPPS/ASC final rule with comment period to indicate new codes for the next calendar year for which the interim payment indicator assigned is subject to comment. The comment indicator "NI" also is assigned to existing codes with substantial revisions to their descriptors such that we consider them to be describing new services, and the interim payment indicator assigned is subject to comment, as discussed in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60622).

The comment indicator "NP" is used in the OPPS/ASC proposed rule to indicate new codes for the next calendar year for which the proposed payment indicator assigned is subject to comment. The comment indicator "NP" also is assigned to existing codes with substantial revisions to their descriptors, such that we consider them to be describing new services, and the proposed payment indicator assigned is subject to comment, as discussed in the CY 2016 OPPS/ASC final rule with comment period (80 FR 70497).

The “CH” comment indicator is used in Addenda AA and BB to the proposed rule (these addenda are available via the internet on the CMS website) to indicate that the payment indicator assignment has changed for an active HCPCS code in the current year and the next calendar year, for example, if an active HCPCS code is newly recognized as payable in ASCs or an active HCPCS code is discontinued at the end of the current calendar year. The “CH” comment indicators that are published in the final rule are provided to alert readers that a change has been made from one calendar year to the next, but do not indicate that the change is subject to comment.

In the CY 2021 OPPS/ASC final rule with comment period, we finalized the addition of ASC payment indicator ‘‘K5’’ – Items, Codes, and Services for which pricing information and claims data are not available. No payment made – to ASC Addendum DD1 (which is available via the Internet on the CMS website) to indicate those services and procedures that CMS anticipates will become payable when claims data or payment information becomes available.

In CY 2024 OPPS/ASC final rule with comment period, we finalized the addition of two ASC payment indicators, “D1”— “Ancillary dental service/item; no separate payment made” and “D2” – “Non office-based dental procedure added in CY 2024 or later”, for new dental codes for CY 2024 and subsequent calendar years to indicate potentially payable dental services and procedures in the ASC setting (88 FR 81907). We added these two codes to Addendum DD1 (which is available via the Internet on the CMS website).

In CY 2025 OPPS/ASC final rule with comment period, we finalized the modification of the descriptor of ASC payment indicator “L6” to “Special payment; New Technology Intraocular Lens (NTIOL) or qualifying non-opioid devices”, to account for non-opioid devices paid for under the ASC payment system pursuant to section 4135 of the CAA, 2023 (89 FR 94317). We added this code to Addendum DD1 (which is available via the internet on the CMS website).

b. Proposed ASC Payment and Comment Indicators for CY 2026

For CY 2026, we propose new and revised Category I and III CPT codes as well as new and revised Level II HCPCS codes. Proposed Category I and III CPT codes that are new and revised for CY 2026 and any new and existing Level II HCPCS codes with substantial revisions to the code descriptors for CY 2026, compared to the CY 2025 descriptors, are included in ASC Addenda AA and BB to this proposed rule and labeled with comment indicator "NP" to indicate that these CPT and Level II HCPCS codes are open for comment as part of the CY 2026 OPPS/ASC proposed rule.

As discussed in section III. of this proposed rule, we propose to create APC groups to pay separately for certain skin substitutes under the OPPS and, as discussed in section XIII.D. of this proposed rule, we also propose to pay separately for skin substitute supplies in the ASC payment system and add such supplies to the ancillary items and services list for CY 2026.

Under the ASC payment system, skin substitute products are currently packaged and assigned an ASC payment indicator of "N1" (Packaged service/item; no separate payment made). We do not believe there is an existing payment indicator available that would adequately describe these supplies and provide the correct separate payment under the ASC payment system. Under this new policy, payment under the ASC payment system for separately-payable skin substitute products would be based on the OPPS conversion factor, not on the ASC conversion factor. Additionally, payment for these skin substitute products would not be subject to the ASC wage index. Therefore, for CY 2026 and subsequent years, we propose to create a new ASC payment indicator "S2" – (Skin substitute supply group; paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate) – to Addendum DD1 to this proposed rule to describe skin substitute products paid separately in an ASC. This "S2" payment indicator would indicate a separately payable ancillary skin substitute supply when provided integral to a separately payable ASC covered surgical procedure.

We refer readers to Addenda DD1 and DD2 of this proposed rule (these addenda are available via the internet on the CMS website) for the complete list of ASC payment and comment indicators proposed for the CY 2026 update.

C. Proposed Payment Policies Under the ASC Payment System

1. Proposed ASC Payment for Covered Surgical Procedures

a. Background

Our ASC payment policies for covered surgical procedures under the revised ASC payment system are described in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66828 through 66831). Under our established policy, we use the ASC standard ratesetting methodology of multiplying the ASC relative payment weight for the procedure by the ASC conversion factor for that same year to calculate the national unadjusted payment rates for procedures with payment indicators "G2" and "A2." Payment indicator "A2" was developed to identify procedures that were included on the list of ASC covered surgical procedures in CY 2007 and, therefore, were subject to transitional payment prior to CY 2011. Although the 4-year transitional period has ended and payment indicator "A2" is no longer required to identify surgical procedures subject to transitional payment, we have retained payment indicator "A2" because it is used to identify procedures that are exempted from the application of the office-based designation.

Payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") are the lower of the PFS nonfacility PE RVU-based amount or the amount calculated using the ASC standard rate setting methodology for the procedure. As detailed in section XIII.C.3.b. of this proposed rule, we update the payment amounts for office-based procedures (payment indicators "P2," "P3," and "R2") using the most recent available MPFS and OPPS data. We compare the estimated current year rate for each of the office-based procedures, calculated according to the ASC standard rate setting methodology, to the PFS nonfacility PE RVU-based amount to

determine which is lower and, therefore, would be the current year payment rate for the procedure under our final policy for the revised ASC payment system (§ 416.171(d)).

The rate calculation established for device-intensive procedures (payment indicator "J8") is structured so only the service (non-device) portion of the rate is subject to the ASC conversion factor. We update the payment rates for device-intensive procedures to incorporate the most recent device offset percentages calculated under the ASC standard ratesetting methodology, as discussed in section XIII.C.4. of this proposed rule.

In the CY 2014 OPPS/ASC final rule with comment period (78 FR 75081), we finalized our proposal to calculate the CY 2014 payment rates for ASC covered surgical procedures according to our established methodologies, with the exception of device removal procedures. For CY 2014, we finalized a policy to conditionally package payment for device removal procedures under the OPPS. Under the OPPS, a conditionally packaged procedure (status indicators "Q1" and "Q2") describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a covered surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are always packaged (payment indicator "N1") under the ASC payment system. Under the OPPS, device removal procedures are conditionally packaged and, therefore, would be packaged under the ASC payment system. There is no Medicare payment made when a device removal procedure is performed in an ASC without another surgical procedure included on the claim; therefore, no Medicare payment would be made if a device was removed but not replaced. To ensure that the ASC payment system provides separate payment for surgical procedures that only involve device removal – conditionally packaged in the OPPS (status indicator "Q2") – we have continued to provide separate payment since CY 2014 and assign the current ASC payment indicators associated with these procedures.

b. Update to ASC Covered Surgical Procedure Payment Rates for CY 2026

We propose to update ASC payment rates for CY 2026 and subsequent years using the established rate calculation methodologies under § 416.171 and using our definition of device-intensive procedures, as discussed in section XIII.C.4. of this proposed rule. As the proposed OPPS relative payment weights are generally based on geometric mean costs, we propose that the ASC payment system will generally use the geometric mean cost to determine proposed relative payment weights under the ASC standard methodology. We propose to continue to use the amount calculated under the ASC standard ratesetting methodology for procedures assigned payment indicators "A2" and "G2."

We propose to calculate payment rates for office-based procedures (payment indicators "P2," "P3," and "R2") and device-intensive procedures (payment indicator "J8") according to our established policies and to identify device-intensive procedures using the methodology discussed in section XIII.C.4. of this proposed rule. Therefore, we propose to update the payment amount for the service portion (the non-device portion) of the device-intensive procedures using the standard ASC ratesetting methodology and the payment amount for the device portion based on the proposed CY 2026 device offset percentages that have been calculated using the standard OPPS APC ratesetting methodology. We propose that payment for office-based procedures would be at the lesser of the proposed CY 2026 MPFS nonfacility PE RVU-based amount or the proposed CY 2026 ASC payment amount calculated according to the ASC standard ratesetting methodology.

As we did for CYs 2014 through 2025, for CY 2026, we propose to continue our policy for device removal procedures, such that device removal procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2") will be assigned the current ASC payment indicators associated with those procedures and will continue to be paid separately under the ASC payment system.

c. Proposed Payment for ASC Add-On Procedures Eligible for Complexity Adjustments under the OPPS

In this section, we discuss the policy to provide increased payment under the ASC payment system for combinations of certain "J1" service codes and add-on procedure codes that are eligible for a complexity adjustment under the OPPS.

(1) OPPS C-APC Complexity Adjustment Policy

Under the OPPS, complexity adjustments are utilized to provide increased payment for certain comprehensive services. As discussed in section II.A.2.b. of this proposed rule, we apply a complexity adjustment by promoting qualifying paired "J1" service code combinations or paired code combinations of "J1" services and add-on codes from the originating Comprehensive APC (C-APC) (the C-APC to which the designated primary service is first assigned) to the next higher paying C-APC in the same clinical family of C-APCs. A "J1" status indicator refers to a hospital outpatient service paid through a C-APC. We package payment for all add-on codes, which are codes that describe a procedure or service always performed in addition to a primary service or procedure, into the payment for the C-APC. However, certain combinations of primary service codes and add-on codes may qualify for a complexity adjustment.

We apply complexity adjustments when the paired code combination represents a complex, costly form or version of the primary service when the frequency and cost thresholds are met. The frequency threshold is met when there are 25 or more claims reporting the code combination, and the cost threshold is met when there is a violation of the 2 times rule, as specified in section 1833(t)(2) of the Act and described in section III.A.2.b. of this proposed rule, in the originating C-APC. These paired code combinations that meet the frequency and cost threshold criteria represent those that exhibit materially greater resource requirements than the primary service. After designating a single primary service for a claim, we evaluate that service in combination with each of the other procedure codes reported on the claim that are either assigned to status indicator "J1" or add-on codes to determine if there are paired code

combinations that meet the complexity adjustment criteria. Once we have determined that a particular combination of "J1" services, or combinations of a "J1" service and add-on code, represents a complex version of the primary service because it is sufficiently costly, frequent, and a subset of the primary comprehensive service overall according to the criteria described previously, we promote the claim to the next higher cost C-APC within the clinical family unless the primary service is already assigned to the highest cost APC within the C-APC clinical family or assigned to the only C-APC in a clinical family. We do not create new C-APCs with a comprehensive geometric mean cost that is higher than the highest geometric mean cost (or only) C-APC in a clinical family just to accommodate potential complexity adjustments. Therefore, the highest payment for any claim including a code combination for services assigned to a C-APC would be the highest paying C-APC in the clinical family (79 FR 66802).

As previously stated, we package payment for add-on codes into the C-APC payment rate. If any add-on code reported in conjunction with the "J1" primary service code does not qualify for a complexity adjustment, payment for the add-on service continues to be packaged into the payment for the primary service and the primary service code reported with the add-on code is not reassigned to the next higher cost C-APC. We list the proposed complexity adjustments for "J1" and add-on code combinations for CY 2026, along with all of the other proposed complexity adjustments, in Addendum J to this proposed rule (which is available via the Internet on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*).

(2) CY 2026 ASC Special Payment Policy Proposal for OPPS Complexity-Adjusted C-APCs

For CY 2026, we propose to continue the special payment policy and methodology for OPPS complexity-adjusted C-APCs that was finalized in the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080).

For those ASC complexity adjustment codes for which we have claims data, we propose to use the claims data to calculate the code combination utilization and estimated payments for

the ASC payment system budget neutrality calculations for CY 2026. The ASC complexity adjustment budget neutrality calculations are discussed further in section XIII.H.2.a. of this proposed rule. The full list of the proposed ASC complexity adjustment codes for CY 2026 can be found in the CY 2026 proposed ASC Addendum AA and the supplemental policy file, which also includes both the existing ASC complexity adjustment codes and proposed additions and published with the proposed rule on the CMS website at*https://www.cms.gov/medicare/medicare-fee-for-service-payment/ascpayment/asc-regulations-and-notices*. Since the complexity adjustment assignments change each year under the OPPS, the proposed list of ASC complexity adjustment codes eligible for the proposed payment policy has changed slightly from the previous year. Additionally, since complexity adjustment assignments may change between the proposed rule and final rule under the OPPS, the final list of ASC complexity adjustment codes eligible for this payment policy may be slightly different than the proposed list of ASC complexity adjustment codes.

d. Proposed Low Volume APCs and Limit on ASC Payment Rates for Procedures Assigned to Low Volume APCs

As stated in section XIII.D.1.b. of the CY 2025 OPPS/ASC proposed rule, the ASC payment system generally uses OPPS geometric mean costs under the standard methodology to determine proposed relative payment weights under the standard ASC ratesetting methodology.

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63743 through 63747), we adopted a universal low volume APC policy for CY 2022 and subsequent calendar years. Under our policy, we expanded the low volume adjustment policy that is applied to procedures assigned to New Technology APCs to also apply to clinical and brachytherapy APCs. Specifically, a clinical APC or brachytherapy APC with fewer than 100 claims per year would be designated as a low volume APC. For items or services assigned to a low volume APC, we use up to 4 years of claims data to establish a payment rate for the APC as we currently do for low volume services assigned to New Technology APCs. The payment rate for a low volume APC

or a low volume New Technology procedure would be based on the highest of the median cost, arithmetic mean cost, or geometric mean cost calculated using multiple years of claims data.

Based on claims data available for this proposed rule, we propose to designate six brachytherapy APCs and four clinical APCs as low volume APCs under the ASC payment system. The four clinical APCs and six brachytherapy APCs meet our criteria of having fewer than 100 single claims in the relevant claims year (CY 2024 for this CY 2026 OPPS/ASC proposed rule) and therefore, we propose that they would be subject to our universal low volume APC policy and the APC cost metric would be based on the greater of the median cost, arithmetic mean cost, or geometric mean cost using up to 4 years of claims data. Nine of the ten APCs were designated as low volume APCs in CY 2025. Based on data for this CY 2026 OPPS/ASC proposed rule, APC 2645 (Brachytx, non-stranded, gold-198) has 103 single claims and no longer meets our criteria to be designated as a low volume APC; however, APC 2643 (Brachytx, non-stranded, c-131) has only 88 single claims and does meet our criteria to be designated as a low volume APC.

Table 76 includes the CY 2024 claims available for ratesetting for each of the APCs we are proposing to designate as a low volume APC for CY 2026.

TABLE 76: PROPOSED LOW VOLUME APCS USING STANDARD (ASC) RATESETTING METHODOLOGY FOR CY 2026

APC	APC Description	CY 2024 Claims Available for Ratesetting
2632	Iodine I-125 sodium iodide	1
2635	Brachytx, non-str, HA, P-103	9
2636	Brachy linear, non-str, P-103	0
2642	Brachytx, stranded, C-131	49
2643	Brachytx, non-stranded,c-131	88
2647	Brachytx, NS, Non-HDRIr-192	3
5244	Level 4 Blood Product Exchanges and Related Services	1
5494	Level 4 Intraocular Procedures	9
5495	Level 5 Intraocular Procedures	34
5496	Level 6 Intraocular Procedures	11

2. Proposed Payment for Covered Ancillary Services

a. Background

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of service and its payment policy under the OPPS. Our overall policy provides separate ASC payment for certain ancillary items and services integrally related to the provision of ASC covered surgical procedures that are paid separately under the OPPS and provides packaged ASC payment for other ancillary items and services that are packaged or conditionally packaged (status indicators "N," "Q1," and "Q2") under the OPPS.

In the CY 2013 OPPS/ASC rulemaking (77 FR 45169 and 77 FR 68457 through 68458), we further clarified our policy regarding the payment indicator assignment for procedures that are conditionally packaged in the OPPS (status indicators "Q1" and "Q2"). Under the OPPS, a conditionally packaged procedure describes a HCPCS code where the payment is packaged when it is provided with a significant procedure but is separately paid when the service appears on the claim without a significant procedure. Because ASC services always include a surgical procedure, HCPCS codes that are conditionally packaged under the OPPS are generally packaged (payment indicator "N1") under the ASC payment system (except for device removal procedures, as discussed in the CY 2022 OPPS/ASC proposed rule (86 FR 42083)). Thus, our policy generally aligns ASC payment bundles with those under the OPPS (72 FR 42495). In all cases, in order for ancillary items and services also to be paid, the ancillary items and services must be provided integral to the performance of ASC covered surgical procedures for which the ASC bills Medicare.

Our ASC payment policies generally provide separate payment for drugs and biologicals that are separately paid under the OPPS at the OPPS rates and package payment for drugs and biologicals for which payment is packaged under the OPPS. However, as discussed in the CY 2022 OPPS/ASC final rule with comment period, for CY 2022, we finalized a policy to unpackage and pay separately at ASP plus 6 percent for the cost of non-opioid pain management

drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS under § 416.174 (86 FR 63483).

We generally pay for separately payable radiology services at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (72 FR 42497). However, as finalized in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72050), payment indicators for all nuclear medicine procedures (defined as CPT codes in the range of 78000 through 78999) that are designated as radiology services that are paid separately when provided integral to a surgical procedure on the ASC list are set to "Z2" so that payment is made based on the ASC standard ratesetting methodology rather than the MPFS nonfacility PE RVU amount ("Z3"), regardless of which is lower (§ 416.171(d)(1)).

Similarly, we also finalized our policy to set the payment indicator to "Z2" for radiology services that use contrast agents so that payment for these procedures will be based on the OPPS relative payment weight using the ASC standard ratesetting methodology and, therefore, will include the cost for the contrast agent (§ 416.171(d)(2)).

ASC payment policy for brachytherapy sources mirrors the payment policy under the OPPS. ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS or, if OPPS rates are unavailable, at contractor-priced rates (72 FR 42499). Since December 31, 2009, ASCs have been paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS.

Our ASC policies also provide separate payment for: (1) certain items and services that CMS designates as contractor-priced, including, but not limited to, the procurement of corneal tissue; and (2) certain implantable items that have pass-through payment status under the OPPS. These categories do not have prospectively established ASC payment rates according to ASC payment system policies (72 FR 42502 and 42508 through 42509; § 416.164(b)). Under the

ASC payment system, we have designated corneal tissue acquisition and hepatitis B vaccines as contractor-priced. Corneal tissue acquisition is contractor-priced based on the invoice costs for acquiring the corneal tissue for transplantation. Hepatitis B vaccines are contractor-priced based on invoiced costs for the vaccine.

Devices that are eligible for pass-through payment under the OPPS are separately paid under the ASC payment system and are contractor-priced. Under the revised ASC payment system (72 FR 42502), payment for the surgical procedure associated with the pass-through device is made according to our standard methodology for the ASC payment system, based on only the service (non-device) portion of the procedure's OPPS relative payment weight if the APC weight for the procedure includes other packaged device costs. We also refer to this methodology as applying a "device offset" to the ASC payment for the associated surgical procedure. This ensures that duplicate payment is not provided for any portion of an implanted device with OPPS pass-through payment status.

In the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized that, beginning in CY 2015, certain diagnostic tests within the medicine range of CPT codes for which separate payment is allowed under the OPPS are covered ancillary services when they are integral to an ASC covered surgical procedure. We finalized that diagnostic tests within the medicine range of CPT codes include all Category I CPT codes in the medicine range established by CPT, from 90000 to 99999, and Category III CPT codes and Level II HCPCS codes that describe diagnostic tests that crosswalk or are clinically similar to procedures in the medicine range established by CPT. In the CY 2015 OPPS/ASC final rule with comment period, we also finalized our policy to pay for these tests at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the ASC standard ratesetting methodology (79 FR 66933 through 66934). We finalized that the diagnostic tests for which the payment is based on the ASC standard ratesetting methodology be assigned to payment indicator "Z2" and revised the definition of payment indicator "Z2" to

include a reference to diagnostic services and those for which the payment is based on the PFS nonfacility PE RVU-based amount be assigned payment indicator "Z3," and revised the definition of payment indicator "Z3" to include a reference to diagnostic services.

b. Proposed Payment for Covered Ancillary Items and Services for CY 2026

We propose to update the ASC payment rates and to make changes to ASC payment indicators, as necessary, to maintain consistency between the OPPS and ASC payment system regarding the packaged or separately payable status of services and the proposed CY 2026 OPPS and ASC payment rates and subsequent years' payment rates. We propose to continue to set the CY 2026 ASC payment rates and subsequent years' payment rates for brachytherapy sources and separately payable drugs and biologicals equal to the OPPS payment rates for CY 2026 and subsequent years' payment rates.

Covered ancillary services and their proposed payment indicators for CY 2026 are listed in Addendum BB of this proposed rule (which is available via the internet on the CMS website). For those covered ancillary services where the payment rate is the lower of the rate under the ASC standard rate setting methodology and the PFS proposed rates (similar to our office-based payment policy), the proposed payment indicators and rates set forth in this proposed rule are based on a comparison using the proposed PFS rates effective January 1, 2026. For a discussion of the PFS rates, we refer readers to the CY 2026 PFS proposed rule which is available on the CMS website at *https://www.cms.gov/medicare/payment/fee-schedules/physician/federal-regulation-n*otices.

3. Covered Surgical Procedures Designated as Office-Based Procedures

a. Background

In the August 2, 2007 ASC final rule with comment period, we finalized our policy to designate as "office-based" those procedures that are added to the ASC Covered Procedures List (CPL) in CY 2008 or later years that we determine are furnished predominantly (more than 50 percent of the time) in physicians' offices based on consideration of the most recent available

volume and utilization data for each individual procedure code and/or, if appropriate, the clinical characteristics, utilization, and volume of related codes. In that final rule, we also finalized our policy to exempt all procedures on the CY 2007 ASC list from application of the office-based classification (72 FR 42512). The procedures that were added to the ASC CPL beginning in CY 2008 that we determined were office-based were identified in Addendum AA to that final rule with payment indicator "P2" (Office-based surgical procedure added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight); "P3" (Office-based surgical procedures added to ASC list in CY 2008 or later with MPFS nonfacility PE RVUs; payment based on MPFS nonfacility PE RVUs); or "R2" (Office-based surgical procedure added to ASC list in CY 2008 or later without MPFS nonfacility PE RVUs; payment based on OPPS relative payment weight), depending on whether we estimated the procedure would be paid according to the ASC standard ratesetting methodology based on its OPPS relative payment weight or at the MPFS nonfacility PE RVU-based amount.

Consistent with our final policy to annually review and update the ASC CPL to include all covered surgical procedures eligible for payment in ASCs, each year we identify covered surgical procedures as either temporarily office-based (these are new procedure codes with little or no utilization data that we have determined are clinically similar to other procedures that are permanently office-based), permanently office-based, or nonoffice-based, after taking into account updated volume and utilization data.

b. CY 2026 Proposed Office-Based Procedures

In developing this proposed rule, we followed our policy to annually review and update the covered surgical procedures for which ASC payment is made and to identify new procedures that may be appropriate for ASC payment, including their potential designation as office-based. Historically, we also review the most recent claims volume and utilization data (CY 2024 claims) and the clinical characteristics for all covered surgical procedures that are currently assigned a payment indicator in CY 2025 of "G2" (Non office-based surgical procedure added in

CY 2008 or later; payment based on OPPS relative payment weight) as well as for those procedures assigned one of the temporary office-based payment indicators, specifically "P2," "P3," or "R2" in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94322 through 94326).

Our review of the CY 2024 volume and utilization data of covered surgical procedures currently assigned a payment indicator of "G2" (Non office-based surgical procedure added in CY 2008 or later; payment based on OPPS relative payment weight) resulted in the identification of one surgical procedure – CPT code 21930 (Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm) – that we believed met the criteria for designation as permanently office-based. The data indicated that this procedure is performed more than 50 percent of the time in physicians' offices, and the services are of a level of complexity consistent with other procedures performed routinely in physicians' offices. We have included CPT code 21930 in our list of surgical procedures we propose to permanently designate as office-based for CY 2026 in Table 77.

As discussed in the August 2, 2007 ASC final rule with comment period (72 FR 42533 through 42535), we finalized our policy to designate certain new surgical procedures as temporarily office-based until adequate claims data are available to assess their predominant sites of service, whereupon if we confirm their office-based nature, the procedures are permanently assigned to the list of office-based procedures. In the absence of claims data, we use other available information, including our clinical advisors' judgment, predecessor CPT and Level II HCPCS codes, information submitted by representatives of specialty societies and professional associations, and information submitted by commenters during the public comment period.

In Table 153 of the CY 2025 OPPS/ASC final rule with comment period, we finalized assigning temporary office-based designations to nine surgical procedures for CY 2025 (89 FR 94325 through 94326). As discussed in section XIII.B. of this proposed rule, two of the nine procedures were deleted effective April 2025 – HCPCS codes G0564 and G0565. For two

of the remaining seven surgical procedures, interested parties submitted information that suggested CPT code 15013 (Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin) and its automated counterpart HCPCS C8002 (Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)) are not most similar to CPT code 11310 (Shaving of epidermal or dermal lesion, single lesion, face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less) as we stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94322 through 94324) since CPT code 15013 must be performed with other skin cell suspension autograft procedure codes and the entirety of the procedure – harvesting of skin, preparation and application of the skin cell suspension autograft – is not expected to be predominantly performed in an office setting. After reviewing the information and consulting with our medical officers, we agree that the entirety of the procedure is not expected to be performed in a physician office setting and that CPT code 11310 would not be an accurate crosswalk for site-of-service utilization. Therefore, as shown in Table 78, in this proposed rule, we propose to permanently remove the temporarily office-based designation for CPT code 15013 and HCPCS code C8002.

We reviewed CY 2024 volume and utilization data for the remaining five surgical procedures designated as temporarily office-based in the CY 2025 OPPS/ASC final rule with comment period. As shown in Table 77 and Table 78, for one of the five surgical procedures – CPT code 0864T – there are greater than 50 claims available and the volume and utilization indicated this procedure was performed predominantly in the office setting. Therefore, we propose to no longer designate this procedure as temporarily office-based and to permanently designate this procedure as office-based and assign one of the office-based payment indicators, specifically “P2”, “P3”, or “R2.”

TABLE 77: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NEWLY DESIGNATED AS PERMANENTLY OFFICE-BASED FOR CY 2026

CY 2026 CPT/HCPCS Code	Long Descriptor	Final CY 2025 ASC Payment Indicator	Proposed CY 2026 ASC Payment Indicator*
21930	Excision, tumor, soft tissue of back or flank, subcutaneous; less than 3 cm	G2	P3*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2026 PFS proposed rates.

TABLE 78: ASC COVERED SURGICAL PROCEDURES PROPOSED TO BE NO LONGER DESIGNATED AS TEMPORARILY OFFICE-BASED FOR CY 2026

CY 2026 CPT/HCPCS Code	Long Descriptor	Final CY 2025 ASC Payment Indicator	Proposed CY 2026 ASC Payment Indicator*
0864T	Low-intensity extracorporeal shock wave therapy involving corpus cavernosum, low energy	R2	R2*
15013	Preparation of skin cell suspension autograft, requiring enzymatic processing, manual mechanical disaggregation of skin cells, and filtration; first 25 sq cm or less of harvested skin	R2	G2
C8002	Preparation of skin cell suspension autograft, automated, including all enzymatic processing and device components (do not report with manual suspension preparation)	R2	G2

* Payment indicators were based on a comparison of the proposed rates according to the ASC standard ratesetting methodology and the CY 2026 PFS proposed rates.

For the remaining four procedures that were designated as temporarily office-based in the CY 2025 OPPS/ASC final rule with comment period and temporarily assigned one of the office-based payment indicators, specifically “P2,” “P3,” or “R2,” there were fewer than 50 claims; therefore, there was an insufficient number of claims to determine if the office setting was the predominant setting of care for these procedures. Therefore, as shown in Table 79, we propose to continue to designate such procedures as temporarily office-based for CY 2026 and assign one of the office-based payment indicators.

For CY 2026, we are not proposing to designate any new CY 2026 CPT codes for ASC covered surgical procedures as temporarily office-based.

TABLE 79: CY 2026 PAYMENT INDICATORS FOR NEW AND EXISTING ASC COVERED SURGICAL PROCEDURES PROPOSING TO DESIGNATE AS TEMPORARILY OFFICE-BASED

CY 2026 CPT/HCPCS Code	Long Descriptor	Final CY 2025 ASC Payment Indicator	Proposed CY 2026 ASC Payment Indicator*
0588T	Revision or removal of integrated single device neurostimulation system including electrode array and receiver or pulse generator, including analysis, programming, and imaging guidance when performed, posterior tibial nerve	R2	R2*
53866	Catheterization with removal of temporary device for ischemic remodeling (ie, pressure necrosis) of bladder neck and prostate	P3	P3*
64598	Revision or removal of neurostimulator electrode array, peripheral nerve, with integrated neurostimulator	R2	R2*
67229	Treatment of extensive or progressive retinopathy, 1 or more sessions, preterm infant (less than 37 weeks gestation at birth), performed from birth up to 1 year of age (e.g., retinopathy of prematurity), photocoagulation or cryotherapy	R2	R2*

* Payment indicators were based on a comparison of the final rates according to the ASC standard ratesetting methodology and the CY 2026 PFS proposed rates.

The procedures for which the proposed office-based designation for CY 2026 is temporary are also indicated by an asterisk in Addendum AA to this proposed rule (which is available via the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ASCPayment/ASC-Regulations-and-Notices*.).

4. Device-Intensive ASC Covered Surgical Procedures

a. Background

We refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59041), for a summary of our existing policies regarding ASC covered surgical procedures that are designated as device-intensive.

b. CY 2026 Proposed Device Intensive Procedures

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59040 through 59043), we modified our criteria for device-intensive procedures to better capture costs for procedures with significant device costs. We adopted a policy to allow procedures that involve surgically inserted or implanted, high-cost, single-use devices to qualify as device-intensive procedures. In addition, we modified our criteria to lower the device offset percentage threshold from 40 percent to 30 percent. The device offset percentage is the percentage of device costs within a procedure's total costs. Specifically, for CY 2019 and subsequent years, we adopted a policy that device-intensive procedures would be subject to the following criteria:

● All procedures must involve implantable or insertable devices assigned a CPT or HCPCS code;

● The required devices (including single-use devices) must be surgically inserted or implanted; and

● The device offset amount must be significant, which is defined as exceeding 30 percent of the procedure's mean cost. Corresponding to this change in the cost criterion, we adopted a policy that the default device offset for new codes that describe procedures that involve the implantation of medical devices will be 31 percent beginning in CY 2019. For new codes describing procedures that are payable when furnished in an ASC and involve the implantation of a medical device, we adopted a policy that the default device offset would be applied in the same manner as the policy we adopted in section IV.B.2 of the CY 2019 OPPS/ASC final rule with comment period (83 FR 58944 through 58948). We amended § 416.171(b)(2) of the regulations to reflect these new device criteria.

In addition, as also adopted in section IV.B.2. of the CY 2019 OPPS/ASC final rule with comment period, to further align the device-intensive policy with the criteria used for device pass-through status, we specified, for CY 2019 and subsequent years, that for purposes of satisfying the device-intensive criteria, a device-intensive procedure must involve a device that:

● Has received FDA marketing authorization, has received an FDA investigational device exemption (IDE) and has been classified as a Category B device by FDA in accordance with 42 CFR 405.203 through 405.207 and 405.211 through 405.215, or meets another appropriate FDA exemption from premarket review;

● Is an integral part of the service furnished;

● Is used for one patient only;

● Comes in contact with human tissue;

● Is surgically implanted or inserted (either permanently or temporarily); and

● Is not any of the following:

++ Equipment, an instrument, apparatus, implement, or item of this type for which depreciation and financing expenses are recovered as depreciable assets as defined in Chapter 1 of the Medicare Provider Reimbursement Manual (CMS Pub. 15-1); or

++ A material or supply furnished incident to a service (for example, a suture, customized surgical kit, scalpel, or clip, other than a radiological site marker).

In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63773 through 63775), we modified our approach to assigning device-intensive status to surgical procedures under the ASC payment system. First, we adopted a policy of assigning device-intensive status to procedures that involve surgically inserted or implanted, high-cost, single-use devices if their device offset percentage exceeds 30 percent under the ASC standard ratesetting methodology, even if the procedure is not designated as device-intensive under the OPPS. Second, we adopted a policy that if a procedure is assigned device-intensive status under the OPPS, but has a device offset percentage below the device-intensive threshold under the standard ASC ratesetting methodology, the procedure will be assigned device-intensive status under the ASC payment system with a default device offset percentage of 31 percent. The policies were adopted to provide consistency between the OPPS and ASC payment system and provide a more

appropriate payment rate for surgical procedures with significant device costs under the ASC payment system.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72078 through 72080), we finalized our policy to create certain C-codes, or ASC complexity adjustment codes that describe certain combinations of a primary covered surgical procedure as well as a packaged (payment indicator = "N1") procedure that are otherwise eligible for a complexity adjustment under the OPPS (as listed in Addendum J). Each ASC complexity adjustment code's APC assignment is based on its corresponding OPPS complexity adjustment code's APC assignment. In the CY 2023 OPPS/ASC final rule with comment period, we stated our belief that it would be appropriate for these ASC complexity adjustment codes to qualify for device-intensive status under the ASC payment system if the primary procedure of the code was also designated as device-intensive. Under our current policy, the ASC complexity adjustment code retains the device portion of the primary procedure (also called the "device offset amount") and not the device offset percentage. Therefore, for device-intensive ASC complexity adjustment codes, we set the device portion of the combined procedure equal to the device portion of the primary procedure and calculate the device offset percentage by dividing the device portion by the ASC complexity adjustment code's APC payment rate. Further, we apply our standard ASC payment system ratesetting methodology to the non-device portion of the ASC complexity adjustment code's APC payment rate; that is, we multiply the OPPS relative weight by the ASC budget neutrality adjustment and the ASC conversion factor and sum that amount with the device portion to calculate the ASC payment rate.

In the CY 2025 OPPS/ASC final rule with comment period, we finalized a modification to our policy regarding default device offset percentages for new codes that meet our criteria for device-intensive status. Under both the OPPS and ASC payment system, for new device-intensive procedures that lack claims data, or lack claims data from a predecessor code or a clinically-similar code that uses the same device, we apply the greater of the APC-wide device

offset percentage or 31 percent (the previous default device offset percentage). We believe that an APC-wide average device offset percentage is, in most cases, a better reflection of device costs when the typical device costs of procedures assigned to such APC are significantly greater than 31 percent. This policy does not apply to new device-intensive procedures assigned to New Technology APCs.

In section V.B.8.i. of this proposed rule, we discuss the implementation of the Final Remedy for the 340B-Acquired Drug Payment Policy for Calendar Years 2018-2022 rule and the impact of the OPPS conversion factor on the ASC payment system. Since most ASC payment rates for surgical procedures are constructed from OPPS relative weights or the MPFS unadjusted nonfacility PE RVU-based amount, the remedy's proposed prospective offset to the OPPS conversion has a very limited impact on the ASC payment system. The only impact of the proposed reduction to the OPPS conversion factor is the payment rate for device-intensive procedures under the ASC payment system. Since the ASC payment system holds device portions constant between the two settings, the device portion is the device offset percentage multiplied by the OPPS payment rate.

Historically, in our proposed rules, device portions for device-intensive procedures would be based on the proposed prospective OPPS conversion factor multiplied by the proposed prospective OPPS relative weights. However, for this CY 2026 OPPS/ASC proposed rule, we believe it would be inaccurate and inappropriate to use OPPS payment rates that have been reduced by the remedy's prospective offset since this could accumulate to have a potentially noticeable impact on ASC payment rates for certain device-intensive procedures over time. Since the ASC payment system would otherwise set the device portion in the ASC setting at the amount without the two percent reduction to OPPS payment rates, we believe it would not be an accurate reflection of the device costs of covered surgical procedures in the ASC setting if we were to incorporate the 2 percent prospective offset that we propose in this proposed rule. Further, we are concerned beneficiaries could have access issues to certain device-intensive

procedures in the ASC setting if we maintained a 2-percent reduction to the payment rates for device-intensive procedures for each calendar year we applied the prospective offset. Therefore, we are proposing that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not incorporate the two percent prospective offset to the OPPS conversion factor as a result of the 340B remedy offset that we propose to implement in this proposed rule. For proposed CY 2026 device offset percentages, which include device offset percentages based on CY 2024 claims processed through March 31, 2025, we refer readers to Addendum FF of this proposed rule. Final CY 2026 device offset percentages may differ from the proposed percentages, as we rely on the most recently available claims data for the CY 2026 OPPS/ASC final rule with comment period (CY 2024 claims data processed through June 30th).

c. Adjustment to ASC Payments for No Cost/Full Credit and Partial Credit Devices

Our ASC payment policy for costly devices implanted or inserted in ASCs at no cost/full credit or partial credit is set forth in § 416.179 of our regulations and is consistent with the OPPS policy that was in effect until CY 2014. We refer readers to the CY 2008 OPPS/ASC final rule with comment period (72 FR 66845 through 66848) for a full discussion of the ASC payment adjustment policy for no cost/full credit and partial credit devices. ASC payment is reduced by 100 percent of the device offset amount when a hospital furnishes a specified device without cost or with a full credit and by 50 percent of the device offset amount when the hospital receives partial credit in the amount of 50 percent or more of the cost for the specified device.

Effective CY 2014, under the OPPS, we finalized our proposal to reduce OPPS payment for applicable APCs by the full or partial credit a provider receives for a device, capped at the device offset amount. Although we finalized our proposal to modify the policy of reducing payments when a hospital furnishes a specified device without cost or with full or partial credit under the OPPS, in the CY 2014 OPPS/ASC final rule with comment period (78 FR 75076 through 75080), we finalized our proposal to maintain our ASC policy for reducing payments to

ASCs for specified device-intensive procedures when the ASC furnishes a device without cost or with full or partial credit. Unlike the OPPS, there is currently no mechanism within the ASC claims processing system for ASCs to submit to CMS the amount of the actual credit received when furnishing a specified device at full or partial credit. Therefore, under the ASC payment system, we finalized our proposal for CY 2014 to continue to reduce ASC payments by 100 percent or 50 percent of the device offset amount when an ASC furnishes a device without cost or with full or partial credit, respectively.

Under current ASC policy, all ASC device-intensive covered surgical procedures are subject to the no cost/full credit and partial credit device adjustment policy. Specifically, when a device-intensive procedure is performed to implant or insert a device that is furnished at no cost or with full credit from the manufacturer, the ASC appends the HCPCS "FB" modifier on the line in the claim with the procedure to implant or insert the device. The contractor reduces payment to the ASC by the device offset amount that we estimate represents the cost of the device when the necessary device is furnished without cost or with full credit to the ASC. We continue to believe that the reduction of ASC payment in these circumstances is necessary to pay appropriately for the covered surgical procedure furnished by the ASC.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we adopted a policy to reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the new device. The ASC will append the HCPCS "FC" modifier to the HCPCS code for the device-intensive surgical procedure when the facility receives a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a new device, ASCs have the option of either: (1) submitting the claim for the device-intensive procedure to their Medicare contractor after the procedure's performance, but

prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount. As finalized in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66926), to ensure our policy covers any situation involving a device-intensive procedure where an ASC may receive a device at no cost or receive full credit or partial credit for the device, we apply our "FB"/ "FC" modifier policy to all device-intensive procedures.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) we stated we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. In the CY 2020 OPPS/ASC final rule with comment period, we finalized continuing our existing policies for CY 2020. We note that we inadvertently omitted language that this policy would apply not just in CY 2019 but also in subsequent calendar years. We intended to apply this policy in CY 2019 and subsequent calendar years. Therefore, we finalized our proposal to apply our policy for partial credits specified in the CY 2019 OPPS/ASC final rule with comment period (83 FR 59043 through 59044) in CY 2022 and subsequent calendar years (86 FR 63775 through 63776). Specifically, for CY 2022 and subsequent calendar years, we would reduce the payment for a device-intensive procedure for which the ASC receives partial credit by one-half of the device offset amount that would be applied if a device was provided at no cost or with full credit, if the credit to the ASC is 50 percent or more (but less than 100 percent) of the cost of the device. To report that the ASC received a partial credit of 50 percent or more (but less than 100 percent) of the cost of a device,

ASCs have the option of either: (1) submitting the claim for the device intensive procedure to their Medicare contractor after the procedure's performance, but prior to manufacturer acknowledgment of credit for the device, and subsequently contacting the contractor regarding a claim adjustment, once the credit determination is made; or (2) holding the claim for the device implantation or insertion procedure until a determination is made by the manufacturer on the partial credit and submitting the claim with the "FC" modifier appended to the implantation procedure HCPCS code if the partial credit is 50 percent or more (but less than 100 percent) of the cost of the device. Beneficiary coinsurance would be based on the reduced payment amount.

We are not proposing any changes to our policies related to no cost/full credit or partial credit devices for CY 2026.

5. Requirement in the Physician Fee Schedule CY 2026 Proposed Rule for HOPDs and ASCs to Report Discarded Amounts of Certain Single-dose or Single-use Package Drugs

Section 90004 of the Infrastructure Investment and Jobs Act (Pub. L. 117-9, November 15, 2021) ("the Infrastructure Act") amended section 1847A of the Act to re-designate subsection (h) as subsection (i) and insert a new subsection (h), which requires manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug.

The CY 2026 PFS proposed rule includes proposals related to the discarded drug refund policy, including proposals that may impact hospital outpatient departments (HOPDs) and ambulatory surgical centers (ASCs). Similar to our CY 2023, CY 2024, and CY 2025 notices in the OPPS/ASC proposed rules (87 FR 71988, 88 FR 49760, and 89 FR 59421 through 59422), we are including a notice in this CY 2026 proposed rule to ensure interested parties are aware of these proposals and know to refer to the CY 2026 Physician Fee Schedule proposed rule for a full description of the proposed policy. Interested parties are asked to submit comments on any proposals to further implement section 90004 of the Infrastructure Act to the CY 2026 PFS proposed rule. Public comments on these proposals will be addressed in the CY 2026 PFS final

rule with comment period. We note that this same notice appeared in section V.B. of this proposed rule.

D. Proposed Additions to ASC Covered Surgical Procedures and Covered Ancillary Services Lists

1. Current Review Process for the List of ASC Covered Surgical Procedures

Section 1833(i)(1) of the Act requires us, in part, to specify, in consultation with appropriate medical organizations, surgical procedures that are appropriately performed on an inpatient basis in a hospital but that can also be safely performed in an ASC, a CAH, or an HOPD, and to review and update the list of ASC covered surgical procedures at least every 2 years. We evaluate the ASC covered procedures list (ASC CPL) each year to determine whether procedures should be added to or removed from the list, and changes to the list are often made in response to specific concerns raised by interested parties.

Under our regulations at §§ 416.2 and 416.166, covered surgical procedures furnished on or after January 1, 2022, are surgical procedures that meet the general standards specified in § 416.166(b) and are not excluded under the general exclusion criteria specified in § 416.166(c). Specifically, under § 416.166(b), the general standards provide that covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the Internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure.

Section 416.166(c) sets out the general exclusion criteria used under the ASC payment system to evaluate the safety of procedures for performance in an ASC. The general exclusion criteria provide that covered surgical procedures do not include those surgical procedures that: (1) generally result in extensive blood loss; (2) require major or prolonged invasion of body cavities; (3) directly involve major blood vessels; (4) are generally emergent or life-threatening

in nature; (5) commonly require systemic thrombolytic therapy; (6) are designated as requiring inpatient care under § 419.22(n); (7) can only be reported using a CPT unlisted surgical procedure code; or (8) are otherwise excluded under § 411.15.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59029 through 59030), we defined a surgical procedure under the ASC payment system as any procedure described within the range of Category I CPT codes that the CPT Editorial Panel of the AMA defines as ''surgery'' (CPT codes 10000 through 69999) (72 FR 42476), as well as procedures that are described by Level II HCPCS codes or by Category I CPT codes or by Category III CPT codes that directly crosswalk or are clinically similar to procedures in the CPT surgical range that we determined met the general standards established in previous years for addition to the ASC CPL.

For a detailed discussion of the history of our policies for adding surgical procedures to the ASC CPL, we refer readers to the CY 2021 through CY 2025 OPPS/ASC final rules with comment period (85 FR 86143 through 86145; 86 FR 63777 through 63805; 87 FR 72068 through 72076; 88 FR 81923 through 81945; and 89 FR 94331 through 94334).

2. Proposed Changes to the List of ASC Covered Surgical Procedures for CY 2026

Historically, we have reviewed the clinical characteristics of procedures and consulted with appropriate medical organizations, other interested parties, and our clinical advisors to determine if those procedures would meet our existing regulatory criteria under 42 CFR 416.2 and 42 CFR 416.166.

In the CY 2021 OPPS/ASC final rule with comment period, we significantly revised our policy for adding surgical procedures to the ASC CPL to provide that the general exclusion and general standard criteria that we used to identify covered surgical procedures would be safety factors for physicians to consider for a specific beneficiary when determining whether to perform a covered surgical procedure (85 FR 86143 through 86153). We also stated that we would add surgical procedures when we identified a surgical procedure that met general standards criteria or

when we were notified of a surgical procedure that could meet general standards criteria and we confirmed that the procedure met those requirements.

In the CY 2022 OPPS/ASC final rule with comment period, we reinstated the general standard and general exclusion criteria as part of the review process, rather than safety factors for physicians to consider, and renamed the notifications process finalized in the CY 2021 rule as a nominations process, later re-named the "Pre-Proposed Rule CPL Recommendation Process" (86 FR 63776 through 63782). Under this process, which became effective in CY 2024, an external party can recommend a surgical procedure by March 1 of a calendar year for the list of ASC covered surgical procedures for the following calendar year. As a result of the reinstatement of the general standard and general exclusion criteria, we finalized the removal of 255 procedures that had been added to the ASC CPL in CY 2021. We also maintained these criteria and the Pre-Proposed Rule CPL Recommendation Process during the CY 2023 through CY 2025 rulemaking cycles.

In the CY 2022 OPPS/ASC final rule with comment period, commenters were largely split on the issue of reinstating the general standard and general exclusion criteria at § 416.166 that were in place prior to CY 2021. Many commenters opposed this proposal and recommended that CMS not re-adopt these criteria. Commenters contended that this policy may substitute administrative criteria for physician clinical judgment, reduce beneficiary choice, and increase costs since the lack of payment in the ASC setting may push these procedures to be performed in the higher-cost hospital setting.

For CY 2026, we propose to revise our regulatory criteria at 42 CFR 416.166 to evaluate potential additions to the ASC CPL, similar to the changes we finalized in the CY 2021 OPPS/ASC final rule with comment period. Specifically, we propose to revise our regulatory criteria by removing certain general standard and general exclusion criteria at 42 CFR 416.166(b) and (c), moving them to a new section as nonbinding physician considerations for patient safety. Under the revised criteria, we propose to add certain surgical procedures to the

ASC CPL, beginning in CY 2026, in order to expand access, while maintaining the safety for Medicare beneficiaries through the nonbinding physician considerations for patient safety.

a. ASC CPL Review Process for CY 2026

(1) Proposed Changes to General Standards and Exclusion Criteria for CY 2026

For CY 2026, we are continuing to build on our efforts to maximize patient and physician choice and access to care by exploring broader approaches to adding procedures to the ASC CPL in order to further increase the availability of ASCs as an alternative and often lower cost site of care for Medicare beneficiaries. An expansion of the ASC CPL would maximize the ability of ASCs to divert patients that can be safely treated in an ASC setting away from the hospital setting, which would preserve the capacity of hospitals to treat more acute patients. Expanding the procedures placed on the ASC CPL would also build on the policy changes we have made in recent years to further site neutrality between the HOPD and ASC settings.

In light of these objectives, we propose to modify the existing general standard criteria under 42 CFR 416.166(b) that currently require covered surgical procedures to be surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website, separately paid under the OPPS, not expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to require active medical monitoring and care at midnight following the procedure. We would retain the condition that procedures be separately paid under the OPPS and move the latter two standards to a new section outlining possible physician considerations in making site-of-service decisions.

We also propose to eliminate five of the current general exclusion criteria at 42 CFR 416.166(c)(1) through (c)(5) and move them to the new physician considerations section. We believe these five exclusionary criteria may no longer be necessary to determine what procedures can be safely added to the ASC CPL because many ASCs are currently able to safely provide services with these characteristics, based on prior interested parties' feedback and public

comments we have received. This would also allow physicians practicing in the ASC setting, who have the greatest familiarity and insight into the needs of individual beneficiaries, to use their complex medical judgement to determine whether they can safely perform a procedure in the ASC, given the entirety of the circumstances, including the clinical profile of the patient, the surgical back-up available at the ASC, and the ability to safely and timely respond to unexpected complications.

Under this proposal, we would keep the remaining three general exclusion criteria at 42 CFR 416.166(c)(6) through (c)(8) because the original reasons we adopted them in CY 2008 continue to exist, subject to the proposed modifications to 416.166(c)(6). These criteria would continue to exclude certain procedures from the ASC CPL, namely those that are designated as requiring inpatient care under 42 CFR 419.22(n), can only be reported using a CPT unlisted surgical procedure code, or are otherwise excluded under 42 CFR 411.15. We believe that these proposed criteria are sufficient guardrails to ensure, along with appropriate patient selection and complex medical judgement of the physician, that the procedure can be performed safely on an ambulatory basis, including procedures that involve these five currently excluded characteristics. We believe that this proposal could advance the goals of increasing physician and patient choice and expanding site neutral options in conjunction with patient safety considerations.

With respect to the existing general exclusion at 42 CFR 416.166(c)(6), which excludes procedures designated as requiring inpatient care under 42 CFR 419.22(n) from classification as covered surgical procedures, this proposal would modify this standard since the IPO list is proposed for elimination beginning in CY 2026 with a 3-year transition period, as described in section IX. of this proposed rule. While we recognize the need to revisit the criterion at 42 CFR 416.166(c)(6) following the elimination of the IPO list, we believe that maintaining this criterion for CY 2026 would allow for consistency between the two lists during the 3-year phaseout period. We note that if a service comes off the IPO list at any time, then the general exclusion at 42 CFR 416.166(c)(6) would cease to apply to the service.

We acknowledge that this approach is a departure from the existing criteria that we established effective beginning in 2008, and from our policy finalized in the CY 2022 OPPS/ASC rule. However, we believe that this approach would expand and build upon our 2008 policy intent. Although there are some differences when comparing our CY 2008 criteria and the proposed CY 2026 criteria, such as removing the general standards and several of the original general exclusion criteria, permitting the addition of procedures to the ASC CPL that would have been prohibited by those criteria, and the different accreditation requirements and conditions of participation requirements between HOPDs and ASCs, these concerns have largely been addressed by the progress in medical practice and ASC capabilities in the 17 years since the criteria were developed as previously noted. In particular, given advances in the practice of medicine and the evolving nature of ASCs, we believe ASCs are now better equipped to safely perform procedures that were once too complex or risky to be performed safely on Medicare beneficiaries in the ASC setting. As previously mentioned, although ASCs and hospitals have different health and safety requirements, many ASCs often undergo accreditation as a condition of state licensure and share some similar licensure and compliance requirements with hospitals. Each of these requirements provides additional safeguards for the health and safety of Medicare beneficiaries receiving surgical procedures in an ASC. Additionally, in the CY 2022 OPPS/ASC final rule with comment period, when we reinstated the ASC CPL criteria that were in effect during CY 2020, we stated that many of the surgical procedures added to the list in CY 2021 may pose a significant safety risk to a typical Medicare beneficiary when performed in an ASC (86 FR 63777). However, we believe that these procedures are safe to perform in an ASC setting because all procedures identified are already payable in the HOPD setting and, therefore, are already safely performed on an ambulatory basis, consistent with the statutory requirement under section 1833(i)(1) of the Act. In addition, while several of the identified procedures may typically require hospital care that lasts beyond midnight, we expect that appropriately selected

patient populations in the ASC setting would be healthier and less complex and would likely not require active monitoring or medical care past midnight beyond the procedure.

(2) Proposed Review Process

CMS will add surgical procedures to the ASC CPL in rulemaking as we become aware of new surgical procedures that meet the four requirements at § 416.166(b)(2). A member of the public may also notify CMS of a surgical procedure they believe meets the requirements at new § 416.166(b)(2) through the pre-proposed rule recommendation process or the public comment period. CMS will confirm whether the procedure does meet those requirements and will add it to the ASC CPL if it does meet that criteria. In accordance with the new proposed regulatory text at § 416.166(d), physicians would then assess whether their specific patients can or cannot safely receive such covered surgical procedure in the ASC setting based on patient-specific considerations.

b. Proposed Procedure Additions for CY 2026

For CY 2026, we proposed to update the ASC CPL by adding 276 potential surgery or surgery-like codes to the list that we believe would meet the proposed revised ASC CPL criteria under 42 CFR 416.166. This includes procedures submitted through our pre-proposed rule nominations process for addition to the ASC CPL under the proposed revised criteria.

c. Summary of Proposals

For CY 2026, we propose to revise the ASC CPL criteria under 42 CFR 416.166, modifying the general standard criteria and eliminating five of the general exclusion criteria. Using these revised criteria, we propose to add approximately 276 potential surgery or surgery-like codes to the CPL that are not on the CY 2025 IPO list. Additionally, we propose to add 271 surgery or surgery-like codes to the CPL that are currently on the IPO list, if we finalize our proposal to remove these services from the IPO list for CY 2026. These codes, along with their long descriptors and proposed payment indicator assignments, are listed in Tables 80 and 81. We believe that these proposed policies will increase the flexibility for physicians to exercise their

complex medical judgment, factoring in patient safety considerations, and for patients to choose from more settings of care in which to receive surgical procedures.

TABLE 80: PROPOSED ADDITIONS TO THE LIST OF ASC COVERED PROCEDURES FOR CY 2026

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
20100	Exploration of penetrating wound (separate procedure); neck	G2
20101	Exploration of penetrating wound (separate procedure); chest	G2
20102	Exploration of penetrating wound (separate procedure); abdomen/flank/back	G2
20660	Application of cranial tongs, caliper, or stereotactic frame, including removal (separate procedure)	G2
21049	Excision of benign tumor or cyst of maxilla; requiring extra-oral osteotomy and partial maxillectomy (eg, locally aggressive or destructive lesion[s])	G2
21141	Reconstruction midface, lefort i; single piece, segment movement in any direction (eg, for long face syndrome), without bone graft	G2
21142	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, without bone graft	J8
21143	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, without bone graft	G2
21172	Reconstruction superior-lateral orbital rim and lower forehead, advancement or alteration, with or without grafts (includes obtaining autografts)	G2
21175	Reconstruction, bifrontal, superior-lateral orbital rims and lower forehead, advancement or alteration (eg, plagiocephaly, trigonocephaly, brachycephaly), with or without grafts (includes obtaining autografts)	G2
21193	Reconstruction of mandibular rami, horizontal, vertical, c, or l osteotomy; without bone graft	G2
21196	Reconstruction of mandibular rami and/or body, sagittal split; with internal rigid fixation	G2
21255	Reconstruction of zygomatic arch and glenoid fossa with bone and cartilage (includes obtaining autografts)	J8
21256	Reconstruction of orbit with osteotomies (extracranial) and with bone grafts (includes obtaining autografts) (eg, micro-ophthalmia)	J8
21261	Periorbital osteotomies for orbital hypertelorism, with bone grafts; combined intra- and extracranial approach	G2
21263	Periorbital osteotomies for orbital hypertelorism, with bone grafts; with forehead advancement	G2
21346	Open treatment of nasomaxillary complex fracture (lefort ii type); with wiring and/or local fixation	G2
21347	Open treatment of nasomaxillary complex fracture (lefort ii type); requiring multiple open approaches	J8
21366	Open treatment of complicated (eg, comminuted or involving cranial nerve foramina) fracture(s) of malar area, including zygomatic arch and malar tripod; with bone grafting (includes obtaining graft)	G2
21385	Open treatment of orbital floor blowout fracture; transantral approach (caldwell-luc type operation)	G2
21386	Open treatment of orbital floor blowout fracture; periorbital approach	G2
21387	Open treatment of orbital floor blowout fracture; combined approach	G2
21395	Open treatment of orbital floor blowout fracture; periorbital approach with bone graft (includes obtaining graft)	G2
21408	Open treatment of fracture of orbit, except blowout; with bone grafting (includes obtaining graft)	G2
21422	Open treatment of palatal or maxillary fracture (lefort i type);	J8
21470	Open treatment of complicated mandibular fracture by multiple surgical approaches including internal fixation, interdental fixation, and/or wiring of dentures or splints	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
21601	Excision of chest wall tumor including rib(s)	G2
21742	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), without thoracoscopy	G2
21743	Reconstructive repair of pectus excavatum or carinatum; minimally invasive approach (nuss procedure), with thoracoscopy	G2
22100	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; cervical	G2
22101	Partial excision of posterior vertebral component (eg, spinous process, lamina or facet) for intrinsic bony lesion, single vertebral segment; thoracic	G2
22630	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar;	J8
22632	Arthrodesis, posterior interbody technique, including laminectomy and/or discectomy to prepare interspace (other than for decompression), single interspace, lumbar; each additional interspace (list separately in addition to code for primary procedure)	N1
22633	Arthrodesis, combined posterior or posterolateral technique with posterior interbody technique including laminectomy and/or discectomy sufficient to prepare interspace (other than for decompression), single interspace, lumbar;	J8
22848	Pelvic fixation (attachment of caudal end of instrumentation to pelvic bony structures) other than sacrum (list separately in addition to code for primary procedure)	N1
23473	Revision of total shoulder arthroplasty, including allograft when performed; humeral or glenoid component	J8
24150	Radical resection of tumor, shaft or distal humerus	J8
24935	Stump elongation, upper extremity	G2
25170	Radical resection of tumor, radius or ulna	G2
25909	Amputation, forearm, through radius and ulna; re-amputation	G2
27027	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle), unilateral	G2
27057	Decompression fasciotomy(ies), pelvic (buttock) compartment(s) (eg, gluteus medius-minimus, gluteus maximus, iliopsoas, and/or tensor fascia lata muscle) with debridement of nonviable muscle, unilateral	J8
27179	Open treatment of slipped femoral epiphysis; osteoplasty of femoral neck (heyman type procedure)	G2
27235	Percutaneous skeletal fixation of femoral fracture, proximal end, neck	G2
27477	Arrest, epiphyseal, any method (eg, epiphysiodesis); tibia and fibula, proximal	J8
27485	Arrest, hemiepiphyseal, distal femur or proximal tibia or fibula (eg, genu varus or valgus)	G2
27722	Repair of nonunion or malunion, tibia; with sliding graft	J8
28360	Reconstruction, cleft foot	G2
28805	Amputation, foot; transmetatarsal	G2
31241	Nasal/sinus endoscopy, surgical; with ligation of sphenopalatine artery	G2
31292	Nasal/sinus endoscopy, surgical, with orbital decompression; medial or inferior wall	G2
31293	Nasal/sinus endoscopy, surgical, with orbital decompression; medial and inferior wall	G2
31294	Nasal/sinus endoscopy, surgical, with optic nerve decompression	G2
31584	Laryngoplasty; with open reduction and fixation of (eg, plating) fracture, includes tracheostomy, if performed	G2
31587	Laryngoplasty, cricoid split, without graft placement	G2
31600	Tracheostomy, planned (separate procedure);	G2
31601	Tracheostomy, planned (separate procedure); younger than 2 years	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
31610	Tracheostomy, fenestration procedure with skin flaps	G2
31660	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 1 lobe	J8
31661	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes	J8
31785	Excision of tracheal tumor or carcinoma; cervical	G2
32551	Tube thoracostomy, includes connection to drainage system (eg, water seal), when performed, open (separate procedure)	G2
32560	Instillation, via chest tube/catheter, agent for pleurodesis (eg, talc for recurrent or persistent pneumothorax)	G2
32561	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); initial day	G2
32562	Instillation(s), via chest tube/catheter, agent for fibrinolysis (eg, fibrinolytic agent for break up of multiloculated effusion); subsequent day	G2
32601	Thoracoscopy, diagnostic (separate procedure); lungs, pericardial sac, mediastinal or pleural space, without biopsy	G2
32604	Thoracoscopy, diagnostic (separate procedure); pericardial sac, with biopsy	G2
32606	Thoracoscopy, diagnostic (separate procedure); mediastinal space, with biopsy	G2
32607	Thoracoscopy; with diagnostic biopsy(ies) of lung infiltrate(s) (eg, wedge, incisional), unilateral	G2
32608	Thoracoscopy; with diagnostic biopsy(ies) of lung nodule(s) or mass(es) (eg, wedge, incisional), unilateral	G2
32609	Thoracoscopy; with biopsy(ies) of pleura	G2
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction	G2
33272	Removal of subcutaneous implantable defibrillator electrode	G2
34101	Embolectomy or thrombectomy, with or without catheter; axillary, brachial, innominate, subclavian artery, by arm incision	G2
34111	Embolectomy or thrombectomy, with or without catheter; radial or ulnar artery, by arm incision	G2
34201	Embolectomy or thrombectomy, with or without catheter; femoropopliteal, aortoiliac artery, by leg incision	J8
34203	Embolectomy or thrombectomy, with or without catheter; popliteal-tibio-peroneal artery, by leg incision	J8
34421	Thrombectomy, direct or with catheter; vena cava, iliac, femoropopliteal vein, by leg incision	J8
34471	Thrombectomy, direct or with catheter; subclavian vein, by neck incision	G2
34501	Valvuloplasty, femoral vein	G2
34510	Venous valve transposition, any vein donor	G2
34520	Cross-over vein graft to venous system	G2
34530	Saphenopopliteal vein anastomosis	G2
35011	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm and associated occlusive disease, axillary-brachial artery, by arm incision	G2
35045	Direct repair of aneurysm, pseudoaneurysm, or excision (partial or total) and graft insertion, with or without patch graft; for aneurysm, pseudoaneurysm, and associated occlusive disease, radial or ulnar artery	G2
35180	Repair, congenital arteriovenous fistula; head and neck	G2
35184	Repair, congenital arteriovenous fistula; extremities	G2
35190	Repair, acquired or traumatic arteriovenous fistula; extremities	G2
35201	Repair blood vessel, direct; neck	G2
35206	Repair blood vessel, direct; upper extremity	G2
35226	Repair blood vessel, direct; lower extremity	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
35231	Repair blood vessel with vein graft; neck	G2
35236	Repair blood vessel with vein graft; upper extremity	G2
35256	Repair blood vessel with vein graft; lower extremity	G2
35261	Repair blood vessel with graft other than vein; neck	G2
35266	Repair blood vessel with graft other than vein; upper extremity	G2
35286	Repair blood vessel with graft other than vein; lower extremity	G2
35321	Thromboendarterectomy, including patch graft, if performed; axillary-brachial	G2
35860	Exploration for postoperative hemorrhage, thrombosis or infection; extremity	G2
35879	Revision, lower extremity arterial bypass, without thrombectomy, open; with vein patch angioplasty	G2
35881	Revision, lower extremity arterial bypass, without thrombectomy, open; with segmental vein interposition	J8
35883	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with nonautogenous patch graft (eg, polyester, eptfe, bovine pericardium)	G2
35884	Revision, femoral anastomosis of synthetic arterial bypass graft in groin, open; with autogenous vein patch graft	G2
35903	Excision of infected graft; extremity	G2
36460	Transfusion, intrauterine, fetal	G2
36838	Distal revascularization and interval ligation (dril), upper extremity hemodialysis access (steal syndrome)	G2
37183	Revision of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract recannulization/dilatation, stent placement and all associated imaging guidance and documentation)	J8
37191	Insertion of intravascular vena cava filter, endovascular approach including vascular access, vessel selection, and radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance (ultrasound and fluoroscopy), when performed	J8
37195	Thrombolysis, cerebral, by intravenous infusion	G2
37213	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed;	J8
37214	Transcatheter therapy, arterial or venous infusion for thrombolysis other than coronary, any method, including radiological supervision and interpretation, continued treatment on subsequent day during course of thrombolytic therapy, including follow-up catheter contrast injection, position change, or exchange, when performed; cessation of thrombolysis including removal of catheter and vessel closure by any method	G2
37244	Vascular embolization or occlusion, inclusive of all radiological supervision and interpretation, intraprocedural roadmapping, and imaging guidance necessary to complete the intervention; for arterial or venous hemorrhage or lymphatic extravasation	G2
37565	Ligation, internal jugular vein	G2
37600	Ligation; external carotid artery	G2
37605	Ligation; internal or common carotid artery	G2
37606	Ligation; internal or common carotid artery, with gradual occlusion, as with selverstone or crutchfield clamp	G2
37615	Ligation, major artery (eg, post-traumatic, rupture); neck	G2
37619	Ligation of inferior vena cava	G2
38120	Laparoscopy, surgical, splenectomy	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
38207	Transplant preparation of hematopoietic progenitor cells; cryopreservation and storage	G2
38208	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, without washing, per donor	G2
38209	Transplant preparation of hematopoietic progenitor cells; thawing of previously frozen harvest, with washing, per donor	G2
38210	Transplant preparation of hematopoietic progenitor cells; specific cell depletion within harvest, t-cell depletion	G2
38211	Transplant preparation of hematopoietic progenitor cells; tumor cell depletion	G2
38212	Transplant preparation of hematopoietic progenitor cells; red blood cell removal	G2
38213	Transplant preparation of hematopoietic progenitor cells; platelet depletion	G2
38214	Transplant preparation of hematopoietic progenitor cells; plasma (volume) depletion	G2
38215	Transplant preparation of hematopoietic progenitor cells; cell concentration in plasma, mononuclear, or buffy coat layer	G2
38240	Hematopoietic progenitor cell (hpc); allogeneic transplantation per donor	G2
38720	Cervical lymphadenectomy (complete)	G2
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed	G2
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	G2
42842	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; without closure	G2
42844	Radical resection of tonsil, tonsillar pillars, and/or retromolar trigone; closure with local flap (eg, tongue, buccal)	G2
43020	Esophagotomy, cervical approach, with removal of foreign body	G2
43280	Laparoscopy, surgical, esophagogastric fundoplasty (eg, nissen, toupet procedures)	G2
43281	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; without implantation of mesh	G2
43282	Laparoscopy, surgical, repair of paraesophageal hernia, includes fundoplasty, when performed; with implantation of mesh	G2
43420	Closure of esophagostomy or fistula; cervical approach	G2
43497	Lower esophageal myotomy, transoral (ie, peroral endoscopic myotomy [poem])	G2
43510	Gastrotomy; with esophageal dilation and insertion of permanent intraluminal tube (eg, celestin or mousseaux-barbin)	G2
43647	Laparoscopy, surgical; implantation or replacement of gastric neurostimulator electrodes, antrum	J8
43648	Laparoscopy, surgical; revision or removal of gastric neurostimulator electrodes, antrum	G2
43651	Laparoscopy, surgical; transection of vagus nerves, truncal	G2
43652	Laparoscopy, surgical; transection of vagus nerves, selective or highly selective	G2
43770	Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric restrictive device (eg, gastric band and subcutaneous port components)	J8
43772	Laparoscopy, surgical, gastric restrictive procedure; removal of adjustable gastric restrictive device component only	G2
43773	Laparoscopy, surgical, gastric restrictive procedure; removal and replacement of adjustable gastric restrictive device component only	G2
43830	Gastrostomy, open; without construction of gastric tube (eg, stamm procedure) (separate procedure)	G2
43831	Gastrostomy, open; neonatal, for feeding	G2
44180	Laparoscopy, surgical, enterolysis (freeing of intestinal adhesion) (separate procedure)	G2
44186	Laparoscopy, surgical; jejunostomy (eg, for decompression or feeding)	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
44950	Appendectomy;	G2
44955	Appendectomy; when done for indicated purpose at time of other major procedure (not as separate procedure) (list separately in addition to code for primary procedure)	N1
44970	Laparoscopy, surgical, appendectomy	G2
47370	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); radiofrequency	G2
47371	Laparoscopy, surgical, ablation of 1 or more liver tumor(s); cryosurgical	G2
47490	Cholecystostomy, percutaneous, complete procedure, including imaging guidance, catheter placement, cholecystogram when performed, and radiological supervision and interpretation	G2
47550	Biliary endoscopy, intraoperative (choledochoscopy) (list separately in addition to code for primary procedure)	N1
49185	Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (eg, ultrasound, fluoroscopy) and radiological supervision and interpretation when performed	G2
49323	Laparoscopy, surgical; with drainage of lymphocele to peritoneal cavity	G2
49405	Image-guided fluid collection drainage by catheter (eg, abscess, hematoma, seroma, lymphocele, cyst); visceral (eg, kidney, liver, spleen, lung/mediastinum), percutaneous	G2
49491	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; reducible	G2
49492	Repair, initial inguinal hernia, preterm infant (younger than 37 weeks gestation at birth), performed from birth up to 50 weeks postconception age, with or without hydrocelectomy; incarcerated or strangulated	G2
50020	Drainage of perirenal or renal abscess, open	G2
50541	Laparoscopy, surgical; ablation of renal cysts	G2
50542	Laparoscopy, surgical; ablation of renal mass lesion(s), including intraoperative ultrasound guidance and monitoring, when performed	G2
50543	Laparoscopy, surgical; partial nephrectomy	G2
50544	Laparoscopy, surgical; pyeloplasty	G2
50945	Laparoscopy, surgical; ureterolithotomy	G2
51060	Transvesical ureterolithotomy	G2
51845	Abdomino-vaginal vesical neck suspension, with or without endoscopic control (eg, stamey, raz, modified pereyra)	G2
51860	Cystorrhaphy, suture of bladder wound, injury or rupture; simple	G2
51990	Laparoscopy, surgical; urethral suspension for stress incontinence	G2
53500	Urethrolysis, transvaginal, secondary, open, including cystourethroscopy (eg, postsurgical obstruction, scarring)	G2
54332	1-stage proximal penile or penoscrotal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54336	1-stage perineal hypospadias repair requiring extensive dissection to correct chordee and urethroplasty by use of skin graft tube and/or island flap	G2
54411	Removal and replacement of all components of a multi-component inflatable penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54417	Removal and replacement of non-inflatable (semi-rigid) or inflatable (self-contained) penile prosthesis through an infected field at the same operative session, including irrigation and debridement of infected tissue	J8
54535	Orchiectomy, radical, for tumor; with abdominal exploration	G2
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
55867	Laparoscopy, surgical prostatectomy, simple subtotal (including control of postoperative bleeding, vasectomy, meatotomy, urethral calibration and/or dilation, and internal urethrotomy), includes robotic assistance, when performed	G2
57106	Vaginectomy, partial removal of vaginal wall;	G2
57107	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy)	G2
57109	Vaginectomy, partial removal of vaginal wall; with removal of paravaginal tissue (radical vaginectomy) with bilateral total pelvic lymphadenectomy and para-aortic lymph node sampling (biopsy)	G2
57284	Paravaginal defect repair (including repair of cystocele, if performed); open abdominal approach	J8
57285	Paravaginal defect repair (including repair of cystocele, if performed); vaginal approach	G2
57292	Construction of artificial vagina; with graft	G2
57330	Closure of vesicovaginal fistula; transvesical and vaginal approach	G2
57423	Paravaginal defect repair (including repair of cystocele, if performed), laparoscopic approach	G2
57555	Excision of cervical stump, vaginal approach; with anterior and/or posterior repair	G2
58263	Vaginal hysterectomy, for uterus 250 g or less; with removal of tube(s), and/or ovary(s), with repair of enterocele	G2
58270	Vaginal hysterectomy, for uterus 250 g or less; with repair of enterocele	G2
58290	Vaginal hysterectomy, for uterus greater than 250 g;	G2
58291	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s)	G2
58292	Vaginal hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s), with repair of enterocele	G2
58294	Vaginal hysterectomy, for uterus greater than 250 g; with repair of enterocele	G2
58770	Salpingostomy (salpingoneostomy)	G2
58920	Wedge resection or bisection of ovary, unilateral or bilateral	G2
58925	Ovarian cystectomy, unilateral or bilateral	G2
59030	Fetal scalp blood sampling	G2
59409	Vaginal delivery only (with or without episiotomy and/or forceps);	G2
59612	Vaginal delivery only, after previous cesarean delivery (with or without episiotomy and/or forceps);	G2
60252	Thyroidectomy, total or subtotal for malignancy; with limited neck dissection	G2
60271	Thyroidectomy, including substernal thyroid; cervical approach	G2
60502	Parathyroidectomy or exploration of parathyroid(s); re-exploration	G2
60520	Thymectomy, partial or total; transcervical approach (separate procedure)	G2
61623	Endovascular temporary balloon arterial occlusion, head or neck (extracranial/intracranial) including selective catheterization of vessel to be occluded, positioning and inflation of occlusion balloon, concomitant neurological monitoring, and radiologic supervision and interpretation of all angiography required for balloon occlusion and to exclude vascular injury post occlusion	J8
61626	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; non-central nervous system, head or neck (extracranial, brachiocephalic branch)	J8
61720	Creation of lesion by stereotactic method, including burr hole(s) and localizing and recording techniques, single or multiple stages; globus pallidus or thalamus	G2
61891	Revision or replacement of skull-mounted cranial neurostimulator pulse generator or receiver with connection to depth and/or cortical strip electrode array(s)	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
61892	Removal of skull-mounted cranial neurostimulator pulse generator or receiver with cranioplasty, when performed	G2
62000	Elevation of depressed skull fracture; simple, extradural	G2
62351	Implantation, revision or repositioning of tunneled intrathecal or epidural catheter, for long-term medication administration via an external pump or implantable reservoir/infusion pump; with laminectomy	J8
63011	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), 1 or 2 vertebral segments; sacral	G2
63012	Laminectomy with removal of abnormal facets and/or pars inter-articularis with decompression of cauda equina and nerve roots for spondylolisthesis, lumbar (gill type procedure)	G2
63015	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; cervical	G2
63016	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; thoracic	G2
63017	Laminectomy with exploration and/or decompression of spinal cord and/or cauda equina, without facetectomy, foraminotomy or discectomy (eg, spinal stenosis), more than 2 vertebral segments; lumbar	G2
63035	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc; each additional interspace, cervical or lumbar (list separately in addition to code for primary procedure)	N1
63040	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; cervical	G2
63043	Laminotomy (hemilaminectomy), with decompression of nerve root(s), including partial facetectomy, foraminotomy and/or excision of herniated intervertebral disc, reexploration, single interspace; each additional cervical interspace (list separately in addition to code for primary procedure)	N1
63048	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; each additional vertebral segment, cervical, thoracic, or lumbar (list separately in addition to code for primary procedure)	N1
63057	Transpedicular approach with decompression of spinal cord, equina and/or nerve root(s) (eg, herniated intervertebral disc), single segment; each additional segment, thoracic or lumbar (list separately in addition to code for primary procedure)	N1
63064	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; single segment	G2
63066	Costovertebral approach with decompression of spinal cord or nerve root(s) (eg, herniated intervertebral disc), thoracic; each additional segment (list separately in addition to code for primary procedure)	N1
63075	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, single interspace	G2
63076	Discectomy, anterior, with decompression of spinal cord and/or nerve root(s), including osteophytectomy; cervical, each additional interspace (list separately in addition to code for primary procedure)	N1
63265	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; cervical	G2
63266	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; thoracic	G2
63267	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; lumbar	G2
63268	Laminectomy for excision or evacuation of intraspinal lesion other than neoplasm, extradural; sacral	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
63741	Creation of shunt, lumbar, subarachnoid-peritoneal, -pleural, or other; percutaneous, not requiring laminectomy	J8
64804	Sympathectomy, cervicothoracic	G2
64911	Nerve repair; with autogenous vein graft (includes harvest of vein graft), each nerve	J8
69725	Decompression facial nerve, intratemporal; including medial to geniculate ganglion	G2
69955	Total facial nerve decompression and/or repair (may include graft)	G2
69960	Decompression internal auditory canal	G2
69970	Removal of tumor, temporal bone	G2
93650	Intracardiac catheter ablation of atrioventricular node function, atrioventricular conduction for creation of complete heart block, with or without temporary pacemaker placement	J8
93653	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of supraventricular tachycardia by ablation of fast or slow atrioventricular pathway, accessory atrioventricular connection, cavo-tricuspid isthmus or other single atrial focus or source of atrial re-entry	J8
93654	Comprehensive electrophysiologic evaluation with insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia with right atrial pacing and recording and catheter ablation of arrhythmogenic focus, including intracardiac electrophysiologic 3-dimensional mapping, right ventricular pacing and recording, left atrial pacing and recording from coronary sinus or left atrium, and his bundle recording, when performed; with treatment of ventricular tachycardia or focus of ventricular ectopy including left ventricular pacing and recording, when performed	J8
93655	Intracardiac catheter ablation of a discrete mechanism of arrhythmia which is distinct from the primary ablated mechanism, including repeat diagnostic maneuvers, to treat a spontaneous or induced arrhythmia (list separately in addition to code for primary procedure)	N1
93656	Comprehensive electrophysiologic evaluation with transseptal catheterizations, insertion and repositioning of multiple electrode catheters, induction or attempted induction of an arrhythmia including left or right atrial pacing/recording, and intracardiac catheter ablation of atrial fibrillation by pulmonary vein isolation, including intracardiac electrophysiologic 3-dimensional mapping, intracardiac echocardiography with imaging supervision and interpretation, right ventricular pacing/recording, and his bundle recording, when performed	J8
93657	Additional linear or focal intracardiac catheter ablation of the left or right atrium for treatment of atrial fibrillation remaining after completion of pulmonary vein isolation (list separately in addition to code for primary procedure)	N1
0184T	Excision of rectal tumor, transanal endoscopic microsurgical approach (ie, tems), including muscularis propria (ie, full thickness)	G2
0221T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; lumbar	G2
0222T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; each additional vertebral segment (list separately in addition to code for primary procedure)	N1
0505T	Endovenous femoral-popliteal arterial revascularization, with transcatheter placement of intravascular stent graft(s) and closure by any method, including percutaneous or open vascular access, ultrasound guidance for vascular access	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
	when performed, all catheterization(s) and intraprocedural roadmapping and imaging guidance necessary to complete the intervention, all associated radiological supervision and interpretation, when performed, with crossing of the occlusive lesion in an extraluminal fashion	
0515T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; complete system (includes electrode and generator [transmitter and battery])	G2
0516T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; electrode only	G2
0517T	Insertion of wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming, and imaging supervision and interpretation, when performed; both components of pulse generator (battery and transmitter) only	G2
0518T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; battery component only	G2
0519T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; both components (battery and transmitter)	G2
0520T	Removal and replacement of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	J8
0645T	Transcatheter implantation of coronary sinus reduction device including vascular access and closure, right heart catheterization, venous angiography, coronary sinus angiography, imaging guidance, and supervision and interpretation, when performed	G2
0692T	Therapeutic ultrafiltration	G2
0744T	Insertion of bioprosthetic valve, open, femoral vein, including duplex ultrasound imaging guidance, when performed, including autogenous or nonautogenous patch graft (eg, polyester, eptfe, bovine pericardium), when performed	G2
0861T	Removal of pulse generator for wireless cardiac stimulator for left ventricular pacing; both components (battery and transmitter)	G2
0862T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; battery component only	G2
0863T	Relocation of pulse generator for wireless cardiac stimulator for left ventricular pacing, including device interrogation and programming; transmitter component only	G2
C9602	Percutaneous transluminal coronary atherectomy, with drug eluting intracoronary stent, with coronary angioplasty when performed; single major coronary artery or branch	J8
C9603	Percutaneous transluminal coronary atherectomy, with drug-eluting intracoronary stent, with coronary angioplasty when performed; each additional branch of a major coronary artery (list separately in addition to code for primary procedure)	N1
C9604	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; single vessel	J8
C9605	Percutaneous transluminal revascularization of or through coronary artery bypass graft (internal mammary, free arterial, venous), any combination of drug-eluting intracoronary stent, atherectomy and angioplasty, including distal protection when performed; each additional branch subtended by the bypass graft (list separately in addition to code for primary procedure)	N1
C9607	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; single vessel	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
C9608	Percutaneous transluminal revascularization of chronic total occlusion, coronary artery, coronary artery branch, or coronary artery bypass graft, any combination of drug-eluting intracoronary stent, atherectomy and angioplasty; each additional coronary artery, coronary artery branch, or bypass graft (list separately in addition to code for primary procedure)	N1
C9760	Non-randomized, non-blinded procedure for nyha class ii, iii, iv heart failure; transcatheter implantation of interatrial shunt, including right and left heart catheterization, transeptal puncture, trans-esophageal echocardiography (tee)/intracardiac echocardiography (ice), and all imaging with or without guidance (e.g., ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	G2
C9779	Endoscopic submucosal dissection (esd), including endoscopy or colonoscopy, mucosal closure, when performed	G2
C9780	Insertion of central venous catheter through central venous occlusion via inferior and superior approaches (e.g., inside-out technique), including imaging guidance	J8
C9782	Blinded procedure for new york heart association (nyha) class ii or iii heart failure, or canadian cardiovascular society (ccs) class iii or iv chronic refractory angina; transcatheter intramyocardial transplantation of autologous bone marrow cells (e.g., mononuclear) or placebo control, autologous bone marrow harvesting and preparation for transplantation, left heart catheterization including ventriculography, all laboratory services, and all imaging with or without guidance (e.g., transthoracic echocardiography, ultrasound, fluoroscopy), performed in an approved investigational device exemption (ide) study	J8
C9783	Blinded procedure for transcatheter implantation of coronary sinus reduction device or placebo control, including vascular access and closure, right heart catheterization, venous and coronary sinus angiography, imaging guidance and supervision and interpretation when performed in an approved investigational device exemption (ide) study	J8
C9785	Endoscopic outlet reduction, gastric pouch application, with endoscopy and intraluminal tube insertion, if performed, including all system and tissue anchoring components	G2
C9792	Blinded or nonblinded procedure for symptomatic new york heart association (nyha) class ii, iii, iva heart failure; transcatheter implantation of left atrial to coronary sinus shunt using jugular vein access, including all imaging necessary to intra procedurally map the coronary sinus for optimal shunt placement (e.g., tee or ice ultrasound, fluoroscopy), performed under general anesthesia in an approved investigational device exemption (ide) study)	G2
C9901	Endoscopic defect closure within the entire gastrointestinal tract, including upper endoscopy (including diagnostic, if performed) or colonoscopy (including diagnostic, if performed), with all system and tissue anchoring components	G2
G0413	Percutaneous skeletal fixation of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, (includes ilium, sacroiliac joint and/or sacrum)	J8

TABLE 81: IPO LIST REMOVALS PROPOSED FOR ADDITION TO THE LIST OF ASC COVERED PROCEDURES FOR CY 2026

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
0095T	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N1

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
0098T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	N1
0164T	Removal of total disc arthroplasty, (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N1
0165T	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, lumbar (list separately in addition to code for primary procedure)	N1
0202T	Posterior vertebral joint(s) arthroplasty (eg, facet joint[s] replacement), including facetectomy, laminectomy, foraminotomy, and vertebral column fixation, injection of bone cement, when performed, including fluoroscopy, single level, lumbar spine	J8
0219T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; cervical	J8
0220T	Placement of a posterior intrafacet implant(s), unilateral or bilateral, including imaging and placement of bone graft(s) or synthetic device(s), single level; thoracic	J8
0656T	Anterior lumbar or thoracolumbar vertebral body tethering; up to 7 vertebral segments	J8
0657T	Anterior lumbar or thoracolumbar vertebral body tethering; 8 or more vertebral segments	J8
0790T	Revision (eg, augmentation, division of tether), replacement, or removal of thoracolumbar or lumbar vertebral body tethering, including thoracoscopy, when performed	J8
20661	Application of halo, including removal; cranial	J8
20664	Application of halo, including removal, cranial, 6 or more pins placed, for thin skull osteology (eg, pediatric patients, hydrocephalus, osteogenesis imperfecta)	J8
20802	Removal of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	J8
20805	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, each additional interspace, cervical (list separately in addition to code for primary procedure)	J8
20808	Anesthesia for interpelviabdominal (hindquarter) amputation	J8
20816	Replantation, digit, excluding thumb (includes metacarpophalangeal joint to insertion of flexor sublimis tendon), complete amputation	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
20824	Replantation, thumb (includes carpometacarpal joint to mp joint), complete amputation	J8
20827	Replantation, thumb (includes distal tip to mp joint), complete amputation	J8
20838	Anesthesia for open procedures involving upper two-thirds of femur; radical resection	J8
20955	Bone graft with microvascular anastomosis; fibula	J8
20956	Bone graft with microvascular anastomosis; iliac crest	J8
20957	Bone graft with microvascular anastomosis; metatarsal	J8
20962	Bone graft with microvascular anastomosis; other than fibula, iliac crest, or metatarsal	J8
20969	Free osteocutaneous flap with microvascular anastomosis; other than iliac crest, metatarsal, or great toe	J8
20970	Free osteocutaneous flap with microvascular anastomosis; iliac crest	J8
21045	Excision of malignant tumor of mandible; radical resection	G2
21145	Reconstruction midface, lefort i; single piece, segment movement in any direction, requiring bone grafts (includes obtaining autografts)	J8
21146	Reconstruction midface, lefort i; 2 pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted unilateral alveolar cleft)	J8
21147	Reconstruction midface, lefort i; 3 or more pieces, segment movement in any direction, requiring bone grafts (includes obtaining autografts) (eg, ungrafted bilateral alveolar cleft or multiple osteotomies)	J8
21151	Reconstruction midface, lefort ii; any direction, requiring bone grafts (includes obtaining autografts)	J8
21154	Reconstruction midface, lefort iii (extracranial), any type, requiring bone grafts (includes obtaining autografts); without lefort i	J8
21155	Reconstruction midface, lefort iii (extracranial), any type, requiring bone grafts (includes obtaining autografts); with lefort i	J8
21159	Reconstruction midface, lefort iii (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); without lefort i	J8
21160	Reconstruction midface, lefort iii (extra and intracranial) with forehead advancement (eg, mono bloc), requiring bone grafts (includes obtaining autografts); with lefort i	J8
21179	Reconstruction, entire or majority of forehead and/or supraorbital rims; with grafts (allograft or prosthetic material)	J8
21180	Reconstruction, entire or majority of forehead and/or supraorbital rims; with autograft (includes obtaining grafts)	J8
21182	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting less than 40 sq cm	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
21183	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 40 sq cm but less than 80 sq cm	J8
21184	Reconstruction of orbital walls, rims, forehead, nasoethmoid complex following intra- and extracranial excision of benign tumor of cranial bone (eg, fibrous dysplasia), with multiple autografts (includes obtaining grafts); total area of bone grafting greater than 80 sq cm	J8
21188	Reconstruction midface, osteotomies (other than lefort type) and bone grafts (includes obtaining autografts)	J8
21247	Reconstruction of mandibular condyle with bone and cartilage autografts (includes obtaining grafts) (eg, for hemifacial microsomia)	J8
21268	Orbital repositioning, periorbital osteotomies, unilateral, with bone grafts; combined intra- and extracranial approach	J8
21343	Open treatment of depressed frontal sinus fracture	J8
21344	Open treatment of complicated (eg, comminuted or involving posterior wall) frontal sinus fracture, via coronal or multiple approaches	J8
21348	Open treatment of nasomaxillary complex fracture (lefort ii type); with bone grafting (includes obtaining graft)	J8
21423	Open treatment of palatal or maxillary fracture (lefort i type); complicated (comminuted or involving cranial nerve foramina), multiple approaches	J8
21431	Closed treatment of craniofacial separation (lefort iii type) using interdental wire fixation of denture or splint	J8
21432	Open treatment of craniofacial separation (lefort iii type); with wiring and/or internal fixation	J8
21433	Open treatment of craniofacial separation (lefort iii type); complicated (eg, comminuted or involving cranial nerve foramina), multiple surgical approaches	J8
21435	Open treatment of craniofacial separation (lefort iii type); complicated, utilizing internal and/or external fixation techniques (eg, head cap, halo device, and/or intermaxillary fixation)	J8
21436	Open treatment of craniofacial separation (lefort iii type); complicated, multiple surgical approaches, internal fixation, with bone grafting (includes obtaining graft)	J8
21510	Incision, deep, with opening of bone cortex (eg, for osteomyelitis or bone abscess), thorax	J8
21602	Excision of chest wall tumor involving rib(s), with plastic reconstruction; without mediastinal lymphadenectomy	J8
21603	Excision of chest wall tumor involving rib(s), with plastic reconstruction; with mediastinal lymphadenectomy	J8
21615	Excision first and/or cervical rib;	G2
21616	Excision first and/or cervical rib; with sympathectomy	G2
21620	Ostectomy of sternum, partial	G2
21627	Sternal debridement	G2
21630	Radical resection of sternum	G2
21705	Division of scalenus anticus; with resection of cervical rib	G2
21740	Reconstructive repair of pectus excavatum or carinatum; open	J8
21750	Closure of median sternotomy separation with or without debridement (separate procedure)	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
21825	Open treatment of sternum fracture with or without skeletal fixation	J8
22010	Incision and drainage, open, of deep abscess (subfascial), posterior spine; cervical, thoracic, or cervicothoracic	G2
22015	Incision and drainage, open, of deep abscess (subfascial), posterior spine; lumbar, sacral, or lumbosacral	G2
22110	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; cervical	G2
22112	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; thoracic	G2
22114	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; lumbar	G2
22116	Partial excision of vertebral body, for intrinsic bony lesion, without decompression of spinal cord or nerve root(s), single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N1
22206	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); thoracic	G2
22207	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); lumbar	G2
22208	Osteotomy of spine, posterior or posterolateral approach, 3 columns, 1 vertebral segment (eg, pedicle/vertebral body subtraction); each additional vertebral segment (list separately in addition to code for primary procedure)	N1
22210	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; cervical	J8
22212	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; thoracic	J8
22214	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; lumbar	J8
22216	Osteotomy of spine, posterior or posterolateral approach, 1 vertebral segment; each additional vertebral segment (list separately in addition to primary procedure)	N1
22220	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; cervical	J8
22222	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; thoracic	G2
22224	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; lumbar	G2
22226	Osteotomy of spine, including discectomy, anterior approach, single vertebral segment; each additional vertebral segment (list separately in addition to code for primary procedure)	N1
22318	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; without grafting	J8
22319	Open treatment and/or reduction of odontoid fracture(s) and or dislocation(s) (including os odontoideum), anterior approach, including placement of internal fixation; with grafting	J8
22325	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; lumbar	J8
22326	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; cervical	G2
22327	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; thoracic	J8
22328	Open treatment and/or reduction of vertebral fracture(s) and/or dislocation(s), posterior approach, 1 fractured vertebra or dislocated segment; each additional fractured vertebra or dislocated segment (list separately in addition to code for primary procedure)	N1
22532	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
22533	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	G2
22534	Arthrodesis, lateral extracavitary technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic or lumbar, each additional vertebral segment (list separately in addition to code for primary procedure)	N1
22548	Arthrodesis, anterior transoral or extraoral technique, clivus-c1-c2 (atlas-axis), with or without excision of odontoid process	J8
22556	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); thoracic	J8
22558	Arthrodesis, anterior interbody technique, including minimal discectomy to prepare interspace (other than for decompression); lumbar	J8
22586	Arthrodesis, pre-sacral interbody technique, including disc space preparation, discectomy, with posterior instrumentation, with image guidance, includes bone graft when performed, l5-s1 interspace	J8
22590	Arthrodesis, posterior technique, craniocervical (occiput-c2)	J8
22595	Arthrodesis, posterior technique, atlas-axis (c1-c2)	G2
22600	Arthrodesis, posterior or posterolateral technique, single level; cervical below c2 segment	J8
22610	Arthrodesis, posterior or posterolateral technique, single level; thoracic (with lateral transverse technique, when performed)	J8
22800	Arthrodesis, posterior, for spinal deformity, with or without cast; up to 6 vertebral segments	J8
22802	Arthrodesis, posterior, for spinal deformity, with or without cast; 7 to 12 vertebral segments	G2
22804	Arthrodesis, posterior, for spinal deformity, with or without cast; 13 or more vertebral segments	G2
22808	Arthrodesis, anterior, for spinal deformity, with or without cast; 2 to 3 vertebral segments	J8
22810	Arthrodesis, anterior, for spinal deformity, with or without cast; 4 to 7 vertebral segments	G2
22812	Arthrodesis, anterior, for spinal deformity, with or without cast; 8 or more vertebral segments	G2
22818	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); single or 2 segments	G2
22819	Kyphectomy, circumferential exposure of spine and resection of vertebral segment(s) (including body and posterior elements); 3 or more segments	G2
22830	Exploration of spinal fusion	J8
22836	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; up to 7 vertebral segments	J8
22837	Anterior thoracic vertebral body tethering, including thoracoscopy, when performed; 8 or more vertebral segments	J8
22838	Revision (eg, augmentation, division of tether), replacement, or removal of thoracic vertebral body tethering, including thoracoscopy, when performed	J8
22841	Internal spinal fixation by wiring of spinous processes (list separately in addition to code for primary procedure)	N1

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
22843	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 7 to 12 vertebral segments (list separately in addition to code for primary procedure)	N1
22844	Posterior segmental instrumentation (eg, pedicle fixation, dual rods with multiple hooks and sublaminar wires); 13 or more vertebral segments (list separately in addition to code for primary procedure)	N1
22846	Anterior instrumentation; 4 to 7 vertebral segments (list separately in addition to code for primary procedure)	N1
22847	Anterior instrumentation; 8 or more vertebral segments (list separately in addition to code for primary procedure)	N1
22849	Reinsertion of spinal fixation device	J8
22850	Removal of posterior nonsegmental instrumentation (eg, harrington rod)	G2
22852	Removal of posterior segmental instrumentation	G2
22855	Removal of anterior instrumentation	G2
22857	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); single interspace, lumbar	J8
22860	Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression); second interspace, lumbar (list separately in addition to code for primary procedure)	N1
22861	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	J8
22862	Revision including replacement of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	J8
22864	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; cervical	G2
22865	Removal of total disc arthroplasty (artificial disc), anterior approach, single interspace; lumbar	G2
23200	Radical resection of tumor; clavicle	G2
23210	Radical resection of tumor; scapula	G2
23220	Radical resection of tumor, proximal humerus	G2
23335	Removal of prosthesis, includes debridement and synovectomy when performed; humeral and glenoid components (eg, total shoulder)	J8
23474	Revision of total shoulder arthroplasty, including allograft when performed; humeral and glenoid component	J8
23900	Interthoracoscapular amputation (forequarter)	G2
23920	Disarticulation of shoulder;	G2
24900	Amputation, arm through humerus; with primary closure	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
24920	Amputation, arm through humerus; open, circular (guillotine)	G2
24930	Amputation, arm through humerus; re-amputation	G2
24931	Amputation, arm through humerus; with implant	J8
24940	Cineplasty, upper extremity, complete procedure	J8
25900	Amputation, forearm, through radius and ulna;	G2
25905	Amputation, forearm, through radius and ulna; open, circular (guillotine)	G2
25915	Krukenberg procedure	G2
25920	Disarticulation through wrist;	G2
25924	Disarticulation through wrist; re-amputation	G2
25927	Transmetacarpal amputation;	G2
26551	Transfer, toe-to-hand with microvascular anastomosis; great toe wrap-around with bone graft	J8
26553	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, single	J8
26554	Transfer, toe-to-hand with microvascular anastomosis; other than great toe, double	J8
26556	Transfer, free toe joint, with microvascular anastomosis	J8
26992	Incision, bone cortex, pelvis and/or hip joint (eg, osteomyelitis or bone abscess)	G2
27005	Tenotomy, hip flexor(s), open (separate procedure)	G2
27025	Fasciotomy, hip or thigh, any type	J8
27030	Arthrotomy, hip, with drainage (eg, infection)	G2
27036	Capsulectomy or capsulotomy, hip, with or without excision of heterotopic bone, with release of hip flexor muscles (ie, gluteus medius, gluteus minimus, tensor fascia latae, rectus femoris, sartorius, iliopsoas)	G2
27054	Arthrotomy with synovectomy, hip joint	J8
27070	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (eg, osteomyelitis or bone abscess); superficial	J8
27071	Partial excision, wing of ilium, symphysis pubis, or greater trochanter of femur, (craterization, saucerization) (eg, osteomyelitis or bone abscess); deep (subfascial or intramuscular)	J8
27075	Radical resection of tumor; wing of ilium, 1 pubic or ischial ramus or symphysis pubis	J8
27076	Radical resection of tumor; ilium, including acetabulum, both pubic rami, or ischium and acetabulum	G2
27077	Radical resection of tumor; innominate bone, total	G2
27078	Radical resection of tumor; ischial tuberosity and greater trochanter of femur	G2
27090	Removal of hip prosthesis; (separate procedure)	G2
27091	Removal of hip prosthesis; complicated, including total hip prosthesis, methylmethacrylate with or without insertion of spacer	J8
27120	Acetabuloplasty; (eg, whitman, colonna, haygroves, or cup type)	J8
27122	Acetabuloplasty; resection, femoral head (eg, girdlestone procedure)	J8
27125	Hemiarthroplasty, hip, partial (eg, femoral stem prosthesis, bipolar arthroplasty)	J8
27132	Conversion of previous hip surgery to total hip arthroplasty, with or without autograft or allograft	J8
27134	Revision of total hip arthroplasty; both components, with or without autograft or allograft	J8
27137	Revision of total hip arthroplasty; acetabular component only, with or without autograft or allograft	J8
27138	Revision of total hip arthroplasty; femoral component only, with or without allograft	J8
27140	Osteotomy and transfer of greater trochanter of femur (separate procedure)	J8
27146	Osteotomy, iliac, acetabular or innominate bone;	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
27147	Osteotomy, iliac, acetabular or innominate bone; with open reduction of hip	J8
27151	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy	J8
27156	Osteotomy, iliac, acetabular or innominate bone; with femoral osteotomy and with open reduction of hip	J8
27158	Osteotomy, pelvis, bilateral (eg, congenital malformation)	J8
27161	Osteotomy, femoral neck (separate procedure)	J8
27165	Osteotomy, intertrochanteric or subtrochanteric including internal or external fixation and/or cast	J8
27170	Bone graft, femoral head, neck, intertrochanteric or subtrochanteric area (includes obtaining bone graft)	J8
27175	Treatment of slipped femoral epiphysis; by traction, without reduction	G2
27176	Treatment of slipped femoral epiphysis; by single or multiple pinning, in situ	J8
27177	Open treatment of slipped femoral epiphysis; single or multiple pinning or bone graft (includes obtaining graft)	J8
27178	Open treatment of slipped femoral epiphysis; closed manipulation with single or multiple pinning	J8
27181	Open treatment of slipped femoral epiphysis; osteotomy and internal fixation	J8
27185	Epiphyseal arrest by epiphysiodesis or stapling, greater trochanter of femur	J8
27187	Prophylactic treatment (nailing, pinning, plating or wiring) with or without methylmethacrylate, femoral neck and proximal femur	J8
27222	Closed treatment of acetabulum (hip socket) fracture(s); with manipulation, with or without skeletal traction	G2
27226	Open treatment of posterior or anterior acetabular wall fracture, with internal fixation	J8
27227	Open treatment of acetabular fracture(s) involving anterior or posterior (one) column, or a fracture running transversely across the acetabulum, with internal fixation	J8
27228	Open treatment of acetabular fracture(s) involving anterior and posterior (two) columns, includes t-fracture and both column fracture with complete articular detachment, or single column or transverse fracture with associated acetabular wall fracture, with internal fixation	J8
27232	Closed treatment of femoral fracture, proximal end, neck; with manipulation, with or without skeletal traction	G2
27236	Open treatment of femoral fracture, proximal end, neck, internal fixation or prosthetic replacement	J8
27240	Closed treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with manipulation, with or without skin or skeletal traction	G2
27244	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with plate/screw type implant, with or without cerclage	J8
27245	Treatment of intertrochanteric, peritrochanteric, or subtrochanteric femoral fracture; with intramedullary implant, with or without interlocking screws and/or cerclage	J8
27248	Open treatment of greater trochanteric fracture, includes internal fixation, when performed	J8
27253	Open treatment of hip dislocation, traumatic, without internal fixation	G2
27254	Open treatment of hip dislocation, traumatic, with acetabular wall and femoral head fracture, with or without internal or external fixation	J8
27258	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc);	G2
27259	Open treatment of spontaneous hip dislocation (developmental, including congenital or pathological), replacement of femoral head in acetabulum (including tenotomy, etc); with femoral shaft shortening	J8
27268	Closed treatment of femoral fracture, proximal end, head; with manipulation	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
27269	Open treatment of femoral fracture, proximal end, head, includes internal fixation, when performed	J8
27280	Arthrodesis, sacroiliac joint, open, includes obtaining bone graft, including instrumentation, when performed	J8
27282	Arthrodesis, symphysis pubis (including obtaining graft)	J8
27284	Arthrodesis, hip joint (including obtaining graft);	J8
27286	Arthrodesis, hip joint (including obtaining graft); with subtrochanteric osteotomy	J8
27290	Interpelviabdominal amputation (hindquarter amputation)	G2
27295	Disarticulation of hip	G2
27303	Incision, deep, with opening of bone cortex, femur or knee (eg, osteomyelitis or bone abscess)	J8
27365	Radical resection of tumor, femur or knee	G2
27448	Osteotomy, femur, shaft or supracondylar; without fixation	G2
27450	Osteotomy, femur, shaft or supracondylar; with fixation	J8
27454	Osteotomy, multiple, with realignment on intramedullary rod, femoral shaft (eg, sofield type procedure)	J8
27455	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); before epiphyseal closure	G2
27457	Osteotomy, proximal tibia, including fibular excision or osteotomy (includes correction of genu varus [bowleg] or genu valgus [knock-knee]); after epiphyseal closure	J8
27465	Osteoplasty, femur; shortening (excluding 64876)	J8
27466	Osteoplasty, femur; lengthening	J8
27470	Repair, nonunion or malunion, femur, distal to head and neck; without graft (eg, compression technique)	J8
27472	Repair, nonunion or malunion, femur, distal to head and neck; with iliac or other autogenous bone graft (includes obtaining graft)	J8
27486	Revision of total knee arthroplasty, with or without allograft; 1 component	J8
27487	Revision of total knee arthroplasty, with or without allograft; femoral and entire tibial component	J8
27488	Removal of prosthesis, including total knee prosthesis, methylmethacrylate with or without insertion of spacer, knee	J8
27495	Prophylactic treatment (nailing, pinning, plating, or wiring) with or without methylmethacrylate, femur	J8
27506	Open treatment of femoral shaft fracture, with or without external fixation, with insertion of intramedullary implant, with or without cerclage and/or locking screws	J8
27507	Open treatment of femoral shaft fracture with plate/screws, with or without cerclage	J8
27511	Open treatment of femoral supracondylar or transcondylar fracture without intercondylar extension, includes internal fixation, when performed	J8
27513	Open treatment of femoral supracondylar or transcondylar fracture with intercondylar extension, includes internal fixation, when performed	J8
27514	Open treatment of femoral fracture, distal end, medial or lateral condyle, includes internal fixation, when performed	J8
27519	Open treatment of distal femoral epiphyseal separation, includes internal fixation, when performed	J8
27535	Open treatment of tibial fracture, proximal (plateau); unicondylar, includes internal fixation, when performed	J8
27536	Open treatment of tibial fracture, proximal (plateau); bicondylar, with or without internal fixation	J8

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
27540	Open treatment of intercondylar spine(s) and/or tuberosity fracture(s) of the knee, includes internal fixation, when performed	J8
27556	Open treatment of knee dislocation, includes internal fixation, when performed; without primary ligamentous repair or augmentation/reconstruction	J8
27557	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair	J8
27558	Open treatment of knee dislocation, includes internal fixation, when performed; with primary ligamentous repair, with augmentation/reconstruction	J8
27580	Arthrodesis, knee, any technique	J8
27590	Amputation, thigh, through femur, any level;	G2
27591	Amputation, thigh, through femur, any level; immediate fitting technique including first cast	G2
27592	Amputation, thigh, through femur, any level; open, circular (guillotine)	G2
27596	Amputation, thigh, through femur, any level; re-amputation	G2
27598	Disarticulation at knee	G2
27645	Radical resection of tumor; tibia	G2
27646	Radical resection of tumor; fibula	G2
27703	Arthroplasty, ankle; revision, total ankle	J8
27712	Osteotomy; multiple, with realignment on intramedullary rod (eg, sofield type procedure)	J8
27715	Osteoplasty, tibia and fibula, lengthening or shortening	J8
27724	Repair of nonunion or malunion, tibia; with iliac or other autograft (includes obtaining graft)	J8
27725	Repair of nonunion or malunion, tibia; by synostosis, with fibula, any method	J8
27727	Repair of congenital pseudarthrosis, tibia	J8
27880	Amputation, leg, through tibia and fibula;	G2
27881	Amputation, leg, through tibia and fibula; with immediate fitting technique including application of first cast	G2
27882	Amputation, leg, through tibia and fibula; open, circular (guillotine)	G2
27886	Amputation, leg, through tibia and fibula; re-amputation	G2
27888	Amputation, ankle, through malleoli of tibia and fibula (eg, syme, pirogoff type procedures), with plastic closure and resection of nerves	G2
28800	Amputation, foot; midtarsal (eg, chopart type procedure)	G2
35372	Thromboendarterectomy, including patch graft, if performed; deep (profunda) femoral	J8
35800	Exploration for postoperative hemorrhage, thrombosis or infection; neck	G2
37182	Insertion of transvenous intrahepatic portosystemic shunt(s) (tips) (includes venous access, hepatic and portal vein catheterization, portography with hemodynamic evaluation, intrahepatic tract formation/dilatation, stent placement and all associated imaging guidance and documentation)	J8
37617	Ligation, major artery (eg, post-traumatic, rupture); abdomen	G2
38562	Limited lymphadenectomy for staging (separate procedure); pelvic and para-aortic	G2
43840	Gastrorrhaphy, suture of perforated duodenal or gastric ulcer, wound, or injury	G2
44300	Placement, enterostomy or cecostomy, tube open (eg, for feeding or decompression) (separate procedure)	G2
44314	Revision of ileostomy; complicated (reconstruction in-depth) (separate procedure)	G2

HCPCS Code	Long Descriptor	Proposed CY 2026 PI
44345	Revision of colostomy; complicated (reconstruction in-depth) (separate procedure)	G2
44346	Revision of colostomy; with repair of paracolostomy hernia (separate procedure)	G2
44602	Suture of small intestine (enterorrhaphy) for perforated ulcer, diverticulum, wound, injury or rupture; single perforation	G2
49010	Exploration, retroperitoneal area with or without biopsy(s) (separate procedure)	G2
49255	Omentectomy, epiploectomy, resection of omentum (separate procedure)	G2
51840	Anterior vesicourethropexy, or urethropexy (eg, marshall-marchetti-krantz, burch); simple	G2
56630	Vulvectomy, radical, partial;	G2
61624	Transcatheter permanent occlusion or embolization (eg, for tumor destruction, to achieve hemostasis, to occlude a vascular malformation), percutaneous, any method; central nervous system (intracranial, spinal cord)	J8
G0412	Open treatment of iliac spine(s), tuberosity avulsion, or iliac wing fracture(s), unilateral or bilateral for pelvic bone fracture patterns which do not disrupt the pelvic ring includes internal fixation, when performed	J8
G0414	Open treatment of anterior pelvic bone fracture and/or dislocation for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation when performed (includes pubic symphysis and/or superior/inferior rami)	J8
G0415	Open treatment of posterior pelvic bone fracture and/or dislocation, for fracture patterns which disrupt the pelvic ring, unilateral or bilateral, includes internal fixation, when performed (includes ilium, sacroiliac joint and/or sacrum)	J8

3. Covered Ancillary Services

Covered ancillary services are specified in § 416.164(b) and, as stated previously, are eligible for separate ASC payment. As provided at § 416.164(b), we make separate ASC payments for ancillary items and services when they are provided integral to ASC covered surgical procedures that include the following: (1) brachytherapy sources; (2) certain implantable items that have pass-through payment status under the OPPS; (3) certain items and services that we designate as contractor-priced, including, but not limited to, procurement of corneal tissue; (4) certain drugs and biologicals for which separate payment is allowed under the OPPS; (5) certain radiology services for which separate payment is allowed under the OPPS; and (6) non-opioid pain management drugs that function as a supply when used in a surgical

procedure. Payment for ancillary items and services that are not paid separately under the ASC payment system is packaged into the ASC payment for the covered surgical procedure.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59062 through 59063), consistent with the established ASC payment system policy (72 FR 42497), we finalized the policy to update the ASC list of covered ancillary services to reflect the payment status for the services under the OPPS and to continue this reconciliation of packaged status for subsequent calendar years. As discussed in prior rulemaking, maintaining consistency with the OPPS may result in changes to ASC payment indicators for some covered ancillary services. For example, if a covered ancillary service was separately paid under the ASC payment system in CY 2024, but will be packaged under the CY 2025 OPPS, we would also package the ancillary service under the ASC payment system for CY 2025 to maintain consistency with the OPPS. Comment indicator "CH" is used in Addendum BB (which is available via the Internet on the CMS website) to indicate covered ancillary services for which we proposed a change in the ASC payment indicator to reflect a proposed change in the OPPS treatment of the service for CY 2025.

In the CY 2022 OPPS/ASC final rule with comment period, we finalized our proposal to revise 42 CFR 416.164(b)(6) to include, as ancillary items that are integral to a covered surgical procedure and for which separate payment is allowed, non-opioid pain management drugs and biologicals that function as a supply when used in a surgical procedure as determined by CMS (86 FR 63490).

New CPT and HCPCS codes for covered ancillary services for CY 2026 can be found in section XIII.B. of this proposed rule. All ASC covered ancillary services and their proposed payment indicators for CY 2026 are also included in Addendum BB to this proposed rule (which is available via the Internet on the CMS website).

4. Proposed Changes to the List of ASC Covered Items and Services for CY 2026

As we discussed in section III. of this proposed rule, beginning January 1, 2026, we propose to remove skin substitutes from the list of packaged items and services at 42 CFR 419.2(b)(16) under the OPPS and under 42 CFR 416.164(a)(5) under the ASC payment system. Our proposal is intended to establish a consistent and uniform framework for how these products are treated across different outpatient settings of care to help ensure equitable access and appropriate payment for these services. While we do not believe these products are commonly used in the ASC setting, we believe extending our uniform framework from the physician office and hospital outpatient setting to the ASC setting will help ensure equitable access to these products in the future across the different sites of outpatient care.

Our payment policies under the ASC payment system for covered ancillary services generally vary according to the particular type of item or service and its payment policy under the OPPS. Drugs and biologicals that are separately paid under the ASC payment system are paid at the prospective rates adopted under the OPPS. Similar to how ASCs are paid for brachytherapy sources provided integral to ASC covered surgical procedures at prospective rates adopted under the OPPS, we propose to pay for groups of skin substitute products at annual prospective rates adopted under the OPPS, effective January 1, 2026. Additionally, these prospective rates would not be subject to the ASC wage index adjustment and beneficiaries would be responsible for 20 percent coinsurance.

To separately pay for the provision of certain groups of skin substitute products when used during a covered surgical procedure, we propose to revise 42 CFR 416.164(b) to include groups of skin substitute products as covered ancillary items and services that are integral to a covered surgical procedure. As discussed in section XIII.B.6. of this proposed rule, we propose to identify HCPCS skin substitute codes which may be separately payable with our proposed payment indicator of "S2" – Skin substitute supply group paid separately when provided integral to a surgical procedure on ASC list; payment based on OPPS rate. Therefore, for those existing skin substitute products for which we propose to separately pay for, we are revising the payment

indicator from "N1" – Packaged service/item; no separate payment made – to payment indicator "S2" effective January 1, 2026. Additionally for new skin substitute products which we propose to add to the list of ASC covered ancillary items and services, we propose to assign these skin substitute products an ASC payment indicator of "S2".

F. Proposed CY 2026 Non-Opioid Policy for Pain Relief Under the OPPS and ASC Payment System

1. Background on Access to Non-Opioid Treatments for Pain Relief

The Consolidated Appropriations Act (CAA), 2023 (Pub. L. 117-328), was signed into law on December 29, 2022. Section 4135(a) and (b) of the CAA, 2023, titled Access to Non-Opioid Treatments for Pain Relief, amended section 1833(t)(16) and section 1833(i) of the Social Security Act, respectively, to provide for temporary additional payments for non-opioid treatments for pain relief (as that term is defined in section 1833(t)(16)(G)(i) of the Act). In particular, section 1833(t)(16)(G) provides that with respect to a non-opioid treatment for pain relief furnished on or after January 1, 2025, and before January 1, 2028, the Secretary shall not package payment for the non-opioid treatment for pain relief into payment for a covered OPD service (or group of services) and shall make an additional payment for the non-opioid treatment for pain relief as specified in clause (ii) of that section. Clauses (ii) and (iii) of section 1833(t)(16)(G) of the Act provide for the amount of additional payment and set a limitation on that amount.

Paragraph (10) of section 1833(i) of the Act cross-references the OPPS provisions about the additional payment amount and payment limitation for non-opioid treatments for pain relief and applies them to payment under the ASC payment system. In particular, paragraph (A) of paragraph (10) of section 1833(i) of the Act, as added by section 4135(b) of the CAA, 2023, provides that in the case of surgical services furnished on or after January 1, 2025, and before January 1, 2028, additional payments shall be made under the ASC payment system for non-opioid treatments for pain relief in the same amount provided in clause (ii) and subject to the

limitation in clause (iii) of section 1833(t)(16)(G) of the Act for the OPPS. Paragraph (B) of section 1833(i)(10) of the Act provides that a drug or biological that meets the requirements of 42 CFR 416.174 and is a non-opioid treatment for pain relief shall also receive additional payment in the amount provided in clause (ii) and subject to the limitation in clause (iii) of section 1833(t)(16)(G) of the Act.

Additional payments under this policy began on January 1, 2025. As stated in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94343 through 94344), the statute directs CMS to provide "additional payment", and for purposes of this policy, we interpret this language to be equivalent to "separate payment," since CMS provides an additional payment by unpackaging the product and then making a separate payment. "Separate payment" is the more commonly used terminology in the OPPS rule and likely more familiar to readers. To avoid confusion, we will continue to use "separate payment" throughout the rest of this section, which we believe to be synonymous with "additional payment."

For CY 2025, CMS finalized its implementation methodology for section 4135 of the CAA, 2023, and finalized regulation text at 42 CFR 416.174 and 42 CFR 419.43(k), which outline the payment for non-opioid pain management drugs, biologicals, and medical devices under both the ASC payment system and OPPS, respectively.

As noted in the preceding paragraphs, section 4135 of the CAA, 2023, provides for temporary separate payments for certain non-opioid treatments for pain relief in both the hospital outpatient department and ambulatory surgical center settings from January 1, 2025, through December 31, 2027. Specifically, these separate payments are for qualifying drugs, biologicals, and devices that, among other requirements, have their payment packaged into payment for a

covered OPD service (or group of services). Pursuant to section 1833(t)(2)(E) of the Act, the temporary separate payments must be made in a budget neutral manner.

For background information on the ASC Payment Policy for Non-Opioid Post-Surgery Pain Management Drugs and Biologicals prior to CY 2025, please see the summary provided in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94343).

2. Final CY 2025 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

In CY 2025, we finalized our implementation of Section 4135 of CAA, 2023 (89 FR 94343 through 94361) to provide for separate payments for certain non-opioid treatment for pain relief in the hospital outpatient department and ambulatory surgical center settings on a temporary basis. These payment policies and the statutory language authorizing their implementation are discussed in the following sections. These policies are also outlined in regulation text finalized at 42 CFR 416.174 and 419.43.

a. Drugs and Biologicals Subject to the ASC Non-Opioid Policy (42 CFR 416.174)

Section 1833(i)(10)(B), titled "Transition," provides that a drug or biological that meets the requirements of the regulation at 42 CFR 416.174, the current ASC non-opioid policy, and also meets the definition of a non-opioid treatment for pain relief at section 1833(t)(16)(G)(iv) shall receive separate payments under section 4135 of the CAA, 2023, subject to the payment limitation. In light of this requirement, we finalized that drugs and biologicals that meet the definition of a non-opioid treatment for pain relief for purposes of section 4135 that were subject to the ASC policy for non-opioid treatments authorized by section 6082 of the SUPPORT Act in CY 2024, would instead receive separate payments, subject to the limitation, for the duration of the payment period for section 4135. The policy was finalized to be in effect for the duration of the payment period for section 4135.

b. Definition of Non-Opioid Treatment for Pain Relief

Section 1833(t)(16)(G)(iv) of the Act defines a non-opioid treatment for pain relief. In order for a drug or biological product to qualify as a non-opioid treatment for pain relief,

pursuant to section 1833(t)(16)(G)(iv)(I), the product must have "a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors." In order for a medical device to qualify as a non-opioid treatment for pain relief, pursuant to section 1833(t)(16)(G)(iv)(II)(bb), the medical devices must be "used to deliver a therapy to reduce postoperative pain, or produce post-surgical or regional analgesia." This subparagraph also defines such a device as having "an application under section 515 of the Federal Food, Drug, and Cosmetic Act that has been approved with respect to the device, been cleared for market under section 510(k) of such Act, or is exempt from the requirements of section 510(k) of such Act pursuant to subsection (l) or (m) or section 510 of such Act or section 520(g) of such Act" and "demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal."

c. Evidence Requirement for Medical Devices

To determine whether a medical device fulfills the statutory requirement that it has demonstrated the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, we finalized in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345) a policy to review all data submitted during the public comment period to determine if the device demonstrates the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids. In CY 2025, we encouraged interested parties submitting non-opioid device recommendations to submit any relevant literature that demonstrates that the named medical device replaces, reduces, or avoids opioid use per this statutory provision with their public comments. We review any literature submitted and determine whether it meets this evidence criterion. There is no requirement that commenters submit any data or literature with their device recommendations. If there is no data or literature submitted for a medical device, or

if the materials submitted do not demonstrate any ability of the medical device to replace, reduce, or avoid opioids, the medical device would not meet this evidence criterion and would not qualify for separate payment under section 4135.

d. Non-Opioid Product Indications

(1) FDA-Approved Indications for Drugs and Biologicals

Section 1833(t)(16)(G)(iv)(I) of the Act specifies that to meet the definition of a non-opioid treatment for pain relief and to be eligible for separate payment, a drug or biological product must have a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors.

Given these statutory requirements, we finalized a policy in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346) only to approve separate payment for drug or biological products with an FDA-approved indication that closely aligns with the statutorily required indication language to reduce post-operative pain or produce post-surgical or regional analgesia. We noted that products with an indication that does not meet this statutory requirement would not qualify. We specifically stated that products with only a general pain indication will not qualify.

As discussed in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94345 through 94346), we note that Congress specifically included language requiring that drugs or biologicals have "a label indication approved by the Food and Drug Administration to reduce postoperative pain, or produce postsurgical or regional analgesia, without acting upon the body's opioid receptors." Therefore, products with an indication that does not meet the statutory requirement will not qualify. We also noted that many patients who receive services paid under the OPPS and ASC payment system are often in a post-surgical environment, given the nature of the procedures typically performed in an ASC or HOPD.

(2) Intended Use for Medical Devices

Regarding medical devices, section 1833(t)(16)(G)(iv)(II) of the Act specifies that such a device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023. It also must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), have been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. For CY 2025, for medical devices, we finalized without modification our proposal that a device must be used to deliver a therapy to reduce postoperative pain or produce post-surgical or regional analgesia to qualify for separate payment under section 4135 of the CAA, 2023 (89 FR 94346 through 94347). We also finalized that the medical device must have an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA), which has been cleared for market under section 510(k) of the FDCA, or be exempt from the requirements of section 510(k) of the FDCA pursuant to section 510(l) or (m) or 520(g) of the FDCA. (89 FR 94346 through 94347). This is consistent with the regulation text at 42 CFR 419.43(k)(2)(i) through (iv).

e. Amount of Payment

Section 1833(t)(16)(G)(ii)(I) of the Act provides that, for a non-opioid treatment for pain relief that is a drug or biological product, the amount of separate payment is the amount of payment for such product determined under section 1847A of the Act that exceeds the portion of the otherwise applicable Medicare OPD fee schedule that the Secretary determines is associated with the drug or biological, subject to a limitation, as described in the next section. Section 1833(t)(16)(G)(ii)(II) of the Act provides that, for a non-opioid treatment for pain relief that is a medical device, the amount of separate payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee

schedule that the Secretary determines is associated with the device, subject to a limitation, as described in the next section.

We finalized a policy to assign a payment offset of zero dollars for the qualifying drugs, biologicals, and devices for CY 2025 (89 FR 94347 through 94348). A zero dollar offset means that we would not offset or remove the amount that the non-opioid product represents from the procedure payment rate when setting payment rates. We finalized a zero dollar offset for the initial year of the policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Therefore, the separate payment for a drug or biological will be determined by subtracting from the amount calculated using the methodology outlined in section 1847A of the Act the portion of the otherwise applicable Medicare OPD fee schedule associated with the drug or biological, which as previously discussed, we finalized to be zero dollars for CY 2025. For the amount of payment for a medical device, since we are unable to reduce charges to costs for ASCs, the separate payment amount will be contractor-priced by the ASC's Medicare Administrative Contractor reduced by the portion of the otherwise applicable Medicare OPD fee schedule amount associated with the medical device, which as previously discussed, we finalized to be zero dollars for CY 2025. These separate payment amounts are all subject to the payment limitation, described in the subsequent section.

Section 1833(i)(10) of the Act establishes the same separate payment for the ASC setting as for hospital outpatient departments, as described in section 1833(t)(16)(G)(ii) of the Act. Both separate payments are subject to the limitation in section 1833(t)(16)(G)(iii) of the Act, which specifies that the separate payment amount shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished. Given this statutory requirement, we finalized

paying the same separate payment amount for qualifying non-opioid products in both the HOPD and ASC settings.

As the statute requires separate payment for these non-opioid treatments for pain relief, these products cannot be packaged into the procedure payment. Under our current threshold packaging policy, if the estimated per day cost for a drug or biological is less than or equal to the applicable OPPS drug packaging threshold, we package payment for the drug or biological into the payment for the associated procedure. Similarly, under our comprehensive APC (C-APC) policy, we package all payments for services integral, ancillary, supportive, dependent, and adjunctive to the primary service into a single payment for the primary comprehensive service. For CY 2025, we finalized that non-opioid treatments for pain relief would not be subject to the threshold packaging policy and would also be separately paid when used during a comprehensive APC (C-APC) procedure in the HOPD setting (89 FR 94347 through 94348). See section V.B.1.a. of this proposed rule for more information regarding the drug packaging threshold. Section II.A.2.b. of this proposed rule contains further information on threshold packaging and C-APC packaging.

f. Payment Limitation

Section 1833(t)(16)(G)(iii) of the Act states that the separate payment amount specified in clause (ii), (which is described in the previous section) shall not exceed the estimated average of 18 percent of the OPD fee schedule amount for the OPD service (or group of services) with which the non-opioid treatment for pain relief is furnished, as determined by the Secretary. In the CY 2025 OPPS/ASC final rule, we finalized a policy to base the 18 percent payment limitation on the volume weighted average of the payment rates of the top five primary procedures by volume into which a non-opioid treatment for pain relief would have their payment packaged, absent this policy. We also finalized applying the 18 percent payment limitation per date of service billed (89 FR 94349).

g. Payment Limitation with No Claims Data

For drugs, biologicals, and devices with no claims data, such as for newly FDA-approved and marketed products or products that did not previously have their own product-specific HCPCS code by which to track payment and utilization data, we finalized in the 2025 OPPS/ASC final rule with comment period (89 FR 94350) a policy where CMS will utilize the services with which a product would be expected to be furnished and would typically be packaged absent this policy, to calculate the payment limitation based on expected clinical use patterns. The finalized policy stated that CMS will determine the service, or group of services, to use to calculate the payment limitation through engagement with interested parties and a review by CMS Medical Officers and clinical staff during annual rulemaking. In the absence of engagement from interested parties, we will determine clinically appropriate procedures with which we would expect the drug or device to be frequently used in order to determine the payment limitation, including review of FDA approval materials, procedures identified in literature available to CMS, and other relevant materials. We noted that we may update the payment limitation amount in future rulemaking as we gather additional claims data on the utilization of and payment for this product.

3. Proposed CY 2026 Non-Opioid Policy Implementation of Section 4135 of the CAA, 2023

For CY 2026, we propose to continue the policies finalized in the CY 2025 OPPS ASC final rule without modification.

We continue to believe a zero-dollar offset is appropriate for all qualifying products regulated under the non-opioid policy as some of these products are new products or newly separately paid in the OPPS setting and their costs may not be fully reflected yet in the cost of procedures in which they may be used. Additionally, the data used for CY 2026 ratesetting is derived from CY 2024 claims, which was prior to the effective date of this policy in CY 2025. Accordingly, we propose to edit the regulation text at 42 CFR 416.174(c)(1) to remove the following text: “which is determined to be zero dollars for calendar year 2025.” We are

removing this language pertaining to the portion of the otherwise applicable Medicare OPD fee schedule amount for CY 2025, as we will discuss the appropriate amount in each year's rulemaking.

We note that the final payment limitation calculation in the CY 2026 OPPS/ASC final rule with comment period would be based on the proposed procedure payment rates and utilization data available in this proposed rule. Therefore, the values included in Table 83 are approximate payment limitations based on the best data available at the time of writing this proposed rule. We note that the final payment limitations for the CY 2026 OPPS/ASC final rule will also be based on the proposed payment rates in this proposed rule.

Table 82 includes citations to the indications of the drugs and biologicals proposed to have met the statutory requirements and qualify for separate payment for this CY 2026 OPPS/ASC proposed rule. We welcome public comment on all of these policies, including the procedures used to determine the payment limitations that are detailed in Table 83..

We welcome comments regarding additional drugs or devices that readers believe meet the criteria at 42 CFR 416.174 and 42 CFR 419.43(k) and should qualify as non-opioid treatments for pain relief. We will review these comments, evaluate the products against the criteria, and, if appropriate, will finalize additional drugs and devices that meet these criteria as non-opioid treatments for pain relief in the CY 2026 OPPS/ASC final rule with comment period to begin payment in CY 2026. We note that CMS finalized the regulation text at 42 CFR 416.174, which states that CMS will determine if the eligibility requirements are met through that year's rulemaking, due to this required review of materials, the need for input from the public, and the need to maintain budget neutrality per section 1833(t)(2)(E) of the Act

a. Qualifying Products for CY 2026

The following table, Table 82, lists the non-opioid alternatives that we propose will receive separate payment as a non-opioid pain management drug or device under section 4135 criteria for CY 2026.

CMS routinely receives public comments with detailed rationales on why they believe a particular drug, biological, medical device, or other item or service should receive separate payment. As such, we solicit comment on whether there are any additional drugs, biologicals, or medical devices that meet the statutory requirements outlined in sections 1833(t)(16)(G) and 1833(i)(10) of the Act. In addition to soliciting comment on the actual product and how it meets the criteria at 42 CFR 416.174 and 42 CFR 419.43(k), we solicit comment on the top 5 procedures used to calculate the payment limitation, as well as HCPCS coding for the product, which CMS could use to establish the payment rate, if CMS determines that the product discussed in the comment qualifies as a non-opioid treatment for pain relief.

As discussed previously in this section, there are specific requirements that must be met in order for the product to qualify for separate payment. Interested parties that believe that a product not addressed in this proposed rule meets the statutory requirements are encouraged to submit information during the comment period indicating how the product meets the statutory eligibility requirements. If CMS determines that the product(s) does in fact meet the statutory eligibility requirements, we will finalize separate payment for the product(s) in the CY 2026 OPPS/ASC final rule with comment period.

For drugs and biological products not addressed in the proposed rule, if no comment is submitted that outlines how that drug or biological meets the statutory criteria, then CMS will not finalize separate payment for such product for CY 2026. Additionally, for medical devices not addressed in the proposed rule, unless a comment is submitted that both outlines how that device meets the statutory criteria and includes literature that demonstrates that the device has the ability to replace, reduce, or avoid intraoperative or postoperative opioid use or the quantity of opioids prescribed in a clinical trial or through data published in a peer-reviewed journal, CMS will not finalize separate payment for such device for CY 2026.

We note that we propose that the HCPCS codes describing the qualifying devices and drugs in Table 82 will be placed on the ASC covered ancillary procedures list. We note that

Medicare Administrative Contractors (MACs) determine whether a drug, device, procedure, or other service meets all program requirements and conditions for coverage and payment. HOPDs and ASCs only receive payment for qualifying drugs, biologicals, and medical devices when the appropriate MAC determines that the service meets the relevant conditions for coverage and payment. As we have consistently stated in past OPPS/ASC final rules (see, e.g., 87 FR 71879 and 88 FR 81660 through 81661), the fact that a drug, device, procedure or service is assigned a HCPCS code and a payment rate under the OPPS does not imply coverage by the Medicare program, but indicates only how the product, procedure, or service may be paid if covered by the program (see, e.g., Pub 100–04 Medicare Claims Processing, Transmittal 11937).

TABLE 82: PROPOSED LIST OF QUALIFYING PRODUCTS FOR SEPARATE PAYMENT IN CY 2026 UNDER SECTION 4135 OF THE CAA, 2023

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
Exparel	J0666	Injection, bupivacaine liposome, 1mg	Yes[1]
Omidria	J1097	Phenylephrine 10.16 mg/ml and ketorolac 2.88 mg/ml ophthalmic irrigation solution, 1 ml	Yes[2]
Dextenza	J1096	Dexamethasone, lacrimal ophthalmic insert, 0.1 mg	Yes[3]
Zynrelef	C9088	Instillation, bupivacaine and meloxicam, 1 mg/0.03 mg	Yes[4]
Ketorolac tromethamine Injection	J1885	Injection, ketorolac tromethamine, per 15 mg	Yes[5]
ON-Q Pump	C9804	Elastomeric infusion pump (e.g., ON-Q* Pump with Bolus), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[6,7]
SPRINT Peripheral Nerve Stimulator System	C9807	Nerve stimulator, percutaneous, peripheral (e.g., SPRINT Peripheral Nerve Stimulation System), including electrode and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[8,9]
Cryo Nerve Block Therapy	C9808	Nerve cryoablation probe (e.g., cryoICE, cryoSPHERE, cryoSPHERE MAX, cryoICE cryoSPHERE, cryoICE Cryo2), including probe and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain	Yes[10,11,12,13,14,15,16]

Brand Name	HCPCS Code	Long Descriptor	Meets Requirements
		relief in accordance with Section 4135 of the CAA, 2023)	
ambIT Electronic Infusion Pump	C9806	Rotary peristaltic infusion pump (e.g., ambIT Pump), including catheter and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[17,18]
Iovera System	C9809	Cryoablation needle (e.g., iovera System), including needle/tip and all disposable system components, non-opioid medical device (must be a qualifying Medicare non-opioid medical device for post-surgical pain relief in accordance with Section 4135 of the CAA, 2023)	Yes[19,20,21,22,23]
IceMan	C9XX0	Water circulating motorized cold therapy device(e.g., IceMan) including all system components (e.g. pads, console, disposable parts), non-opioid medical device (must be a qualifying medicare non-opioid medical device for post-surgical pain relief in accordance with section 4135 of the caa, 2023)	Yes[24,25,26,27]

[1] Exparel. FDA Package Insert. November 2023. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/022496s051lbl.pdf.*
[2] Omidria. FDA Package Insert. December 2017. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/205388s006lbl.pdf.*
[3] Dextenza. FDA Package Insert. October 2021.*https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/208742s007lbl.pdf.*
[4] Zynrelef. FDA Package Insert. January 2024. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/211988s013lbl.pdf.*
[5] Ketorolac tromethamine Injection. FDA Package Insert. May 2014. *https://www.accessdata.fda.gov/drugsatfda_docs/label/2014/074802s038lbl.pdf.*
[6] On-Q Pump. FDA 510K. February 2019. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181360.pdf.*
[7] Ding DY, Manoli A 3rd, Galos DK, Jain S, Tejwani NC. Continuous Popliteal Sciatic Nerve Block Versus Single Injection Nerve Block for Ankle Fracture Surgery: A Prospective Randomized Comparative Trial. J Orthop Trauma. 2015;29(9):393-398. *https://pubmed.ncbi.nlm.nih.gov/2616525.*
[8] FDA Approval Letter, July 31, 2018. *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K181422.pdf.*
[9] Ilfeld BM, Plunkett A, Vijjeswarapu AM, Hackworth R, Dhanjal S, Turan A, Cohen SP, Eisenach JC, Griffith S, Hanling S, Sessler DI, Mascha EJ, Yang D, Boggs JW, Wongsarnpigoon A, Gelfand H Percutaneous, Peripheral Nerve Stimulation (Neuromodulation) for Postoperative Pain: A Randomized, Sham-controlled Pilot Study, Anesthesiology, April 2021.
[10] *https://www.accessdata.fda.gov/cdrh_docs/pdf18/K182565.pdf.*
[11] *https://www.accessdata.fda.gov/cdrh_docs/pdf20/K200697.pdf.*
[12] *https://www.accessdata.fda.gov/cdrh_docs/pdf23/K233170.pdf.*
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[14] Maxwell CM, Weksler B, Houda J, Fernando HC. Intercostal Cryoablation During Video-Assisted Lung Resection Can Decrease Postoperative Opioid Use. Innovations 2023 18(4):352-356.
[15] Jaroszewski DE, Bostoros P, Farina JM, Botros MM, Aly MR, Peterson M, Lackey J, Pulivarthi KV, Smith B, Craner R, Stearns JD. Evolution of Pain Control for Adult Pectus Excavatum Repair. Ann Thorac Surg. 2024;117(4):829-837
[16] Graves CE, Moyer J, Zobel MJ, Mora R, Smith D, O'Day M, Padilla BE. Intraoperative intercostal nerve cryoablation during the Nuss procedure reduces length of stay and opioid requirement: A randomized clinical trial. J Pediatric Surg. 2019 Nov; 54(11):2250-2256.
[17] FDA 510(k) Clearance K052221; obtained in 2005 by and issued to Sorenson Medical, Inc., which was later acquired by Summit Medical Products, Inc. Avanos acquired substantially all assets of Summit Medical Products, including this FDA 510(k) Clearance K052221, in 2019
[18] Morkos M, DeLeon A, Koeckert M, Gray Z, Liao K, Pan W, Tolpin DA. The Use of Unilateral Erector Spinae Plane Block in Minimally Invasive Cardiac Surgery. J Cardiothorac Vasc Anesth. 2023 Mar;37(3):432-436.
[19] FDA 510(k) No. K220656, available at *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K220656.*

[20] Urban JA, Dolesh K, Martin E. A Multimodal Pain Management Protocol Including Preoperative Cryoneurolysis for Total Knee Arthroplasty to Reduce Pain, Opioid Consumption, and Length of Stay. Arthroplast Today. 2021 Jul 12;10:87-92. doi: 10.1016/j.artd.2021.06.008. PMID: 34286056; PMCID: PMC8280475.
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[22] Ilfeld BM, Finneran JJ, Swisher MW, Said ET, Gabriel RA, Sztain JF, Khatibi B, Armani A, Trescot A, Donohue MC, Schaar A, Wallace AM. Preoperative Ultrasound-guided Percutaneous Cryoneurolysis for the Treatment of Pain after Mastectomy: A Randomized, Participant- and Observer-masked, Sham-controlled Study. Anesthesiology. 2022 Nov 1;137(5):529-542. doi: 10.1097/ALN.0000000000004334. PMID: 35929983.
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[24] See FDA Product Classification, Product Code ILO, *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?id=5437* (identifying ILO devices as Class 2, 510(k) exempt devices, described further at 21 CFR 890.5720); see also FDA 510(k) Premarket Notification, K955057 (Mar. 8, 1996), *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K955057 (*recognizing motorized cold therapy devices used for the "application of ice after surgery or injury to reduce swelling and pain").
[25] FDA, Product Code Database, "ILO", *https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=5437;* see also 21 CFR 890.5720.
[26] *https://www.accessdata.fda.gov/cdrh_docs/pdf/K955057.pdf.*
[27] Jones CA et al. Opioid-sparing pain management protocol after shoulder arthroplasty results in less opioid consumption and higher satisfaction: a prospective, randomized controlled trial. J Shoulder Elbow Surg. 2022 Oct;31(10):2057-2065. doi: 10.1016/j.jse.2022.05.029. Epub 2022 Jul 5. PMID: 35803549.

TABLE 83: PROPOSED PAYMENT LIMITATIONS FOR QUALIFYING PRODUCTS FOR CY 2026

Brand Name (HCPCS Code)	Top Primary Procedures HCPCS Code	Total Units of Drugs/Device packaged into Primary Procedure	Approximate Proposed CY 2026 Procedure Rate	CY 2026 Payment Limit (Volume Weighted Average of 18 percent of Primary Procedure Payment Rate)
Claims Data Available for Volume Weighted Average				
Zynrelef (C9088)	27447	9,837.0	13,460.76	2,411.7
	27130	4,596.0	13,460.76	
	23472	444.0	18,337.97	
	49505	326.5	3,756.07	
	27446	136.5	13,460.76	
Exparel (J0666; C9290)	27447	29,035.0	13,460.76	2,443.20
	23472	12,591.5	18,337.97	
	27130	8,450.0	13,460.76	
	49650	4,402.0	6,325.97	
	29827	4,031.0	7,651.18	
Dextenza (J1096)	66984	2,612.0	2,217.91	419.57
	66982	363.0	2,217.91	
	66991	80.0	5,469.68	
	68841	68.0	2,507.00	
	66183	37.0	4,309.45	
Omidria (J1097)	66984	6,285.5	2,217.91	414.05
	66982	1,075.5	2,217.91	

Brand Name (HCPCS Code)	Top Primary Procedures HCPCS Code	Total Units of Drugs/Device packaged into Primary Procedure	Approximate Proposed CY 2026 Procedure Rate	CY 2026 Payment Limit (Volume Weighted Average of 18 percent of Primary Procedure Payment Rate)
Claims Data Available for Volume Weighted Average				
	66991	123.5	5,469.68	
	65820	63.0	4,309.45	
	66174	44.0	4,309.45	
Ketorolac tromethamine injection (J1885)	27447	108,206.0	13,460.76	1,259.42
	99284	77,961.0	444.72	
	99283	68,680.0	289.98	
	27130	61,562.0	13,460.76	
	G0463	18,359.0	136.26	
No Claims Data Available for Volume Weighted Average*				
ON-Q Elastomeric Infusion Pump** (C9804)	27447	696	13,460.76	2,413.95
	23472	149	18,337.97	
	29827	74	7,651.18	
	49505	49	6,373.93	
	27130	43	13,460.76	
ambIT Electronic Infusion Pump** (C9806)	27447	696	13,460.76	2,413.95
	23472	149	18,337.97	
	29827	74	7,651.18	
	49505	49	6,373.93	
	27130	43	13,460.76	
Cryo Nerve Block Therapy (C9808)	32601	1	6,325.97	1,067.00
	32609	1	6,325.97	
	21811	1	7,651.18	
	21812	1	7,651.18	
	21813	1	1,685.79	
Iovera System (C9809)	64640	1	918.46	265.40
	64624	1	2,030.96	
	-	-	-	
	-	-	-	
	-	-	-	
SPRINT Peripheral Nerve Stimulator System (C9807)	23412	1	7,651.18	2,565.00
	23472	1	18,337.97	
	28705	1	18,337.97	
	27130	1	13,460.76	
	27447	1	13,460.76	
IceMan (C9XX0)	23472	1	18,337.97	2,180.20
	27447	1	13,460.76	
	23470	1	13,460.76	
	23410	1	7,651.18	
	29888	1	7,651.18	
*We assumed equal utilization of the qualifying product among the provided primary procedures unless otherwise advised by commenters.				

Brand Name (HCPCS Code)	Top Primary Procedures HCPCS Code	Total Units of Drugs/Device packaged into Primary Procedure	Approximate Proposed CY 2026 Procedure Rate	CY 2026 Payment Limit (Volume Weighted Average of 18 percent of Primary Procedure Payment Rate)
Claims Data Available for Volume Weighted Average				
**Expected utilization was provided by the manufacturer based on the CY 2025 OPPS/ASC Final Rule (89 FR 94356 through 94357).				

G. Proposed New Technology Intraocular Lenses (NTIOLs)

New Technology Intraocular Lenses (NTIOLs) are intraocular lenses that replace a patient's natural lens that has been removed in cataract surgery and that also meet the requirements listed in § 416.195.

1. NTIOL Application Cycle

Our process for reviewing applications to establish new classes of NTIOLs is as follows:

● Applicants submit their NTIOL requests for review to CMS by the annual deadline which is announced in the annual OPPS/ASC final rule with comment period. For a request to be considered complete, we require submission of the information requested in the guidance document titled "Application Process and Information Requirements for Requests for a New Class of New Technology Intraocular Lenses (NTIOLs) or Inclusion of an IOL in an Existing NTIOL Class" posted on the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/new-technology-intraocular-lenses-ntiols*.

● We announce annually, in the proposed rule updating the ASC and OPPS payment rates for the following calendar year, a list of all requests to establish new NTIOL classes accepted for review during the calendar year in which the proposal is published. In accordance with section 141(b)(3) of Pub. L. 103-432 and our regulations at § 416.185(b), the deadline for receipt of public comments is 30 days following publication of the list of requests to establish a new NTIOL class as published in the proposed rule.

● In the final rule with comment period updating the ASC and OPPS payment rates for the following calendar year, we—

++ Provide a list of determinations made as a result of our review of all new NTIOL class requests and public comments.

++ When a new NTIOL class is created, identify the predominant characteristic of NTIOLs in that class that sets them apart from other IOLs (including those previously approved as members of other expired or active NTIOL classes) and that is associated with an improved clinical outcome.

++ Set the date of implementation of a payment adjustment in the case of approval of an IOL as a member of a new NTIOL class prospectively as of 30 days after publication of the ASC payment update final rule, consistent with the statutory requirement.

++ Announce the deadline for submitting requests for review of an application for a new NTIOL class for the following calendar year.

2. Requests to Establish New NTIOL Classes for CY 2026

We did not receive any requests for review to establish a new NTIOL class for CY 2026 by March 1, 2025, the due date published in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94361).

3. Payment Adjustment

The current payment adjustment for a 5-year period from the implementation date of a new NTIOL class is $50 per lens. Since implementation of the process for adjustment of payment amounts for NTIOLs in 1999, we have not revised the payment adjustment amount, and we do not propose to revise the payment adjustment amount for CY 2026.

H. Proposed Calculation of the ASC Payment Rates and the ASC Conversion Factor

1. Background

In the August 2, 2007, ASC final rule with comment period (72 FR 42493), we established our policy to base ASC relative payment weights and payment rates under the revised

ASC payment system on APC groups and the OPPS relative payment weights. Consistent with that policy and the requirement at section 1833(i)(2)(D)(ii) of the Act that the revised payment system be implemented so that it would be budget neutral, the initial ASC conversion factor (CY 2008) was calculated so that estimated total Medicare payments under the revised ASC payment system in the first year would be budget neutral to estimated total Medicare payments under the prior (CY 2007) ASC payment system (the ASC conversion factor is multiplied by the relative payment weights calculated for many ASC services in order to establish payment rates). That is, application of the ASC conversion factor was designed to result in aggregate Medicare expenditures under the revised ASC payment system in CY 2008 being equal to aggregate Medicare expenditures that would have occurred in CY 2008 in the absence of the revised system, taking into consideration the cap on ASC payments in CY 2007, as required under section 1833(i)(2)(E) of the Act (72 FR 42522). We adopted a policy to make the system budget neutral in subsequent calendar years (72 FR 42532 through 42533; § 416.171(e)).

In the CY 2008 OPPS/ASC final rule with comment period (72 FR 66857 through 66858), we set out a step-by-step illustration of the final budget neutrality adjustment calculation based on the methodology finalized in the August 2, 2007, ASC final rule (72 FR 42521 through 42531) and as applied to updated data available for the CY 2008 OPPS/ASC final rule with comment period. The application of that methodology to the data available for the CY 2008 OPPS/ASC final rule with comment period resulted in a budget neutrality adjustment of 0.65.

For CY 2008, we adopted the OPPS relative payment weights as the ASC relative payment weights for most services and, consistent with the final policy, we calculated the CY 2008 ASC payment rates by multiplying the ASC relative payment weights by the final CY 2008 ASC conversion factor of $41.401. For covered office-based surgical procedures, covered ancillary radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents, as discussed in section XIII.D.2. of the CY 2023 OPPS/ASC proposed rule (87 FR 44715 through 44716)), and

certain diagnostic tests within the medicine range that are covered ancillary services, the established policy is to set the payment rate at the lower of the MPFS unadjusted nonfacility PE RVU-based amount or the amount calculated using the ASC standard ratesetting methodology. Further, as discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66841 through 66843), we also adopted alternative ratesetting methodologies for specific types of services (for example, device-intensive procedures).

As discussed in the August 2, 2007 ASC final rule with comment period (72 FR 42517 through 42518) and as codified at § 416.172(c) of the regulations, the revised ASC payment system accounts for geographic wage variation when calculating individual ASC payments by applying the pre-floor and pre-reclassified IPPS hospital wage indexes to the labor-related share, which is 50 percent of the ASC payment amount based on a GAO report of ASC costs using 2004 survey data. Beginning in CY 2008, CMS accounted for geographic wage variation in labor costs when calculating individual ASC payments by applying the pre-floor and pre-reclassified hospital wage index values that CMS calculates for payment under the IPPS, using updated Core Based Statistical Areas (CBSAs) issued by OMB in June 2003.

The reclassification provision in section 1886(d)(10) of the Act is specific to acute care hospitals. We believe that using the most recently available pre-floor and pre-reclassified IPPS hospital wage indexes result in the most appropriate adjustment to the labor portion of ASC costs. We continue to believe that the pre-floor, pre-reclassified hospital wage indexes, which are updated yearly and are used by several other Medicare payment systems, appropriately account for geographic variation in labor costs for ASCs (89 FR 23424). Therefore, the wage index for an ASC is the pre-floor and pre-reclassified hospital wage index for the fiscal year under the IPPS of the CBSA that maps to the CBSA where the ASC is located.

On July 21, 2023, OMB issued OMB Bulletin No. 23-01, which provided the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the

United States and Puerto Rico based on the standards published on July 16, 2021, in the **Federal Register** (86 FR 37770) and 2020 Census Bureau data. (A copy of this bulletin may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2023/07/OMB-Bulletin-23-01.pdf*.) As discussed in the FY 2025 IPPS/LTCH PPS final rule with comment period (89 FR 69253 through 69266), we finalized our proposal to use the new CBSAs delineations issued by OMB in OMB Bulletin 23-01 for the IPPS hospital wage index beginning in CY 2025. Therefore, because the ASC wage indexes for the calendar year are the pre-floor and pre-reclassified IPPS hospital wage indexes for the fiscal year, in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94362 through 94363) we finalized our proposal to incorporate the new OMB delineations into CY 2025 ASC wage indexes. We believe that using the revised delineations based on OMB Bulletin No. 23-01 will increase the integrity of the ASC wage index system by creating a more accurate representation of current geographic variations in wage levels. In addition to adopting the revised delineations based on OMB Bulletin No. 23-01, we also finalized our proposal to limit year-to-year ASC wage index value changes to no more than a 5-percent decrease, similar to the policy of other Medicare payment systems under Parts A and B. This 5-percent cap, implemented in a budget neutral manner through the wage index scalar, mitigates any large negative impacts of adopting the new delineations and prevents large year-to-year declines in wage index values as a means to reduce volatility in Medicare payments.

The proposed CY 2026 ASC wage indexes fully reflect the OMB labor market area delineations (including the revisions to the OMB labor market delineations discussed previously, as set forth in OMB Bulletin No. 23-01). We note that, in certain instances, there might be urban or rural areas for which there is no IPPS hospital that has wage index data that could be used to set the wage index for that area. When all of the areas contiguous to the urban CBSA of interest are rural and there is no IPPS hospital that has wage index data that could be used to set the wage index for that area, our policy has been to determine the ASC wage index by calculating the average of all wage indexes for urban areas in the State (75 FR 72058 through 72059). In other

situations, where there are no IPPS hospitals located in a relevant labor market area, we apply our current policy of calculating an urban or rural area's wage index by calculating the average of the wage indexes for CBSAs (or metropolitan divisions where applicable) that are contiguous to the area with no wage index. For example, for CY 2026, we are proposing that we continue to apply a proxy wage index based on this methodology to ASCs located in CBSA 25980 (Hinesville, GA) and in CBSA 35 (Rural North Dakota). Further, the proposed CY 2026 ASC wage index includes our policy finalized in the CY 2025 OPPS/ASC final rule with comment period that limits wage index changes to decrease by no more than 5 percent from the final CY 2025 ASC wage index value.

2. Calculation of the ASC Payment Rates

a. Updating the ASC Relative Payment Weights for CY 2026 and Future Years

We update the ASC relative payment weights each year using the national OPPS relative payment weights (and PFS nonfacility PE RVU-based amounts, as applicable) for that same calendar year and uniformly scale the ASC relative payment weights for each update year to make them budget neutral (72 FR 42533). The OPPS relative payment weights are scaled to maintain budget neutrality for the OPPS. We then scale the OPPS relative payment weights again to establish the ASC relative payment weights. To accomplish this, we hold estimated total ASC payment levels constant between calendar years for purposes of maintaining budget neutrality in the ASC payment system. That is, we apply the weight scalar to ensure that projected expenditures from the updated ASC payment weights in the ASC payment system are equal to what would be the current expenditures based on the scaled ASC payment weights. In this way, we ensure budget neutrality and that the only changes to total payments to ASCs result from increases or decreases in the ASC payment update factor.

As discussed in section II.A.1.a. of this proposed rule, we are using the CY 2024 claims data to be consistent with the OPPS claims data for the proposed rule. Consistent with our established policy, we propose to scale the CY 2026 relative payment weights for ASCs

according to the following method. Holding ASC utilization, the ASC conversion factor, and the mix of services constant from CY 2024, we propose to compare the estimated total payment using the CY 2025 ASC relative payment weights with the estimated total payment using the CY 2026 ASC relative payment weights to take into account the changes in the OPPS relative payment weights between CY 2025 and CY 2026.

In consideration of our policy to provide a higher ASC payment rate with ASC complexity adjustment codes for certain primary procedures when performed with add-on packaged services, we incorporated estimated total spending and estimated utilization for these codes in our budget neutrality calculation for CYs 2023 and 2024. For this proposed rule, our estimated change in ASC spending related to our proposed ASC complexity adjustment codes for CY 2026 did not impact the ASC weight scalar.

Additionally, as discussed in section XIII.E. of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94342 through 94361), section 4135(a) and (b) of the CAA, 2023, titled "Access to Non-Opioid Treatments for Pain Relief," amended section 1833(t)(16) and section 1833(i) of the Act, respectively, to provide for temporary separate payments for non-opioid treatments for pain relief. As discussed in further detail in section XIII.E. of the CY 2025 OPPS/ASC final rule, for qualifying non-opioid products, we finalized applying an 18 percent payment limitation on the volume weighted payment average of the top 5 services associated with the use of the qualifying non-opioid product. In CY 2024, four of these qualifying nonopioid products were separately payable without the 18 percent payment limitation – HCPCS Codes C9089 (Bupivacaine implant, 1 mg), C9290 (Inj, bupivacaine liposome), J1096 (Dexametha opth insert 0.1 mg), and J1097 (Phenylep ketorolac opth soln). Therefore, to maintain budget neutrality, we estimated the total anticipated reduction in ASC spending for these qualifying non-opioid products for CY 2025 as a result of the 18 percent payment limitation required by section 4135 of the CAA, 2023. Based on the updated 18 percent payment

limitations and CY 2024 utilization, we estimate that the proposed CY 2026 payment limitations will not impact the ASC weight scalar.

In section XIII.C.2.b. of this proposed rule, we discuss our proposal to unpackage and pay separately for groups of skin substitute products under the ASC payment system beginning January 1, 2026. Currently, these products are packaged into payment for the primary covered surgical procedures. To maintain budget neutrality under the OPPS, the reduction in any APC's relative weights from the loss of skin substitute costs in the APC's geometric mean cost will be offset by an increase in the OPPS weight scalar. To maintain budget neutrality, this increase in the OPPS weight scalar will be offset by a reduction in estimated new OPPS payment for skin substitute APC groups.

Since we ask ASCs not to report packaged items and services on ASC claims, we are unable to perform a similar adjustment and determine existing utilization of skin substitute products from ASC claims. To resolve this limitation but maintain budget neutrality within the ASC payment system, we multiplied the change in the geometric mean costs of covered surgical skin procedure in the ASC setting from unpackaging skin substitute products by the utilization of such skin procedures in the ASC setting to approximate the estimated skin substitute payments in the ASC setting. Based on existing surgical procedure utilization and our estimated utilization of skin substitute products in the ASC setting, our estimated separate payments for skin substitutes in the ASC setting did not impact the ASC weight scalar.

We propose to use the ratio of estimated CY 2025 to estimated CY 2026 total payments (the weight scalar) to scale the ASC relative payment weights for CY 2026. The proposed CY 2026 ASC weight scalar is 0.842. As discussed further in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94363 through 94364), we have historically displayed this figure rounded to the nearest ten thousandth; however, we believe this level of specificity is unnecessarily burdensome for an ASC payment system that is less than one-tenth the size of the OPPS (in which the weight scalar is rounded to the nearest ten-thousandth). Consistent with

historical practice, we propose to scale, using this method (with an ASC weight scalar rounded to the nearest thousandth), the ASC relative payment weights of covered surgical procedures, covered ancillary radiology services, and certain diagnostic tests within the medicine range of CPT codes, which are covered ancillary services for which the ASC payment rates are based on OPPS relative payment weights.

We propose that we would not scale ASC payment for separately payable covered ancillary services that have a predetermined national payment amount (that is, their national ASC payment amounts are not based on OPPS relative payment weights), such as drugs and biologicals that are separately paid or services that are contractor-priced or paid at reasonable cost in ASCs. Any service with a predetermined national payment amount, which includes the device portion of device-intensive procedures, would be included in the ASC budget neutrality comparison, but scaling of the ASC relative payment weights would not apply to those services or the portion of those services. The ASC payment weights for those services without predetermined national payment amounts would be scaled to eliminate any difference in the total payment between the current year and the update year.

However, as discussed in sections V.B.8.i. and XIII.C.4. of this proposed rule, we propose that the OPPS payment rates used for ratesetting under the ASC payment system for CY 2026 and subsequent years would not incorporate the two percent prospective offset to the OPPS conversion factor, as a result of the 340B remedy offset that we are proposing to implement in this proposed rule. Historically, the ASC payment system has generally adopted the OPPS conversion factor used for determining the proposed or final OPPS payment rates for determining the device portions for device-intensive procedures under the ASC payment system. A two percent reduction in the OPPS conversion factor would otherwise reduce ASC payments for device-intensive procedures by approximately one percent; the non-device portions for all covered surgical procedures would otherwise be increased to offset reduction to device portions for device-intensive procedures. For CY 2026, we estimate the reduction to device portions from

the two percent prospective offset would have reduced proposed CY 2026 ASC expenditures for device-intensive procedures by approximately $42 million and would have otherwise increased the ASC weight scalar by 0.1 percent to offset such reduction.

For any given year's ratesetting, we typically use the most recent full calendar year of claims data to model budget neutrality adjustments. We propose to use the CY 2024 claims data to model our budget neutrality adjustment for CY 2026.

b. Updating the ASC Conversion Factor

Under the OPPS, we typically apply a budget neutrality adjustment for provider-level changes, most notably a change in the wage index values for the upcoming year, to the conversion factor. Consistent with our final ASC payment policy, for the CY 2017 ASC payment system and subsequent years, in the CY 2017 OPPS/ASC final rule with comment period (81 FR 79751 through 79753), we finalized our policy to calculate and apply a budget neutrality adjustment to the ASC conversion factor for supplier-level changes in wage index values for the upcoming year, just as the OPPS wage index budget neutrality adjustment is calculated and applied to the OPPS conversion factor.

For CY 2026, we calculated the proposed adjustment for the ASC payment system by using the most recent CY 2024 claims data available and estimating the difference in total payment that would be created by introducing the proposed CY 2026 ASC wage indexes. Specifically, holding CY 2024 ASC utilization, service-mix, and the proposed CY 2026 national payment rates after application of the weight scalar constant, we calculated the total adjusted payment using the CY 2025 ASC wage indexes and the total adjusted payment using the proposed CY 2026 ASC wage indexes which included the 5-percent cap on wage index declines. We used the 50 percent labor-related share for both total adjusted payment calculations. We then compared the total adjusted payment calculated with the CY 2025 ASC wage indexes to the total adjusted payment calculated with the proposed CY 2026 ASC wage indexes and applied the resulting ratio of 0.9999 (the proposed CY 2026 ASC wage index budget neutrality adjustment)

to the CY 2025 ASC conversion factor to calculate the proposed CY 2026 ASC conversion factor.

Section 1833(i)(2)(D)(v) of the Act requires that the ASC conversion factor be reduced by a productivity adjustment in each calendar year. Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP). We finalized the methodology for calculating the productivity adjustment in the CY 2011 PFS final rule with comment period (75 FR 73394 through 73396) and revised it in the CY 2012 PFS final rule with comment period (76 FR 73300 through 73301) and the CY 2016 OPPS/ASC final rule with comment period (80 FR 70500 through 70501). The proposed productivity adjustment for CY 2026 was projected to be 0.8 percentage point, as published in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18266) based on IGI's 2024 fourth quarter forecast.

Section 1833(i)(2)(C)(i) of the Act requires that, if the Secretary has not updated amounts established under the revised ASC payment system in a calendar year, the payment amounts shall be increased by the percentage increase in the Consumer Price Index for all urban consumers (CPI-U), U.S. city average, as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved. The statute does not mandate the adoption of any particular update mechanism, but it requires the payment amounts to be increased by the CPI-U in the absence of any update. Because the Secretary updates the ASC payment amounts annually, we adopted a policy, which we codified at § 416.171(a)(2)(ii)), to update the ASC conversion factor using the CPI-U for CY 2010 and subsequent calendar years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59080), we finalized a policy to apply the hospital market basket update (which is the inpatient hospital market basket percentage increase reduced by the productivity adjustment) to ASC payment system rates for an interim period of 5 years (CY 2019 through CY 2023), during which we would assess whether there was a migration of the performance of procedures from the

hospital setting to the ASC setting as a result of the use of a hospital market basket update, as well as whether there were any unintended consequences, such as less than expected migration of the performance of procedures from the hospital setting to the ASC setting. At that time, the most recently available full year of claims data to assess the expected migration applying the productivity-adjusted hospital market basket update during the interim period was within the period from CY 2019 through CY 2022. However, the impact of the COVID-19 PHE on health care utilization, CY 2020 in particular, was tremendously profound, particularly for elective surgeries, because many beneficiaries avoided healthcare settings, when possible, to avoid possible infection from the SARS-CoV-2 virus. As a result, it was nearly impossible to disentangle the effects from the COVID-19 PHE in our analysis of whether the higher update factor for the ASC payment system caused increased migration to the ASC setting. To analyze whether procedures migrated from the hospital setting to the ASC setting, we needed to use claims data from a period during which the COVID-19 PHE had less of an impact on health care utilization. Therefore, for CY 2024, we finalized our proposal to extend the 5-year interim period an additional 2 years through CY 2024 and CY 2025. We believed hospital outpatient and ASC utilization data from CYs 2023 and 2024 would enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system had an effect on the migration of services from the hospital setting to the ASC setting. We revised our regulations at 42 CFR 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii) which establish the annual update to the ASC conversion factor, to reflect this 2-year extension.

For this CY 2026 OPPS/ASC proposed rule, we propose to extend our utilization of the hospital market basket update factor in the ASC payment system for one additional year, through CY 2026, as we continue to review and evaluate hospital outpatient and ASC utilization data, as well as the migration of surgical procedures between settings. In conjunction with our proposal, we are revising our regulations at 42 CFR 416.171(a)(2)(iii), (iv), (vi), (vii), and (viii), which establish the annual update to the ASC conversion factor, the 2.0 percentage point reduction for

ASCs that fail to meet the standards for reporting ASC quality measures, and the productivity adjustment, to reflect this one year extension.

2. CY 2026 Proposed ASC Conversion Factor

For CY 2026, we propose to utilize the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by the proposed productivity adjustment of 0.8 percentage point, resulting in a proposed hospital market basket update of 2.4 percent for ASCs meeting the quality reporting requirements. Therefore, we propose to apply a proposed 2.4 percent hospital market basket update factor to the CY 2025 ASC conversion factor for ASCs meeting the quality reporting requirements to determine the CY 2026 ASC payment amounts. The ASCQR Program affected payment rates beginning in CY 2014 and, under this program, there is a 2.0 percentage point reduction to the hospital market basket update factor for ASCs that fail to meet the ASCQR Program requirements.

We refer readers to section XIV.E. of the CY 2019 OPPS/ASC final rule with comment period (83 FR 59138 through 59139) and section XIV.E. of this proposed rule for a detailed discussion of our policies regarding payment reduction for ASCs that fail to meet ASCQR Program requirements. We propose to utilize the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by 2.0 percentage points for ASCs that do not meet the quality reporting requirements and then reduced by the proposed 0.8 percentage point productivity adjustment. Therefore, we propose to apply a 0.4 percent hospital market basket update factor to the CY 2025 ASC conversion factor for ASCs not meeting the quality reporting requirements. We also propose that if more recent data are subsequently available (for example, a more recent estimate of the inpatient hospital market basket percentage increase or productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ASC update for the CY 2026 OPPS/ASC final rule with comment period.

For CY 2026, we are adjusting the CY 2025 ASC conversion factor ($54.895) by a wage index budget neutrality factor of 0.9999 in addition to the productivity-adjusted hospital market

basket update of 2.4 percent, discussed previously, which results in a proposed CY 2026 ASC conversion factor of $56.207 for ASCs meeting quality reporting requirements. For ASCs not meeting quality reporting requirements, we are adjusting the CY 2025 ASC conversion factor ($54.895) by the wage index budget neutrality factor of 0.9999 in addition to the reduced productivity-adjusted hospital market basket update of 0.4 percent, discussed above, which results in a proposed CY 2026 ASC conversion factor of $55.109 for ASCs not meeting the quality reporting requirements.

3. Display of the Proposed CY 2026 ASC Payment Rates

Addenda AA and BB to this proposed rule (which are available on the CMS website) display the proposed ASC payment rates for CY 2026 for covered surgical procedures and covered ancillary services, respectively. The proposed payment rates included in Addenda AA and BB to this proposed rule reflect the full ASC payment update and not the reduced payment update used to calculate payment rates for ASCs not meeting the quality reporting requirements under the ASCQR Program.

These Addenda contain several types of information related to the proposed CY 2026 payment rates. Specifically, in Addendum AA, a "Y" in the column titled "To be Subject to Multiple Procedure Discounting" indicates that the surgical procedure would be subject to the multiple procedure payment reduction policy. As discussed in the CY 2008 OPPS/ASC final rule with comment period (72 FR 66829 through 66830), most covered surgical procedures are subject to a 50 percent reduction in the ASC payment for the lower-paying procedure when more than one procedure is performed in a single operative session.

The values displayed in the column titled "Proposed CY 2026 Payment Weight" are the proposed relative payment weights for each of the listed services for CY 2026. The proposed relative payment weights for all covered surgical procedures and covered ancillary services where the ASC payment rates are based on OPPS relative payment weights were scaled for budget neutrality. Therefore, scaling was not applied to the device portion of the

device-intensive procedures; services that are paid at the MPFS nonfacility PE RVU-based amount; separately payable covered ancillary services that have a predetermined national payment amount, such as drugs and biologicals and brachytherapy sources that are separately paid under the OPPS; or services that are contractor-priced or paid at reasonable cost in ASCs. This includes separate payment for non-opioid pain management drugs.

To derive the proposed CY 2026 payment rate displayed in the "Proposed CY 2026 Payment Rate" column, each ASC payment weight in the "Proposed CY 2026 Payment Weight" column was multiplied by the proposed CY 2026 conversion factor. The conversion factor includes a budget neutrality adjustment for changes in the wage index values and the annual update as reduced by the productivity adjustment. The proposed CY 2026 ASC conversion factor uses the proposed CY 2026 productivity-adjusted hospital market basket update factor of 2.4 percent (which is equal to the inpatient hospital market basket percentage increase of 3.2 percent reduced by the productivity adjustment of 0.8 percentage point). We also propose that if more recent data subsequently become available (for example, a more recent estimate of the inpatient hospital market basket percentage increase and the productivity adjustment), we would use such data, if appropriate, to determine the CY 2026 ASC conversion factor in the final rule.

In Addendum BB, there are no relative payment weights displayed in the "Proposed CY 2026 Payment Weight" column for items and services with predetermined national payment amounts, such as separately payable drugs and biologicals. The "Proposed CY 2026 Payment" column displays the proposed CY 2026 national unadjusted ASC payment rates for all items and services. The proposed CY 2026 ASC payment rates listed in Addendum BB for separately payable drugs and biologicals are based on the most recently available data used for payment in physicians' offices. For CY 2021, we finalized adding a new column to ASC Addendum BB titled "Drug Pass-Through Expiration during Calendar Year" where we flag through the use of an asterisk each drug for which pass-through payment is expiring during the calendar year (that

is, on a date other than December 31st).

Addendum EE to this proposed rule provides the HCPCS codes and short descriptors for surgical procedures that are to be excluded from payment in ASCs for CY 2026.

Addendum FF to this proposed rule displays the OPPS payment rate (based on the standard ratesetting methodology), the APC device offset percentage, the device offset percentage for determining device-intensive status (based on the standard ratesetting methodology), and the device portion of the ASC payment rate for CY 2026 for covered surgical procedures.

XIV. Cross-Program Proposals for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs

A. Background

We refer readers to sections XV., XVI., and XVII. of this proposed rule for program specific background information, including the statutory authorities, and previously finalized and newly proposed measure sets, for the Hospital Outpatient Quality Reporting (OQR), Rural Emergency Hospital Quality Reporting (REHQR), and Ambulatory Surgical Center Quality Reporting (ASCQR) Programs, respectively.

B. Measure Concepts under Consideration for Future Years in the Hospital OQR, REHQR, and ASCQR Programs–Request for Information (RFI): Well-Being and Nutrition

We are seeking input on well-being and nutrition measures for consideration in future rulemaking for the Hospital OQR, REHQR, and ASCQR Programs. Well-being is a comprehensive approach to disease prevention and health promotion, as it integrates mental and physical health while emphasizing preventative care to proactively address potential health issues.[141] This comprehensive approach emphasizes person-centered care by promoting the well-

[141] Centers for Disease Control and Prevention. (May 2024). About Emotional Well-Being. Available at *https://www.cdc.gov/emotional-well-being/about/#cdc_behavioral_basics_types-health-benefits. Accessed: April 30, 202.5*

being of patients and family members. We are seeking comments on tools and measures that assess overall health, happiness, and satisfaction in life, which could include aspects of emotional well-being, social connections, purpose, and fulfillment. We would like to receive input and comments on the applicability of tools and constructs that assess the integration of complementary and integrative health, skill building, and self-care.

We are also seeking comments on tools and measures that assess optimal nutrition and preventive care in the Hospital OQR, REHQR, and ASCQR Programs. Assessments for nutritional status may include strategies, guidelines, and practices that promote healthy eating habits and ensure individuals receive the necessary nutrients for maintaining health, growth, and overall well-being. Such assessments may also include aspects of health that support or mediate nutritional status, such as physical activity and sleep. In this context, preventive care plays a vital role by proactively addressing factors that may lead to poor nutritional status or related health issues. These efforts not only support optimal nutrition but also work to prevent conditions that could otherwise hinder an individual's health and nutritional needs.

While we will not be responding to specific comments in response to this RFI in the CY 2026 OPPS/ASC final rule, we intend to use this input to inform our future measure development efforts.

C. Proposed Changes to the Hospital OQR, REHQR, and ASCQR Program Measure Sets

1. Proposed Removal of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure from the Hospital OQR and ASCQR Programs Beginning with the CY 2024 Reporting Period/CY 2026 Payment Determination

We refer readers to the CY 2022 OPPS/ASC final rule where we adopted the COVID-19 Vaccination Coverage Among HCP measure into the Hospital OQR and ASCQR Programs (86 FR 63824 through 63833 and 86 FR 63875 through 63883, respectively) and the CY 2024 OPPS/ASC final rule with comment period where we modified the COVID-19 Vaccination

Coverage Among HCP measure to account for updated vaccine guidance (88 FR 81963 through 81968 and 88 FR 82013 through 82017, respectively).

For the Hospital OQR and ASCQR Programs, we propose to remove the COVID-19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination under removal Factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program (§§ 419.46(i)(3)(i)(H) and 416.320(c)(2)(viii), respectively). Reporting on this measure currently requires reporting data on COVID-19 Vaccination Coverage Among HCP for at least 1 week every month. This requires healthcare facilities 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.[142] The estimated burden of collecting this information annually across all 3,200 hospitals in the Hospital OQR Program is between $1,446,400 and $1,687,680. Across the 4,590 ASCs in the ASCQR Program, the estimated annual burden is between $2,074,680 and $2,420,766. We refer readers to section XXIII. of this proposed rule for more details on this estimated burden calculation.

When we first adopted the COVID-19 Vaccination Coverage Among HCP measure for the Hospital OQR and ASCQR Programs, the U.S. was in the midst of a Public Health Emergency (PHE) that incurred millions of cases and over 718,000 COVID-19 deaths (86 FR 63825 and 86 FR 63875 through 63876, respectively).[143] While preventing the spread of COVID-19 remains a public health goal, the PHE ended on May 11, 2023.[144] In addition, the number of deaths due to COVID-19 in the U.S. has decreased since the adoption of this measure.

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[142] Centers for Disease Control and Prevention. (2025). Weekly COVID-19 Vaccination Module for Healthcare Personnel. Available at *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/2025-hcp-combined-protocol-508.pdf. Accessed: April 30, 2025.*

[143] Centers for Disease Control and Prevention. (2025). COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#trends_totaldeaths_select_00. Accessed: April 30, 2025.*

[144] U.S. Department of Health and Human Services. (2023). COVID-19 Public Health Emergency. Available at *https://www.hhs.gov/coronavirus/covid-19-public-health-emergency/index.html. Accessed: April 30, 2025.*

In August 2021, when this measure was being proposed, the U.S. was averaging over 6,000 deaths related to COVID-19 per week.[145] In April 2023, the last full month of the PHE, weekly number of deaths attributed to COVID-19 averaged around 1,300.[146] With the end of the PHE and the decrease in COVID-19 deaths, we believe the continued costs and burden to healthcare facilities 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 and ASCs to continue to report on the COVID-19 Vaccination Coverage Among HCP measure, removal of this measure would allow for the Hospital OQR and ASCQR Programs to focus on other clinical goals.

If this proposal is finalized as proposed, hospitals and ASCs that do not report their CY 2024 reporting period data for the COVID-19 Vaccination Coverage Among HCP measure to CMS would not be considered noncompliant with the measure for their CY 2026 payment determination (that is, hospitals and ASCs that do not report CY 2024 reporting period data would not be penalized for CY 2026 payments due to this measure). Any COVID-19 Vaccination Coverage Among HCP measure data received by CMS would not be used for public reporting or payment purposes.

If this proposal is not finalized as proposed, hospitals and ASCs that do not report their CY 2024 reporting data for the COVID-19 Vaccination Coverage Among HCP measure to CMS would be considered noncompliant with the measure for their CY 2026 payment determination and would receive a letter of noncompliance. Payment adjustments would apply to CY 2026 payment determination for fee-for-service claims as previously finalized.

We invite public comment on this proposal.

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[145] Centers for Disease Control and Prevention. (2025). COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00. Accessed: April 30, 2025.*
[146] Centers for Disease Control and Prevention. (2025). COVID Data Tracker. Available at *https://covid.cdc.gov/covid-data-tracker/#trends_weeklydeaths_select_00. Accessed: April 30, 2025.*

2. Proposed Removal of the Hospital Commitment to Health Equity (HCHE) measure from the Hospital OQR and REHQR Programs and the Facility Commitment to Health Equity (FCHE) measure from the ASCQR Program Beginning with the CY 2025 Reporting Period/CY 2027 Payment or Program Determination

We refer readers to the CY 2025 OPPS/ASC final rule with comment period where we adopted the Hospital Commitment to Health Equity (hereafter referred to as HCHE) measure into the Hospital OQR and REHQR Programs and the Facility Commitment to Health Equity (hereafter referred to as FCHE) measure into the ASCQR Program (89 FR 94368 through 94381). For the Hospital OQR, REHQR, and ASCQR Programs, we propose to remove the HCHE and FCHE measures beginning with the CY 2025 reporting period/CY 2027 payment or program determination under removal Factor 8, due to the costs associated with achieving a high score on the measure outweighing the benefit of its continued use in the program (§§ 419.46(i)(3)(i)(H), 419.95(e)(3)(i)(H), and 416.320(c)(2)(viii), respectively).

When adopted, we intended the collection of data described in the five domains of these measures to provide hospital, REH, and ASC leadership with meaningful and actionable health data to drive quality improvements to eliminate health disparities. Based on feedback received from hospitals, REHs, and ASCs, as well as a re-focus on clinical outcomes and direct patient care, for which the HCHE and FCHE measures, as structural measures, do not directly measure, the burden of collecting these measures may outweigh the benefits. Removal of these measures would alleviate an estimated annual burden of approximately 533 hours, at a cost of $22,518, across all participating hospitals (89 FR 94523); 6 hours, at a cost of $332, across all participating REHs (89 FR 94530); and 746 hours, at a cost of $41,313 across all participating ASCs (89 FR 94534).

An important goal of the Hospital OQR, REHQR, and ASCQR Programs is moving forward in the least burdensome manner possible while maintaining a parsimonious set of meaningful quality measures and continuing to incentivize improvement in the quality of care

provided to patients. Removing these measures from the Hospital OQR, REHQR and ASCQR Programs serves 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. As such we refer readers to our request for comment on "Measure Concepts under Consideration for Future Years in the Hospital OQR, REHQR, and ASCQR Programs –Request for Information (RFI): Well-Being and Nutrition" in section XIV.B. of this proposed rule.

We acknowledge that some hospitals, REHs, and ASCs may have expended resources to implement some or all of the activities described in the HCHE and FCHE measures attestation statements in order to be able to attest "yes" for measure reporting purposes.

If this proposal is finalized as proposed, hospitals, REHs, and ASCs that do not report their CY 2025 reporting period data for the HCHE or FHCE measure to CMS would not be considered noncompliant with the measure for purposes of their CY 2027 payment or program determination (that is, hospitals, REHs, or ASCs that do not report CY 2025 reporting period data would not be penalized for CY 2027 payments due to this measure, if applicable). Any HCHE or FCHE measure data received by CMS would not be used for public reporting or payment purposes.

If this proposal is not finalized as proposed, hospitals, REHs, or ASCs that do not report their CY 2025 reporting data for the HCHE or FCHE measures to CMS would be considered noncompliant with the measure for their CY 2027 payment or program determination and would receive a letter of noncompliance. Payment adjustments would apply to CY 2027 payment determination fee-for-service (FFS) claims as previously finalized in the Hospital OQR and ASCQR Programs.

We invite public comment on these proposals.

3. Proposed Removal of Two Social Drivers of Health Measures from the Hospital OQR, REHQR, and ASCQR Programs Beginning with the CY 2025 Reporting Period

We propose to remove two social drivers of health (SDOH) process measures from the Hospital OQR, REHQR, and ASCQR Programs beginning with the CY 2025 reporting period: Screening for Social Drivers of Health (adopted at 89 FR 94381 through 94398); and Screen Positive Rate for Social Drivers of Health (adopted at 89 FR 94398 through 94403).

We propose to remove the SDOH measures beginning with the CY 2025 reporting period under removal Factor 8, the costs associated with the measure outweigh the benefit of its continued use in these programs (§§ 419.46(i)(3)(i)(H), 419.95(e)(3)(i)(H), and 416.320(c)(2)(viii), respectively). We have heard from some hospitals, REHs, and ASCs concerned with the costs and resources associated with screening patients via manual processes, manually storing such data, training staff, and altering workflows for these measures. In the CY 2025 OPPS/ASC final rule with comment period, we estimated a total annual burden of 6,878,055 hours at a cost of $168,460,032 in the Hospital OQR Program (89 FR 94523 and 94524), 12,984 hours at a cost of $318,163 in the REHQR Program (89 FR 94530 and 94531), and 711,479 hours at a cost of $17,447,164 in the ASCQR Program (89 FR 94534 and 94535), to screen all admitted patients in accordance with measure specifications for Screening for Social Drivers of Health and report the measure data. For Screen Positive Rate for Social Drivers of Health, we estimated a total annual burden of 533 hours at a cost of $29,518 in the Hospital OQR Program (89 FR 94524), 6 hours at a cost of $332 in the REHQR Program (89 FR 94531 and 94532), and 746 hours at a cost of $41,313 in the ASCQR Program (89 FR 94535), to report the measure data. We note that the HQR system calculates the rate for these two measures, and that hospitals, REHs, and ASCs' responsibility is to report the aggregate number of patients screened, the aggregate number of patients that screened positive, and their total patient population. Further, we note that these measures document an administrative process and report aggregate level results, and do not shed light on the extent to which providers are ultimately connecting patients with resources or services and whether patients are benefiting from these screenings.

We have concluded that the costs of the continued use of these measures in the Hospital OQR, REHQR, and ASCQR Programs outweigh the benefits to facilities and patients. Removal of these measures would alleviate the burden on hospitals, REHs, and ASCs to manually screen each patient and submit data each reporting cycle, allowing hospitals, REHs, and ASCs to focus resources on measurable clinical outcomes and direct patient care. This will also remove the patient burden associated with repeated SDOH screenings across multiple healthcare facilities. We refer readers to our request for comment, "Measure Concepts under Consideration for Future Years in the Hospital OQR, REHQR, and ASCQR Programs–Request for Information (RFI): Well-Being and Nutrition" in section XIV.B. of this proposed rule for more information regarding our areas of focus for new measures. We acknowledge that some hospitals, ASCs and REHs 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 OQR Program continue to incentivize the improvement of care quality and health outcomes for all patients through transparency and use of appropriate quality measures.

We invite public comment on these proposals.

D. Proposed Updates to the Extraordinary Circumstances Exception (ECE) Policy for the Hospital OQR, REHQR, and ASCQR Programs

1. Background

Under our current Extraordinary Circumstances Exception (ECE) regulations, we have granted exceptions to data submission deadlines and requirements for the Hospital OQR, REHQR, and ASCQR Programs in the event of extraordinary circumstances beyond the control of a hospital, REH, or ASC (42 CFR 419.46(e); 419.95(g); 416.310(d), respectively). Extraordinary circumstances may include, but are not limited to, natural disasters or systemic

problems with data collection systems.[147] We refer readers to the CY 2022 OPPS/ASC final rule with comment period (86 FR 63873), the CY 2024 OPPS/ASC final rule with comment period (88 FR 82076), and the CY 2018 OPPS/ASC final rule with comment period (82 FR 59474 through 59475) for further background about the ECE policies for Hospital OQR, REHQR, and ASCQR Programs, respectively. We also refer readers to the QualityNet website for program-specific requirements for submitting an ECE request.[148]

Our ECE policy provides flexibility for Hospital OQR, REHQR, and ASCQR Program participants toward meeting program requirements 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, REH, or ASC to report data later than the reporting deadline. Delayed reporting authorized under our ECE policy allows temporary relief for a hospital, REH, or ASC experiencing an extraordinary circumstance while preserving the benefits of data reporting, such as transparency and informed decision-making for beneficiaries and providers alike. Accordingly, we propose to update our regulations to specify that an ECE could take the form of an extension of time for a hospital, REH, or ASC to comply with a data reporting requirement if CMS determines that this type of relief would be appropriate under the circumstances.

2. Proposal to Update the Extraordinary Circumstances Exception (ECE) Policy for the Hospital OQR, REHQR, and ASCQR Programs

We propose to update the current Hospital OQR, REHQR, and ASCQR Program ECE policies codified at 42 CFR 419.46(e); 419.95(g); and 416.310(d), respectively, to include extensions of time as a form of relief and to further clarify the policy. Specifically, we propose

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[147] Centers for Medicare & Medicaid Services. (May 2024). Quality Program Extraordinary Circumstances Exceptions (ECE) Request Form. QualityNet. Available at *https://qualitynet.cms.gov/files/677e843f50ed8df7419f60e1?filename=HQR_ECE_Req_Form_CY_2025.pdf. Accessed: April 30, 2025.*

[148] Centers for Medicare & Medicaid Services. Hospital OQR Program Extraordinary Circumstances Exceptions (ECE) Policy*: https://qualitynet.cms.gov/outpatient/oqr/participation%23tab2#tab2*; REHQR Program Extraordinary Circumstances Exceptions (ECE) Policy*: https://qualitynet.cms.gov/reh/rehqr/participation#tab2;* and ASCQR Program Extraordinary Circumstances Exceptions (ECE) Policy: *https://qualitynet.cms.gov/asc/ascqr/participation%23tab3#tab2. Accessed: April 30, 2025.*

to update the regulations at 42 CFR 419.46(e)(1); 419.95(g)(1); and 416.310(d)(1) to state 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, REH, or ASC (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, REH, or ASC to comply with one or more applicable reporting requirements with respect to a calendar year.

We propose that the steps for requesting or granting an ECE would remain the same as the current ECE process, detailed by CMS at the QualityNet website or a successor website.[149] However, at proposed § 419.46(e)(2)(i); 419.95(g)(2)(i); and 416.310(d)(2)(i), we propose that a hospital, REH, or ASC, respectively, 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; this proposed change would align the Hospital OQR, REHQR, and ASCQR 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. For the Hospital OQR, REHQR, and ASCQR Programs, at proposed §§ 419.46(e)(2)(ii); 419.95(g)(2)(ii); and 416.310(d)(2)(ii), respectively, we propose that CMS notify the requestor with a decision in writing. If CMS grants an ECE to the hospital, REH or ASC, the written decision will specify whether the hospital, REH, or ASC is exempted from one or more reporting requirements or whether CMS has granted the hospital, REH, or ASC an extension of time to comply with one or more reporting requirements.

Additionally, at §§ 419.46(e)(3); 419.95(g)(3); and 416.310(d)(3), we propose that CMS may grant an ECE to one or more hospitals, REHs, or ASCs that have not requested an ECE if

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[149] Centers for Medicare & Medicaid Services. Hospital OQR Program Extraordinary Circumstances Exceptions (ECE) Policy*: https://qualitynet.cms.gov/outpatient/oqr/participation%23tab2#tab2*; REHQR Program Extraordinary Circumstances Exceptions (ECE) Policy: *https://qualitynet.cms.gov/reh/rehqr/participation#tab2;* and ASCQR Program Extraordinary Circumstances Exceptions (ECE) Policy: *https://qualitynet.cms.gov/asc/ascqr/participation%23tab3#tab2. Accessed: April 30, 2025.*

CMS determines that: a systemic problem with a CMS data collection system directly impacted the ability of the hospital, REH, or ASC 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, REHs, or ASCs are exempted from one or more reporting requirements or whether CMS has granted the hospital, REH, or ASC an extension of time to comply with one or more reporting requirements.

This proposed ECE policy would provide further reporting flexibility for a hospital, REH, or ASC and clarify the ECE process.

We invite public comment on these proposals.

XV. Hospital Outpatient Quality Reporting (OQR) Program

A. Background and History of the Hospital OQR Program

The Hospital Outpatient Quality Reporting (OQR) Program is a pay-for-reporting program intended to ensure transparency and quality of care furnished at hospital outpatient departments (HOPDs). Section 1833(t)(17)(A) of the Social Security Act (the Act) states that subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act) 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 Outpatient Department (OPD) fee schedule increase factor.

We refer readers to the CY 2011 OPPS/ASC final rule with comment period (75 FR 72064 through 72065) for a detailed discussion of the statutory history of the Hospital OQR Program. The Hospital OQR Program requirements are codified at 42 CFR 419.46. We also refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/hospital-quality-initiative/hospital-outpatient-quality-reporting-program* for general background on the Hospital OQR Program, as well as the CMS QualityNet Hospital OQR website at *https://qualitynet.cms.gov/outpatient* for current program requirements and measure specifications.

B. Proposed Changes to the Hospital OQR Program Measure Set

We propose to adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) beginning with voluntary reporting for the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination. In addition, we propose to remove the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure and the Left Without Being Seen measure, beginning with the CY 2028 reporting period/CY 2030 payment determination, if the Emergency Care Access & Timeliness eCQM is finalized as proposed. We propose to modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) measure (Excessive Radiation eCQM) from mandatory reporting to voluntary reporting beginning with the CY 2027 reporting period.

We also refer readers to section XIV.C. of this proposed rule, Cross-Program Proposals, where we discuss our proposals to remove the following Hospital OQR Program measures: (1) COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) Screening for Social Drivers of Health (SDOH) measure beginning with the CY 2025 reporting period; and (4) Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period.

1. Proposed Adoption of the Emergency Care Access & Timeliness eCQM Beginning With Voluntary Reporting for the CY 2027 Reporting Period Followed by Mandatory Reporting Beginning With the CY 2028 Reporting Period/CY 2030 Payment Determination

a. Background

Occupancy and boarding rates in U.S. emergency departments (EDs) continue to worsen

and exceed pre-pandemic levels.[150] ED boarding, defined as holding a patient in the ED after the patient is admitted or placed into observation status at a hospital, often occurs due to shortages of inpatient beds and staff and contributes to ED crowding, leading to safety risks for patients and stressful working conditions for healthcare personnel.[151] A recent report from the Agency for Healthcare Research and Quality (AHRQ) characterized patient ED boarding as a growing public health crisis and engaged interested parties to address the strain on the U.S. healthcare system.[152]

Recent studies indicate that delays in the timeliness of ED care are associated with patient harm.[153, 154] Long ED wait times are also one of the most cited reasons for patients leaving an ED without being evaluated by a clinician.[155] Increased ED length of stay (LOS) is also a strong predictor of poor timeliness of care and is significantly impacted by ED boarding. One study found that for every patient boarded, the median ED LOS for all admitted patients increased by at least 12 minutes.[156] Furthermore, ED boarding and crowding have been associated with poor

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[150] Moore, C. & Heckmann R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront*. Available at *https://www.healthaffairs.org/content/forefront/hospital-boarding-ed-federal-state-and-other-approaches. Accessed: April 30, 2025.*

[151] Moore, C. & Heckmann R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront*. Available at *https://www.healthaffairs.org/content/forefront/hospital-boarding-ed-federal-state-and-other-approaches. Accessed: April 30, 2025.*

[152] Agency for Healthcare Research and Quality. (2025). Technical Report: AHRQ Summit To Address Emergency Department Boarding. Available at *https://www.ahrq.gov/sites/default/files/wysiwyg/topics/ed-boarding-summit-report.pdf. Accessed: April 30, 2025.*

[153] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, *35*(7), 953-960. Available at *https://doi.org/10.1016/j.ajem.2017.01.061. Accessed: April 30, 2025.*

[154] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at *https://doi.org/10.1002/emp2.12401. Accessed: April 30, 2025.*

[155] Janke, A.T., Melnick, E.R., & Venkatesh, A.K. (2022). Monthly Rates of Patients Who Left Before Accessing Care in US Emergency Departments, 2017-2021. *JAMA*, 5(9), e2233708. Available at *https://doi.org/10.1001/jamanetworkopen.2022.33708. Accessed: April 30, 2025.*

[156] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at *https://doi.org/10.1002/emp2.12401. Accessed: April 30, 2025.*

patient outcomes, such as increased mortality,[157] delays in needed care,[158] and negative patient and staff experiences.[159, 160] For instance, evidence shows that ED crowding can harm sepsis patients by delaying administration of lifesaving intravenous (IV) fluids and antibiotics.[161]

Due to growing concerns about the quality and timeliness of care in the ED, as well as the burden associated with two chart-abstracted ED measures adopted in the Hospital OQR Program measure set, the Median Time for Discharged ED Patients measure and the Left Without Being Seen measure, CMS is assessing additional ways to support efforts that reduce patient harm and improve outcomes for patients requiring emergency care.

b. Measure Overview

The Emergency Care Access & Timeliness eCQM[162] is specified for the hospital setting and calculates the proportion of four outcome metrics that quantify access to and timeliness of care in an ED setting against specified thresholds, including: (1) patient wait time – 1 hour; (2) whether the patient left the ED without being evaluated; (3) patient boarding time in the ED

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[157] Hsuan, C., Segel, J.E., Hsia, R.Y., Wang, Y., & Rogowski, J. (2023). Association of emergency department crowding with inpatient outcomes. *Health Services Research*, 58(4), 828–843. Available at *https://doi.org/10.1111/1475-6773.14076. Accessed: April 30, 2025.*

[158] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, 35(7), 953–960. Available at *https://doi.org/10.1016/j.ajem.2017.01.061. Accessed: April 30, 2025.*

[159] Reznek, M.A., Larkin, C.M., Scheulen, J.J., Harbertson, C.A., & Michael, S.S. (2021). Operational factors associated with emergency department patient satisfaction: Analysis of the Academy of Administrators of Emergency Medicine/Association of Academic Chairs of Emergency Medicine national survey. *Academic Emergency Medicine: Official Journal of the Society for Academic Emergency Medicine*, 28(7), 753–760. Available at *https://doi.org/10.1111/acem.14278. Accessed: April 30, 2025.*

[160] Loke, D.E., Green, K.A., Wessling, E.G., Stulpin, E.T., & Fant, A.L. (2023). Clinicians' Insights on Emergency Department Boarding: An Explanatory Mixed Methods Study Evaluating Patient Care and Clinician Well-Being. *Joint Commission Journal on Quality and Patient Safety*, 49(12), 663–670. Available at *https://doi.org/10.1016/j.jcjq.2023.06.017. Accessed: April 30, 2025.*

[161] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, 35(7), 953-960. Available at *https://doi.org/10.1016/j.ajem.2017.01.061. Accessed: April 30, 2025.*

[162] The Emergency Care Access and Timeliness eCQM was previously named the Emergency Care Capacity and Quality (ECCQ) eCQM. The name of the measure has been updated to better reflect the purpose of the measure based on feedback from the Pre-Rulemaking Measure Review (PRMR) Hospital Recommendation Group Meeting on January 16, 2025. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf. Accessed: April 30, 2025.*

(as defined by a Decision to Admit (order) to ED departure for admitted patients) – 4 hours; and (4) patient ED LOS (time from ED arrival to ED physical departure, as defined by the ED departure timestamp) – 8 hours. The Emergency Care Access & Timeliness eCQM provides HOPDs with data for each of these individual numerator components, which are described in greater detail in section XV.B.1.c. of this proposed rule.

The numerator components of the Emergency Care Access & Timeliness eCQM overlap with the patient population and measure specifications of two chart-abstracted measures in the Hospital OQR Program: (1) the Median Time for Discharged ED Patients measure, and (2) the Left Without Being Seen measure. The Median Time for Discharged ED Patients measure assesses the time patients spent in the ED before being sent home, also known as ED throughput. The Left Without Being Seen measure assesses the percentage of patients who leave the ED without being evaluated by a physician/advanced practice nurse/physician's assistant (physician/APN/PA). Numerator component (2) overlaps with the Left Without Being Seen patient population, and numerator component (4) overlaps with the Median Time for Discharged ED Patients measure. In addition to capturing the same data elements as the Median Time for Discharged ED Patients and Left Without Being Seen measures, the Emergency Care Access & Timeliness eCQM measures boarding time in the ED, numerator component (3), and time from arrival to placement in a treatment room, numerator component (1), which are not currently captured by any other measure currently in the Hospital OQR Program measure set.[163]

The proposed removal of two chart-abstracted measures in conjunction with the proposed adoption of the Emergency Care Access & Timeliness eCQM would reduce HOPD burden by requiring the reporting of one digital quality measure instead of two chart-abstracted measures. While the Median Time for Discharged ED Patients and the Left Without Being Seen measures require manual intervention to retrieve data from clinical documentation, the Emergency Care

[163] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e*. *Accessed*: *April 30, 2025.*

Access & Timeliness eCQM allows for automated extraction of patient-level data directly from the electronic health record (EHR). We acknowledge that updating EHRs with new measures requires some initial investment from hospitals, but in the long-term it would automate timely collection of more granular quality information. In addition, we refer readers to the eCQI Resource Center for eCQM implementation guidance: *https://ecqi.healthit.gov/oqr?qt-tabs_oqr=ecqm-resources&global_measure_group=eCQMs*. We also refer readers to section XV.B.2. of this proposed rule for more information on these contingent measure removals.

For more information about the testing, feasibility, scientific acceptability, meaningfulness, and validity of the Emergency Care Access & Timeliness eCQM, we refer readers to *https://p4qm.org/measures/4625e*.

c. Measure Calculation

The measure denominator includes all ED encounters associated with patients of all ages, for all-payers, during a 12-month period of performance. Patients can have multiple encounters during a period of performance, and each encounter is eligible to contribute to the calculation of the measure.[164]

The measure numerator includes any ED encounter in the denominator where the patient experiences any one of the following: (1) the patient waited longer than 1 hour after arrival to the ED to be placed in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical examination; (2) the patient left the ED without being evaluated; (3) the patient boarded in the ED for longer than 4 hours; and (4) the patient had an ED LOS of longer than 8 hours.[165] An encounter is considered part of the numerator if it includes any one of the four numerator events, with events not being mutually exclusive and

[164] For proposed measure specifications, we refer readers to the CMS QualityNet Hospital OQR Program website at *https://qualitynet.cms.gov/outpatient.*

[165] For proposed measure specifications, we refer readers to the CMS QualityNet Hospital OQR Program website at *https://qualitynet.cms.gov/outpatient.*

each contributing only once to the numerator. ED encounters with ED observation stays[166] are excluded from components (3) and (4) but are included in the denominator. Patients who have a "decision to admit" after an ED observation stay remain excluded from criteria (3) calculations.[167]

These four outcomes were selected based on published literature demonstrating that each numerator component is associated with patient harm,[168] as well as input from clinical experts including ED experts and statistical and methodological experts and a Technical Expert Panel (TEP) that was convened by the measure developer.[169] A Patient and Family Engagement (PFE) Work Group provided feedback on experiences with emergency care, noting long wait times to be seen by a provider, long wait times to be transferred, and gaps in the discharge processes.

The numerator thresholds were developed according to evidence and consensus-based clinical guidelines for ED time thresholds, including guidelines developed by The Joint Commission (TJC), the American College of Emergency Physicians (ACEP), and the Emergency Department Benchmarking Alliance as well as input from a TEP, literature reviews, and environmental scans. For example, the four-hour threshold for numerator component (3), boarding time, was developed according to recommendations from TJC and ACEP.[170, 171]

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[166] ED observations stays are defined as an observation encounter where the patient remains physically in an area under control of the ED and under the care of an ED clinician inclusive of observation in a hospital bed. Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[167] Specific codes required to calculate the numerator are outlined in the value set data dictionary and eCQM package (Quality Data Model - QDM output). Please refer to the "Measure Calculation" Section for information: *https://p4qm.org/measures/4625e. Accessed: April 30, 2025*

[168] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[169] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[170] The Joint Commission. (2012). Patient Flow through the Emergency Department. Available at *https://www.jointcommission.org/-/media/tjc/documents/%20standards/r3-reports/r3_report_issue_4.pdf. Accessed: April 30, 2025.*

[171] American College of Emergency Physicians. (2024). Emergency Department Boarding and Crowding. Available at *https://www.acep.org/administration/crowding--boarding. Accessed: April 30, 2025.*

Measure testing for the Emergency Care Access & Timeliness eCQM was conducted by the measure developer across 32 hospital-based EDs, representing a diverse mix of geographic regions, rurality, hospital size, teaching status, trauma level, and EHR vendors, demonstrating that the measure is reliable, valid, and feasible for all required data elements.[172] Measure testing results showed a wide range in overall scores, and across all strata, indicating variation in performance and implying room for quality improvement.[173]

The measure score is first calculated at the individual ED level as the proportion of ED encounters where any one of the four outcomes occurred. Raw measure scores are then standardized by ED case volume using z-scores. The z-score, or standard score, indicates how many standard deviations a data point is from the mean of a normal distribution. It is calculated by subtracting the mean from a data point, then dividing the result by the standard deviation. For the Emergency Care Access & Timeliness eCQM, a volume-adjusted z-score shows how an ED's performance compares to the average for similar-volume EDs, addressing differences in patient population in HOPDs and ensuring fair "like to like" comparisons between EDs of similar size. ED volume strata are defined in volume bands of 20,000 ED visits, and each ED is assigned to only one volume stratum. For CMS Certification Numbers (CCNs) with more than one ED, volume-adjusted z-scores are then combined as a weighted average for that CCN.[174]

The results of the Emergency Care Access & Timeliness eCQM are stratified into four groups, two by age (18 years and older, and under 18 years) and two by mental health diagnoses (with, and without).[175] The stratification of results by age and mental health diagnosis, as well as standardization of measure performance scores by volume, is sufficient to account for

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[172] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[173] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[174] For proposed measure specifications, we refer readers to the CMS QualityNet Hospital OQR Program website at *https://qualitynet.cms.gov/outpatient.*

[175] The principal diagnosis (first listed diagnosis at ED discharge) will be used to define strata inclusion. For this measure's purpose, mental health diagnoses do not include substance use disorder diagnoses. Mental health refers to mental health diagnoses, life stressors and crises, and stress-related physical symptoms.

differences between hospitals without further need for risk adjustment.

For more detail on the proposed measure specifications, we refer readers to the CMS QualityNet Hospital OQR Program website at *https://qualitynet.cms.gov/outpatient*.

d. Pre-Rulemaking Measure Review (PRMR)

As required under section 1890A of the Act, the Secretary must establish and follow a pre-rulemaking process for selection of quality and efficiency measures, including for the Hospital OQR Program. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available "Measures Under Consideration List" (MUC List) by one of several committees convened by the consensus-based entity (CBE), with which we contract in accordance with section 1890 of the Act, for the purpose of providing interested parties input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the Hospital OQR Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94372) for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital Recommendation Group met on January 15 and 16, 2025, to review measures included by the Secretary on the publicly available 2024 MUC List, including the Emergency Care Access & Timeliness eCQM (MUC2024-075), and provided additional recommendations on the potential use of this measure.[176]

The voting results of the PRMR Hospital Recommendation Group for the proposed Emergency Care Access & Timeliness eCQM within the Hospital OQR Program were: 10 members recommended adopting the measure into the Hospital OQR Program; 10 members recommended adoption with conditions; 7 members voted not to recommend the measure for

[176] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

adoption. No voting category reached 75 percent or greater, including the combination of the recommend and the recommend with conditions categories and thus, the Hospital Recommendation Group did not reach consensus.[177]

The PRMR Hospital Recommendation Group noted in their deliberations that the measure will provide important insights into ED wait times which impact experience of care. The Group expressed concern that this measure may cause an increase in cost of care due to patients being transferred from the ED to observation.[178] While we acknowledge that patients transferred from the ED to observation may result in increased short-term costs due to additional monitoring and extended stays, the measure is designed to address significant issues surrounding the access to timely care which have been proven to reduce long-term costs.[179] Hospital Recommendation Group members also expressed concern about the lack of CBE endorsement. We note that we submitted the Emergency Care Access & Timeliness eCQM for CBE endorsement for review in the Fall 2024 cycle and the CBE endorsed the measure with conditions on February 12, 2025.[180]

The Hospital Recommendation Group discussed conditions specific to the Hospital OQR Program, including changing the name of the measure to better reflect the measure's focus.[181]

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[177] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

[178] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

[179] Dyas, S.R., Greenfield, E., Messimer, S., Thotakura, S., Gholston, S., Doughty, T., Hays, M., Ivey, R., Spalding, J., & Phillips, R. (2015). Process-Improvement Cost Model for the Emergency Department. *Journal of Healthcare Management,* 60(6): 442–57. Available at *https://doi.org/10.1097/00115514-201511000-00011*. *Accessed: April 30, 2025.*

[180] Partnership for Quality Measurement. (2024). 2024 Pre-Rulemaking Measure Review Preliminary Assessment. Available at *https://p4qm.org/sites/default/files/2024-12/PRMR-PA-MUC2024-075.pdf*. *Accessed: April 30, 2025.*

[181] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

We agree with this feedback and have changed the name of the measure from the Emergency Care Capacity and Quality eCQM to Emergency Care Access & Timeliness. Group members also recommended refraining from including the Emergency Care Access & Timeliness eCQM in Overall Hospital Quality Star Ratings (Star Ratings) due to the possible duplication of data with existing measures. We note that we propose to remove two existing measures in the Hospital OQR Program, the Median Time for Discharged ED Patients and the Left Without Being Seen measures, to avoid duplicative data collection and reporting. We also note that the Emergency Care Access & Timeliness measure would only be included in the Star Ratings calculation after the existing measures are removed. We refer readers to section XV.B.2. of this proposed rule for more information on the removal of the Median Time for Discharged ED Patients and the Left Without Being Seen measures.

The Hospital Recommendation Group also recommended revising the measure specifications to create separate measure components and explore alternative measures for patient boarding time and patient ED LOS. We acknowledge the Hospital Recommendation Group's concerns and note that multiple TEPs and interested parties supported the inclusion of more than one numerator component as a strategy for internally balancing the measure and that the time thresholds for patient boarding time and ED LOS are based on more than a decade of consensus work. Lastly, Group members recommended stratifying the measure by factors such as care type, region, and hospital or trauma level designation. We emphasize that the approach to stratification by age and mental health diagnosis, as well as volume standardization of the measure performance scores, is sufficient to account for differences between hospitals without further need for additional stratification.[182]

e. Measure Endorsement

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[182] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

Section 1833(t)(17)(C)(i) of the Act provides that the Hospital OQR Program shall include measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus-based entities. A TEP consisting of interested parties, experts, and consumer advocates contributed their input through the Emergency Care Access & Timeliness eCQM measure design process.[183] The Emergency Care Access & Timeliness eCQM was submitted to the CBE for endorsement review in the Fall 2024 cycle (CBE #4625e), and the CBE endorsed the measure with conditions for use in the Hospital OQR Program on February 12, 2025. The conditions include that the measure developer explore within 3 years: (1) the unintended consequences to patients and providers, including burden, by engaging with the patient community and accountable entities (for instance, qualitative assessments and empirical analyses); and (2) the data elements to identify and address where challenges may persist, including engaging accountable entities. If the proposal to adopt the Emergency Care Access & Timeliness eCQM for the Hospital OQR Program is finalized, CMS will monitor the burden on patients and providers and identify areas where challenges may persist as part of the standard measure maintenance.

f. Data Collection, Submission, and Reporting

The Emergency Care Access & Timeliness eCQM is specified in a standard electronic format, utilizing data extracted electronically from EHRs, with all data coming from defined fields in electronic sources. We note that eCQMs allow for retrieval of data directly from an EHR, reducing administrative burden on hospitals and minimizing errors due to manual abstraction of data.[184]

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[183] Yale New Haven Health Services Corporation. (September 2024). Technical Expert Panel (TEP) Evaluation of Measure Emergency Care Capacity and Quality Electronic Clinical Quality Measure (eCQM). Available at *https://mmshub.cms.gov/sites/default/files/ECCQ-TEP-Summary-Report-081624.pdf. Accessed: April 30, 2025.*

[184] Centers for Medicare & Medicaid Services. (2023). Electronic Clinical Quality Measures (eCQMs) Specification, Testing, Standards, Tools, and Community. Available at *https://mmshub.cms.gov/sites/default/files/eCQM-Specifications-Testing-Standards-Tools-Community.pdf. Accessed: April 30, 2025.*

We propose to adopt the Emergency Care Access & Timeliness eCQM beginning with voluntary reporting for the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination. We believe this would provide HOPDs sufficient time to test and integrate the eCQM into existing clinical workflows. Additionally, limiting voluntary reporting to 1 year prioritizes addressing long ED wait times and ED boarding as well as removing two chart-abstracted measures from the Hospital OQR Program measure set to reduce HOPD burden. We refer readers to section XV.C.2. of this proposed rule for a discussion of proposed Emergency Care Access and Timeliness eCQM form, manner, and timing of data submission and reporting requirements.

We refer readers to section XVI.B.1. of this proposed rule where we propose adoption of a similar measure for the Rural Emergency Hospital Quality Reporting Program.

We invite public comment on this proposal.

2. Proposed Removals of the Median Time from ED Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) Measure and the Left Without Being Seen Measure Beginning With the CY 2028 Reporting Period/CY 2030 Payment Determination

The Emergency Care Access & Timeliness eCQM, if finalized as proposed, would serve as a replacement for two existing chart-abstracted measures in the Hospital OQR Program. The Median Time for Discharged ED Patients measure (75 FR 72086) and the Left Without Being Seen measure (75 FR 72088 through 72089) were adopted in the CY 2011 OPPS/ASC final rule with comment period to promote transparency, improve patient care and access to EDs, and reduce avoidable delays in the emergency care setting. The Median Time for Discharged ED Patients measure assesses the time patients spent in the ED before being sent home, also known as ED throughput. The Left Without Being Seen measure assesses the percentage of patients who leave the ED without being evaluated by a physician/advanced practice nurse/physician's assistant (physician/APN/PA). Both measures are chart-abstracted, requiring human review and manual intervention to extract data elements from clinical documentation.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 81963), we did not finalize our proposal to remove the Left Without Being Seen measure due in part to public comments emphasizing the importance of the measure in addressing ED overcrowding and boarding. We stated our intention to identify a more granular measure that could replace the Left Without Being Seen measure, which can now be achieved through the adoption of the Emergency Care Access & Timeliness eCQM. We note that Hospital OQR Program measure specifications can be found at *https://qualitynet.cms.gov/outpatient*.

As stated in section XV.B.1. of this proposed rule, the Emergency Care Access & Timeliness eCQM is specified for the hospital setting and calculates the proportion of four outcome metrics that quantify access to and timeliness of care in an ED setting against specified thresholds. The numerator components of the Emergency Care Access & Timeliness eCQM overlap with data elements of the Median Time for Discharged ED Patients and the Left Without Being Seen measures. The numerator of the Emergency Care Access & Timeliness eCQM is comprised of any ED visit in the denominator where the patient experiences any one of the following: (1) waited longer than 1 hour to be placed in a treatment room or a dedicated treatment area that allows for audiovisual privacy history-taking and physical examination; (2) left the ED without being evaluated by a physician/advanced practice nurse/physician's assistant; (3) boarded (defined as time from a Decision to Admit (order) to ED departure for admitted patients) for longer than 4 hours; or (4) had an ED LOS (time from ED arrival to ED physical departure as defined by the ED departure timestamp) of longer than 8 hours. Numerator component (2) overlaps with the Left Without Being Seen patient population and numerator component (4) overlaps with the Median Time for Discharged ED Patients measure. The Emergency Care Access & Timeliness eCQM also incorporates additional metrics to enhance its comprehensiveness and analytic value, including boarding time in the ED, numerator component

(3), and time from arrival to placement in a treatment room, numerator component (1), which are not currently captured by any other measure in the Hospital OQR Program.[185]

The Emergency Care Access & Timeliness eCQM therefore provides an alternative approach to quality measurement used to address ED boarding and barriers to emergency care by capturing multiple components of quality and capacity. In addition, the Emergency Care Access & Timeliness eCQM allows for retrieval of patient-level data directly from the EHR. As a result, the Emergency Care Access & Timeliness eCQM, along with our previously adopted eCQMs, advances the Hospital OQR Program toward the use of EHR data for quality measurement, leading to more accurate quality data as well as reduced burden for providers. The adoption of the Emergency Care Access & Timeliness eCQM would allow us to employ a more precise assessment of the timeliness and appropriateness of ED visits and to provide additional information important to patients and hospitals on ED boarding and ED LOS.

Our measure removal policy, codified at 42 CFR 419.46(i)(3), identifies eight factors CMS will consider in the removal of quality measures. Removal Factor 4, described at § 419.46(i)(3)(i)(D), is the availability of a more broadly applicable (across settings, populations, or conditions) measure for the topic. Compared to the Median Time for Discharged ED Patients measure and the Left Without Being Seen measure, the Emergency Care Access & Timeliness eCQM is a more broadly applicable measure for the topic. We therefore propose that, if the Emergency Care Access & Timeliness eCQM is adopted in the Hospital OQR Program as proposed in section XV.B.1. of this proposed rule, we would remove the Median Time for Discharged ED Patients measure and the Left Without Being Seen measure under removal Factor 4. We propose that these measure removals would begin with the CY 2028 reporting period/CY 2030 payment determination, when reporting for the Emergency Care Access & Timeliness eCQM is proposed to become mandatory.

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[185] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e*. *Accessed: April 30, 2025.*

We invite public comment on these proposals.

3. Modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Outpatient) Measure (Excessive Radiation eCQM) from Mandatory Reporting Beginning With the CY 2027 Reporting Period/CY 2029 Payment Determination to Continue Voluntary Reporting in the CY 2027 Reporting Period and Subsequent Years.

In the CY 2024 OPPS/ASC final rule with comment period, we finalized our proposal to adopt the Excessive Radiation eCQM with voluntary reporting beginning with the CY 2025 reporting period and mandatory reporting beginning with the CY 2027 reporting period/CY 2029 payment determination, one year later than originally proposed (88 FR 81992). We explained our delay in implementing mandatory reporting of the Excessive Radiation eCQM was in response to commenters' concerns regarding the burden associated with implementing the eCQM.

In this proposed rule, we propose to modify the reporting requirements for the Excessive Radiation eCQM in the Hospital OQR Program by maintaining voluntary reporting instead of mandatory reporting of the measure, beginning with the CY 2027 reporting period. Our proposal to maintain indefinite voluntary reporting of this measure arises from continued feedback expressing concerns about the complex interfaces necessary to develop, maintain, and report the Excessive Radiation eCQM, including the financial burden and operational feasibility needed to translate CT radiology data into standardized eCQM-consumable data used by the measure. In January 2025, we issued a notice to clarify that hospitals and clinicians who choose to report this eCQM can use any vendor's translation software to calculate this measure,[186] consistent with the measure's specifications, and stated our intent to monitor measure results to ensure that all

[186] eCQI Resource Center. Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults eCQM - Measure Clarification. Available at *https://ecqi.healthit.gov/excessive-radiation-dose-or-inadequate-image-quality-diagnostic-computed-tomography-adults-ecqm-measure-clarification. Accessed June 5, 2025.*

reported data for the Excessive Radiation eCQM are both reliable and valid.[187]

The proposed modification from mandatory to voluntary reporting of the Excessive Radiation eCQM beginning with the CY 2027 reporting period would allow HOPDs additional time to integrate, adequately test, and gain experience with implementing the eCQM. This modification would also provide CMS with additional time to monitor implementation progress, including data collection burden and response rates. We will continue to consider feedback regarding this measure and may propose additional changes in future rulemaking.

We invite public comment on this proposal.

4. Summary of Previously Finalized and Newly Proposed Hospital OQR Program Measure Set for CY 2026 to CY 2031 Payment Determinations

Table 84 summarizes the previously finalized and newly proposed Hospital OQR Program measure set for the CY 2026 to CY 2031 payment determinations, which would remove the HCHE, Screening for SDOH, Screen Positive Rate for SDOH, and COVID–19 Vaccination Coverage Among HCP measures as discussed in section XIV.C. of this proposed rule; modify reporting requirements for the Excessive Radiation eCQM from mandatory to voluntary reporting beginning with the CY 2027 reporting period, as discussed in section XV.B.3 of this proposed rule; remove the Left Without Being Seen and the Median Time for Discharged ED Patients measures as discussed in section XV.B.2. of this proposed rule; and add the Emergency Care Access & Timeliness eCQM as discussed in section XV.B.1. of this proposed rule.

TABLE 84: PREVIOUSLY FINALIZED AND PROPOSED HOSPITAL OQR PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

[187] In that notice, we also clarified that while CMS is not requiring vendors to demonstrate their software's capabilities to CMS, hospitals and clinicians that choose to do so may request information from a vendor about a specific software's ability to generate and transform the radiology data into the necessary format.

	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	Chart-Abstracted Measures						
0658	Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients	✓	✓	✓	✓	✓	✓
0661	Head Computed Tomography (CT) or Magnetic Resonance Imaging (MRI) Scan Results for Acute Ischemic Stroke or Hemorrhagic Stroke who Received Head CT or MRI Scan Interpretation Within 45 minutes of ED Arrival	✓	✓	✓	✓	✓	✓
None	Left Without Being Seen*	✓	✓	✓	✓	Proposed for Removal	Proposed for Removal
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients*	✓	✓	✓	✓	Proposed for Removal	Proposed for Removal
	Claims-Based Measures						
None	Abdomen CT - Use of Contrast Material	✓	✓	✓	✓	✓	✓
3490	Admissions and ED Visits for Patients Receiving Outpatient Chemotherapy	✓	✓	✓	✓	✓	✓
None	Breast Cancer Screening Recall Rates	✓	✓	✓	✓	✓	✓
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	✓	✓	✓	✓	✓	✓
2687	Risk-Standardized Hospital Visits Within 7 Days	✓	✓	✓	✓	✓	✓

	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	After Hospital Outpatient Surgery						
	National Healthcare Safety Network Measures						
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)**	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Structural Measures						
None	Hospital Commitment to Health Equity (HCHE)***		Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Process Measures						
None	Screening for Social Drivers of Health (SDOH)****		Voluntary/ Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
None	Screen Positive Rate for SDOH****		Voluntary/ Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Patient-Reported Outcomes-Based Performance Measures						
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO-PM)			Voluntary	✓	✓	✓
None	Risk-Standardized PRO–PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the HOPD Setting (THA/TKA PRO-PM)*****			Voluntary	Voluntary	Voluntary	✓
	Survey-Based Measures						
None	Cataracts: Improvement in	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary

	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	Patient's Visual Function within 90 Days Following Cataract Surgery						
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	Voluntary	✓	✓	✓	✓	✓
	eCQMs						
4625e	Emergency Care Access & Timeliness eCQM******				Proposed for Voluntary Reporting	Proposed for Mandatory Reporting	Proposed for Mandatory Reporting
3663e	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults (Hospital Level—Outpatient) eCQM (Excessive Radiation eCQM)*******		Voluntary	Voluntary	Proposed for Voluntary Reporting	Proposed for Voluntary Reporting	Proposed for Voluntary Reporting
None	ST-Segment Elevation Myocardial Infarction (STEMI) eCQM	✓	✓	✓	✓	✓	✓

✓Measure is mandatory for the specified payment determination year

Voluntary: Submission of this measure is optional and HOPDs are not subject to a payment reduction for not reporting on the measure.

*Proposed for removal in this proposed rule beginning with the CY 2028 reporting period/CY 2030 payment determination.

**Proposed for removal in this proposed rule beginning with the CY 2024 reporting period/CY 2026 payment determination.

***Proposed for removal in this proposed rule beginning with the CY 2025 reporting period/CY 2027 payment determination.

****Proposed for removal in this proposed rule beginning with the CY 2025 reporting period.

*****Measure is voluntary for the CY 2025, CY 2026, and CY 2027 reporting periods, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule (88 FR 81979 through 81986).

******Proposed for adoption in this proposed rule beginning with voluntary reporting for the CY 2027 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination.

*******Proposed modification from mandatory to voluntary reporting beginning with the CY 2027 reporting period.

We refer readers to the QualityNet website at *https://qualitynet.cms.gov/outpatient* for additional information on the reporting periods and submission deadlines for each measure previously finalized in the Hospital OQR Program.

5. Hospital OQR Program Measures and Topics for Future Consideration

We refer readers to section XIV.B. of this proposed rule for our cross-program Request for Information on measure concepts regarding well-being and nutrition for consideration in the Hospital OQR Program.

C. Proposed Updates to the Form, Manner, and Timing of Hospital OQR Program Data Submission

1. Background on Data Submission and Reporting Requirements for eCQMs

We refer readers to § 419.46(j) and the CY 2025 OPPS/ASC final rule with comment period (89 FR 94418 through 94420) for a discussion of our previously finalized eCQM requirements.

2. Proposed Data Submission and Reporting Requirements for the Emergency Care Access & Timeliness eCQM

In section XV.B.1. of this proposed rule, we discuss the proposed adoption of the Emergency Care Access & Timeliness eCQM beginning with voluntary reporting for the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination. For the CY 2027 reporting period, we propose that hospitals that voluntarily submit Emergency Care Access and Timeliness eCQM data could submit data for any quarter(s) (that is, up to all four quarters of data).

Beginning with the CY 2028 reporting period/CY 2030 payment determination, we propose to require that hospitals report all four calendar quarters (1-calendar year) of data for the Emergency Care Access & Timeliness eCQM. We also propose to require Emergency Care Access and Timeliness eCQM data submission by May 15 in the year prior to the affected payment determination year, in alignment with our policies on eCQM submission deadlines, as

finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63867 through 63870). For example, for the CY 2028 reporting period/CY 2030 payment determination, hospitals would be required to submit eCQM data by May 15, 2029. All deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day declared at least in part to be a non-workday for federal employees by statute or Executive Order, would be extended to the first day thereafter. All current CMS policies regarding eCQM data submission requirements – including file format, zero denominator declarations, case thresholds, submission deadlines, and EHR certification requirements outlined at § 419.46(j) and finalized in the CY 2022 or CY 2025 OPPS/ASC final rules (86 FR 63867 through 63870 and 89 FR 94418 through 94420, respectively) would apply to the Emergency Care Access & Timeliness eCQM for both the voluntary and mandatory data submission periods.

We invite public comment on these proposals.

3. Hospital OQR Program Extraordinary Circumstances Exception (ECE) Policy

We refer readers to section XIV.D. of this proposed rule for our cross-program proposal to codify updates to the ECE policy for the Hospital OQR Program.

D. Payment Reduction for Hospitals That Fail to Meet the Hospital OQR Program Requirements for the CY 2026 Payment Determination

1. Background

Section 1833(t)(17) of the Act, which applies to subsection (d) hospitals (as defined under section 1886(d)(1)(B) of the Act), states that hospitals that fail to report data required to be submitted on measures selected by the Secretary, in the form and manner, and at a time, specified by the Secretary will incur a 2.0-percentage point reduction to their Outpatient Department (OPD) fee schedule increase factor; that is, the annual payment update factor. Section 1833(t)(17)(A)(ii) of the Act specifies that any reduction applies only to the payment year involved and will not be taken into account in computing the applicable OPD fee schedule increase factor for a subsequent year.

The application of a reduced OPD fee schedule increase factor results in reduced national unadjusted payment rates that apply to certain outpatient items and services provided by hospitals that are required to report outpatient quality data in order to receive the full payment update factor and that fail to meet the Hospital OQR Program requirements. Hospitals that meet the reporting requirements receive the full OPPS payment update without the reduction. For a more detailed discussion of how this payment reduction was initially implemented, we refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68769 through 68772).

The national unadjusted payment rates for many services paid under the OPPS equal the product of the OPPS conversion factor and the scaled relative payment weight for the APC to which the service is assigned. The OPPS conversion factor, which is updated annually by the OPD fee schedule increase factor, is used to calculate the OPPS payment rate for services with the following status indicators (listed in Addendum B to the proposed rule, which is available via the Internet on the CMS website): "J1," "J2," "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," or "U." Payment for all services assigned to these status indicators will be subject to the reduction of the national unadjusted payment rates for hospitals that fail to meet Hospital OQR Program requirements, with the exception of services assigned to New Technology APCs with assigned status indicator "S" or "T." We refer readers to the CY 2009 OPPS/ASC final rule with comment period (73 FR 68770 through 68771) for a discussion of this policy. In the CY 2017 OPPS/ASC final rule with comment period (81 FR 79796), we clarified that the reporting ratio does not apply to codes with status indicator "Q4" because services and procedures coded with status indicator "Q4" are either packaged or paid through the Clinical Laboratory Fee Schedule and are never paid separately through the OPPS.

The OPD fee schedule increase factor is an input into the OPPS conversion factor, which is used to calculate OPPS payment rates. To reduce the OPD fee schedule increase factor for hospitals that fail to meet reporting requirements, we calculate two conversion factors—a full

market basket conversion factor (that is, the full conversion factor), and a reduced market basket conversion factor (that is, the reduced conversion factor). We then calculate a reduction ratio by dividing the reduced conversion factor by the full conversion factor. We refer to this reduction ratio as the "reporting ratio" to indicate that it applies to payment for hospitals that fail to meet their reporting requirements. Applying this reporting ratio to the OPPS payment amounts results in reduced national unadjusted payment rates that are mathematically equivalent to the reduced national unadjusted payment rates that would result if we multiplied the scaled OPPS relative payment weights by the reduced conversion factor. For example, to determine the reduced national unadjusted payment rates that applied to hospitals that failed to meet their quality reporting requirements for the CY 2010 OPPS/ASC final rule with comment period, we multiplied the final full national unadjusted payment rate found in Addendum B of the CY 2010 OPPS/ASC final rule with comment period by the CY 2010 OPPS final rule with comment period reporting ratio of 0.980 (74 FR 60642).

We note that the only difference in the calculation for the full conversion factor and the calculation for the reduced conversion factor is that the full conversion factor uses the full OPD update, and the reduced conversion factor uses the reduced OPD update. The baseline OPPS conversion factor calculation is the same since all other adjustments would be applied to both conversion factor calculations. Therefore, our standard approach of calculating the reporting ratio as described earlier in this section is equivalent to dividing the reduced OPD update factor by that of the full OPD update factor. In other words:

Full Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor)

Reduced Conversion Factor = Baseline OPPS conversion factor * (1 + OPD update factor – 0.02)

Reporting Ratio = Reduced Conversion Factor / Full Conversion Factor

Which is equivalent to:

Reporting Ratio = (1 + OPD Update factor – 0.02) / (1 + OPD update factor)

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68771 through 68772), we established a policy that the Medicare beneficiary's minimum unadjusted copayment and national unadjusted copayment for a service to which a reduced national unadjusted payment rate applies would each equal the product of the reporting ratio and the national unadjusted copayment or the minimum unadjusted copayment, as applicable, for the service. Under this policy, we apply the reporting ratio to both the minimum unadjusted copayment and national unadjusted copayment for services provided by hospitals that receive the payment reduction for failure to meet the Hospital OQR Program reporting requirements. This application of the reporting ratio to the national unadjusted and minimum unadjusted copayments is calculated according to § 419.41 of our regulations, prior to any adjustment for a hospital's failure to meet the quality reporting standards according to § 419.43(h). Beneficiaries and secondary payers thereby share in the reduction of payments to these hospitals.

In the CY 2009 OPPS/ASC final rule with comment period (73 FR 68772), we established the policy that all other applicable adjustments to the OPPS national unadjusted payment rates apply when the OPD fee schedule increase factor is reduced for hospitals that fail to meet the requirements of the Hospital OQR Program. For example, the following standard adjustments apply to the reduced national unadjusted payment rates: the wage index adjustment, the multiple procedure adjustment, the interrupted procedure adjustment, the rural sole community hospital adjustment, and the adjustment for devices furnished with full or partial credit or without cost. Similarly, OPPS outlier payments made for high cost and complex procedures will continue to be made when outlier criteria are met. For hospitals that fail to meet the quality data reporting requirements, the hospitals' costs are compared to the reduced payments for purposes of outlier eligibility and payment calculation. We established this policy in the OPPS beginning in the CY 2010 OPPS/ASC final rule with comment period (74 FR 60642). For a complete discussion of the OPPS outlier calculation and eligibility criteria,

we refer readers to section II.G. of the CY 2023 OPPS/ASC proposed rule (87 FR 44533 through 44534).

2. Reporting Ratio Application and Associated Adjustment Policy for CY 2026

We propose to continue our established policy of applying the reduction of the OPD fee schedule increase factor through the use of a reporting ratio for those hospitals that fail to meet the Hospital OQR Program requirements for the full CY 2026 annual payment update factor. For the CY 2026 OPPS/ASC proposed rule, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $91.747, equals a proposed conversion factor for hospitals that fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $89.958. We propose to continue to apply the reporting ratio to all services calculated using the OPPS conversion factor. We propose to continue to apply the reporting ratio, when applicable, to all HCPCS codes to which we have proposed status indicator assignments of "J1," "J2," "P," "Q1," "Q2," "Q3," "R," "S," "T," "V," and "U" (other than New Technology APCs to which we have proposed status indicator assignments of "S" and "T"). We propose to continue to exclude services paid under New Technology APCs. We propose to continue to apply the reporting ratio to the national unadjusted payment rates and the minimum unadjusted and national unadjusted copayment rates of all applicable services for those hospitals that fail to meet the Hospital OQR Program reporting requirements. We also propose to continue to apply all other applicable standard adjustments to the OPPS national unadjusted payment rates for hospitals that fail to meet the requirements of the Hospital OQR Program. Similarly, we propose to continue to calculate OPPS outlier eligibility and outlier payment based on the reduced payment rates for those hospitals that fail to meet the reporting requirements. In addition to our proposal to implement the policy through the use of a reporting ratio, we propose to continue to calculate the reporting ratio to four decimals.

For CY 2026, the proposed reporting ratio is 0.9805, which, when multiplied by the proposed full conversion factor of $91.747, equals a proposed conversion factor for hospitals that

fail to meet the requirements of the Hospital OQR Program (that is, the reduced conversion factor) of $89.958.

XVI. Rural Emergency Hospital Quality Reporting (REHQR) Program

A. Background and History of the REHQR Program

The Rural Emergency Hospital Quality Reporting (REHQR) Program is intended to ensure transparency and quality for rural emergency hospitals (REHs), defined at section 1861(kkk)(2) of the Act. Section 1861(kkk)(7)(A) authorizes the Secretary to implement a quality reporting program requiring REHs to submit data on measures in accordance with the Secretary's requirements in section 1861(kkk)(7). Section 1861(kkk)(7)(B)(ii) requires REHs to submit quality measure data to the Secretary "in a form and manner, and at a time, specified by the Secretary." The Act does not require the Secretary to provide incentives for submitting this data under the REHQR Program, nor does it require the Secretary to impose penalties for failing to comply with this requirement under the REHQR Program. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82046 through 82047) for a detailed discussion of the history of the REHQR Program. The REHQR Program requirements are codified at 42 CFR 419.95. We also refer readers to the CMS QualityNet REHQR Program website at *https://qualitynet.cms.gov/reh/rehqr* for current program requirements and measure specifications.[188]

B. Proposed Changes to the REHQR Program Measure Set

We propose to adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) beginning with the CY 2027 reporting period/CY 2029 program determination as an alternative to reporting the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure. We also refer readers to section XIV.C. of this proposed rule where we discuss the following proposed measure removals: (1) Hospital

[188] For additional information on REHs, we refer readers to a CMS Fact Sheet on REHs (Sept. 2024). Available at *https://www.cms.gov/files/document/rural-emergency-hospitals-factsheet-september-2024.pdf.*

Commitment to Health Equity (HCHE) measure, beginning with the CY 2025 reporting period/CY 2027 program determination; (2) Screening for Social Drivers of Health (SDOH) measure, beginning with the CY 2025 reporting period; and (3) Screen Positive Rate for SDOH measure, beginning with the CY 2025 reporting period.

1. Proposed Adoption of the Emergency Care Access & Timeliness eCQM Beginning With Optional Reporting for the CY 2027 Reporting Period/CY 2029 Program Determination

a. Background

Occupancy and boarding rates in United States (U.S.) emergency departments (EDs) continue to worsen and exceed pre-pandemic levels.[189] ED boarding, defined as holding a patient in the ED when there are no available inpatient beds, often occurs due to shortages of inpatient beds and staff. ED boarding time contributes to ED crowding which heightens safety risks for patients and can lead to stressful working conditions for healthcare personnel.[190] A recent report from the Agency for Healthcare Research and Quality (AHRQ) characterized patient ED boarding as a growing public health crisis and engaged interested parties to address the strain on the U.S. healthcare system.[191]

Recent studies indicate that delays in the timeliness of ED care are associated with patient harm.[192, 193] Long ED wait times are also one of the most cited reasons for patients leaving an

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[189] Moore, C. & Heckmann R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront*. Available at *https://www.healthaffairs.org/content/forefront/hospital-boarding-ed-federal-state-and-other-approaches. Accessed: April 30, 2025.*

[190] Moore, C. & Heckmann R. (2025). Hospital Boarding In The ED: Federal, State, And Other Approaches. *Health Affairs Forefront*. Available at *https://www.healthaffairs.org/content/forefront/hospital-boarding-ed-federal-state-and-other-approaches. Accessed: April 30, 2025.*

[191] Agency for Healthcare Research and Quality. (2025). Technical Report: AHQR Summit To Address Emergency Department Boarding. Available at *https://www.ahrq.gov/sites/default/files/wysiwyg/topics/ed-boarding-summit-report.pdf. Accessed: April 30, 2025.*

[192] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, *35*(7), 953–960. Available at *https://doi.org/10.1016/j.ajem.2017.01.061. Accessed: April 30, 2025.*

[193] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at *https://doi.org/10.1002/emp2.12401. Accessed: April 30, 2025.*

ED without being evaluated by a clinician.[194] One recent study indicated that ED crowding can harm sepsis patients by delaying administration of lifesaving intravenous (IV) fluids and antibiotics.[195] ED boarding time can lead to an increased length of stay (LOS) which is also a strong predictor of poor timeliness of care. One study found that for every patient boarded, the median ED LOS for all admitted patients increased by at least 12 minutes.[196] While less studied than inpatient boarding, transfer boarding (defined as keeping the patient in the ED after the decision to transfer has been made), can have similar impacts as inpatient boarding, with greater impacts on patients receiving care in rural settings.[197, 198] The timeliness of care provided at REHs may be further impacted by transfer boarding due to lack of inpatient beds and resources required to coordinate transfers.[199]

Due to growing concerns about the quality and timeliness of care in the ED as well as the burden associated with manually abstracting the chart-abstracted ED measure adopted in the REHQR Program measure set, the Median Time from ED Arrival to ED Departure for

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[194] Janke, A.T., Melnick, E.R., & Venkatesh, A.K. (2022). Monthly Rates of Patients Who Left Before Accessing Care in US Emergency Departments, 2017-2021. *JAMA*, 5(9), e2233708. Available at *https://doi.org/10.1001/jamanetworkopen.2022.33708*. *Accessed: April 30, 2025.*

[195] Gaieski, D.F., Agarwal, A.K., Mikkelsen, M.E., Drumheller, B., Cham Sante, S., Shofer, F.S., Goyal, M., & Pines, J.M. (2017). The impact of ED crowding on early interventions and mortality in patients with severe sepsis. *The American Journal of Emergency Medicine*, *35*(7), 953–960. Available at *https://doi.org/10.1016/j.ajem.2017.01.061*. *Accessed*: *April 30, 2025.*

[196] Laam L.A., Wary A.A., Strony R.S., Fitzpatrick M.H., & Kraus C.K. (2021). Quantifying the impact of patient boarding on emergency department length of stay: All admitted patients are negatively affected by boarding. *Journal of American College Emergency Physicians*, 2(2):e12401. Available at *https://doi.org/10.1002/emp2.12401*. *Accessed*: *April 30, 2025.*

[197] Mohr, N. M., Wu, C., Ward, M. J., McNaughton, C. D., Faine, B., Pomeranz, K., Richardson, K., & Kaboli, P. J. (2022). Transfer boarding delays care more in low-volume rural emergency departments: A cohort study. *The Journal of Rural Health: Official Journal of the American Rural Health Association and the National Rural Health Care Association*, *38(1)*, 282–292. Available at *https://doi.org/10.1111/jrh.12559*. *Accessed*: *April 30, 2025.*

[198] Usher, M., Sahni, N., Herrigel, D., Simon, G., Melton, G.B., Joseph, A., & Olson, A. (2018). Diagnostic Discordance, Health Information Exchange, and Inter-Hospital Transfer Outcomes: A Population Study. *Journal of General Internal Medicine*, 33(9): 1447–53. Available at *https://doi.org/10.1007/s11606-018-4491-x*. *Accessed*: *April 30, 2025.*

[199] McNaughton, C.D., Bonnet, K., Schlundt, D., Mohr, N.M., Chung, S., Kaboli, P.J., & Ward, M.J. (2020). Rural Interfacility Emergency Department Transfers: Framework and Qualitative Analysis. *The Western Journal of Emergency Medicine*, 21(4), 858–865. Available at *https://doi.org/10.5811/westjem.2020.3.46059*. *Accessed*: *April 30, 2025.*

Discharged ED Patients (Median Time for Discharged ED Patients) measure, CMS is assessing additional ways to support efforts that reduce patient harm and improve outcomes for patients requiring emergency care while also providing flexibility for REHs. We previously sought comment on eCQM reporting under the REHQR Program in the CY 2024 OPPS/ASC proposed rule (88 FR 49840 through 49841). Our proposal to adopt the Emergency Care Access & Timeliness eCQM as an optional measure into the REHQR Program measure set, as discussed in section XVI.C.2.c. of this proposed rule, is in response to public comment recommending that CMS add eCQMs as optional measures initially (88 FR 82070). We refer readers to section XVI.C.2. of this proposed rule for proposed eCQM reporting and submission policies and requirements for the REHQR Program.

b. Measure Overview

An intermediate outcome measure, the Emergency Care Access & Timeliness eCQM[200] as specified for the REH setting calculates the proportion of four outcome metrics that quantify access to and the timeliness of care in an ED setting against specified thresholds, including: (1) patient wait time; (2) whether the patient left the ED without being evaluated; (3) patient transfer boarding time in the ED; and (4) patient ED LOS. The numerator components for the Emergency Care Access & Timeliness eCQM are described in detail in section XVI.B.1.c. of this proposed rule. We note that the population and measure specifications for the Median Time for Discharged ED Patients measure overlaps with the Emergency Care Access & Timeliness eCQM for the numerator outcome metric (4), but that the scope of the proposed Emergency Care Access & Timeliness eCQM is broader than the Median Time for Discharged ED Patients measure.[201]

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[200] The Emergency Care Access & Timeliness eCQM was previously named the Emergency Care Capacity and Quality (ECCQ) eCQM. The name of the measure has been updated to better reflect the purpose of the measure based on feedback from the Pre-Rulemaking Measure Review (PRMR) Hospital Recommendation Group Meeting on January 16, 2025. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf.*

[201] The Median Time for Discharged ED Patients was adopted in the REHQR Program in the CY 2024 OPPS/ASC final rule with comment period (88 FR 49832).

The Median Time for Discharged ED Patients measure assesses one component, the time patients spent in the ED before being sent home, also known as ED throughput. The Emergency Care Access & Timeliness eCQM measures four different ED components in a single measure and provides REHs with separate data for each individual component. Additionally, the eCQM measures transfer boarding time in the ED and time from arrival to placement in a treatment room, which is not measured by the Median Time for Discharged ED Patients measure, or any other measure currently in the REHQR Program measure set.[202] As discussed later in section XVI.C.2.c. of this proposed rule, to provide flexibility for REHs, we propose that REHs could elect to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patients measure beginning with the CY 2027 reporting period/CY 2029 program determination. While CMS proposes that the Emergency Care Access & Timeliness eCQM would not be required to be reported by REHs, REHs must nonetheless elect to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patient measure to meet program requirements, beginning with the CY 2027 reporting period/CY 2029 program determination. We believe this timeline would provide REHs sufficient time to test and integrate the Emergency Care Access & Timeliness eCQM into existing clinical workflows.

For more information about the testing, feasibility, scientific acceptability, meaningfulness, and validity of the Emergency Care Access & Timeliness eCQM, we refer readers to the "Feasibility" and "Scientific Acceptability" sections of the Emergency Care Access & Timeliness eCQM listing on the Partnership for Quality Measurement website at *https://p4qm.org/measures/4625e.*

c. Measure Calculation

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[202] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e*. *Accessed*: *April 30, 2025.*

The measure denominator includes all ED encounters by patients of all ages, for all-payers, during a 12-month period of performance. Patients can have multiple encounters during a period of performance and each encounter is eligible to contribute to the calculation of the measure.[203]

The measure numerator includes any ED encounter in the denominator where the patient experiences any one of the following: (1) the patient waited longer than 1 hour after arrival to the ED to be placed in a treatment room or dedicated treatment area that allows for audiovisual privacy during history-taking and physical examination; (2) the patient left the ED without being evaluated; (3) the patient, if transferred, boarded in the ED for longer than 4 hours;[204] or (4) the patient had an ED LOS of longer than 8 hours. An encounter is included in the numerator if any one of the four numerator events occurred with events not being mutually exclusive and each contributing only once to the numerator. ED encounters with ED observation stays[205] are excluded from components (3) and (4).

These four outcomes were selected based on published literature demonstrating that each numerator component is associated with patient harm,[206] as well as clinical (including ED), statistical, and methodological expert input. Additionally, a Technical Expert Panel (TEP) was convened by the measure developer.[207] The Patient and Family Engagement (PFE) Work Group provided feedback on emergency care experiences such as long wait times to be seen by a

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[203] For proposed measure specifications, we refer readers to the CMS QualityNet REHQR Program website at *https://qualitynet.cms.gov/reh/rehqr.*

[204] This measure component is calculated at the encounter level by subtracting "Decision to Transfer" order time from "ED Departure Time" for visits with the ED disposition of "Transferred" (to an acute care hospital), and then flagging as a numerator event if >240 minutes.

[205] ED observations stays are defined as an observation encounter where the patient remains physically in an area under control of the ED and under the care of an ED clinician inclusive of observation in a hospital bed. Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[206] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[207] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

provider, long wait times to be transferred, and gaps in discharge processes.[208]

The numerator thresholds were developed according to evidence and consensus-based clinical guidelines for ED time thresholds from a TEP and environmental scans. For example, the four-hour threshold for numerator component (3), transfer boarding time, was developed per recommendations from The Joint Commission (TJC) and the American College of Emergency Physicians (ACEP).[209] If this proposal to adopt the Emergency Care Access & Timeliness eCQM for the REHQR Program is finalized, CMS would closely monitor the effect of this measure in REHs and may revise thresholds as appropriate.

Measure testing for the Emergency Care Access & Timeliness eCQM was conducted by the measure developer across 32 hospital-based EDs, representing a diverse mix of geographic regions, rurality, hospital size, teaching status, trauma level, and electronic health record (EHR) vendors, demonstrating that the measure is reliable, valid, and feasible for all required data elements.[210] Measure testing results had a wide range in overall scores, and across all strata, indicating variation in performance and implying room for quality improvement.[211] Although data element feasibility testing was performed at only one REH, the measure was also tested at a few rural hospital-based EDs with similar characteristics of pre-conversion REHs (for example, average bed range of under 25).[212] Based on this, we believe these measure testing results are applicable to REHs.

The measure score is calculated at the individual ED level as the proportion of ED

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[208] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[209] Yale New Haven Health Services Corporation. (2024). Technical Expert Panel (TEP) Evaluation of Measure Emergency Care Capacity and Quality Electronic Clinical Quality Measure (eCQM). Available at *https://mmshub.cms.gov/sites/default/files/ECCQ-TEP-Summary-Report-081624.pdf. Accessed: April 30, 2025.*

[210] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[211] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[212] Partnership for Quality Measurement. 7.1 Supplemental Attachment. Available at *https://p4qm.org/sites/default/files/2024-10/4625e-section-7.1-supplemental-attachment.pdf. Accessed: April 30, 2025.*

encounters where any one of the four outcomes occurred, divided by the number of encounters in a performance period. For CMS Certification Numbers (CCNs) with more than one ED, individual ED scores are then combined as a weighted average for that CCN.[213] The results of the Emergency Care Access & Timeliness eCQM are stratified into four groups, two by age (18 and older, and under 18) and two by mental health diagnoses (with, and without).[214] We note that the approach to stratification by age and mental health diagnosis is sufficient to account for differences between REHs without further need for risk adjustment.

For additional details regarding the proposed measure specifications, we refer readers to the CMS QualityNet REHQR Program website at *https://qualitynet.cms.gov/reh/rehqr*https://qualitynet.cms.gov/outpatient.

d. Pre-Rulemaking Measure Review (PRMR)

As required under section 1890A of the Act, the Secretary must establish and follow a pre-rulemaking process for selection of quality and efficiency measures, including for the REHQR Program. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the consensus-based entity (CBE), with which we contract in accordance with section 1890 of the Act, for the purpose of providing interested parties input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the REHQR Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94372) for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations. The PRMR Hospital

[213] Because REHs are typically a low volume setting, volume standardization is not applied to calculate the Emergency Care Access & Timeliness eCQM, unlike the version of the Emergency Care Access & Timeliness eCQM proposed for the Hospital OQR Program in section XV.B.1. this proposed rule.

[214] The principal diagnosis (first listed diagnosis at ED discharge) will be used to define strata inclusion. For this measure's purpose, mental health diagnoses do not include substance use disorder diagnoses. Mental health refers to mental health diagnoses, life stressors and crises, and stress-related physical symptoms.

Recommendation Group 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 Emergency Care Access & Timeliness eCQM (MUC2024-095), and provided additional recommendations on the potential use of this measure.[215]

The voting results of the PRMR Hospital Recommendation Group for the proposed Emergency Care Access & Timeliness eCQM within the REHQR Program were: 9 members recommended adopting the measure into the REHQR Program; 6 members recommended adoption with conditions; 11 members voted not to recommend the measure for adoption. No voting category reached 75 percent or greater, including the combination of the recommend and the recommend with conditions categories and thus, the Hospital Recommendation Group did not reach consensus.[216]

The PRMR Hospital Recommendation Group noted in their deliberations that the measure will provide important insights into ED wait times which impact experience of care. The Group expressed concern that this measure may cause an increase in cost of care due to patients being transferred from the ED to observation.[217] While we acknowledge that patients transferred from the ED to observation may result in increased short-term costs due to additional monitoring and extended stays, the measure is designed to address significant issues surrounding the access to timely care which have been proven to reduce long-term costs.[218] Hospital

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[215] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

[216] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

[217] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf*. *Accessed: April 30, 2025.*

[218] Dyas, S.R., Greenfield, E., Messimer, S., Thotakura, S., Gholston, S., Doughty, T., Hays, M., Ivey, R., Spalding, J., & Phillips, R. (2015). Process-Improvement Cost Model for the Emergency Department. *Journal of Healthcare*

Recommendation Group members also expressed concern about the lack of CBE endorsement. We note that we submitted the Emergency Care Access & Timeliness eCQM for CBE endorsement for review in the Fall 2024 cycle and the CBE endorsed the measure with conditions for use in the REHQR Program on February 12, 2025.[219, 220] We refer readers to section XVI.B.1.e. of this proposed rule for additional details on CBE endorsement.

The Hospital Recommendation Group discussed a few conditions specific to the REHQR Program, including changing the name of the measure to better reflect the measure's focus.[221] We agree with this feedback and have changed the name of the measure from the Emergency Care Capacity and Quality eCQM to Emergency Care Access & Timeliness. Additionally, Group members recommended stratifying the measure by factors such as care type as well as by region and trauma level designation. We emphasize that the approach to stratification by age and mental health diagnosis is sufficient to account for differences between REHs without further need for additional stratification.[222]

The Hospital Recommendation Group recommended revising the measure specifications to create separate measure components with the encouragement to explore additional measures for patient transfer boarding time and ED LOS as well as conducting further testing to expand the measure's applicability to REHs. We acknowledge the Hospital Recommendation Group's

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Management, 60(6): 442–57. Available at *https://doi.org/10.1097/00115514-201511000-00011. Accessed: April 30, 2025.*

[219] Partnership for Quality Measurement. (2024). 2024 Pre-Rulemaking Measure Review Preliminary Assessment. Available at: *https://p4qm.org/sites/default/files/2024-12/PRMR-PA-MUC2024-075.pdf. Accessed: April 30, 2025.*

[220] Partnership for Quality Measurement. (2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report. Available at *https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management/material/EM-Fall-2024-Initial-Recognition-Final-Project-Report.pdf. Accessed: April 30, 2025.*

[221] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf. Accessed: April 30, 2025.*

[222] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf. Accessed: April 30, 2025.*

concerns and note that multiple TEPs and interested parties supported the inclusion of more than one numerator component as a strategy for internally balancing the measure and that time thresholds are based on more than a decade of consensus work.[223, 224, 225] If the proposal to adopt the Emergency Care Access & Timeliness eCQM for the REHQR Program is finalized, CMS will closely monitor the effect of this measure in REHs and revise thresholds as appropriate. We note that out of the 32 hospital-based EDs that were tested for reliability, validity, and feasibility, approximately 20 percent were rural EDs, although not in the REHQR Program. Finally, Group members recommended implementing the Emergency Care Access & Timeliness eCQM with a phased approach with 2 years of voluntary reporting. We note that we propose adoption of the Emergency Care Access & Timeliness eCQM as an optional measure in lieu of the Median Time for Discharged ED Patients measure to provide additional flexibility for REHs given the anticipated implementation burden of this measure.

e. Measure Endorsement and Consideration of Low Case Volumes

Section 1861(kkk)(7)(C)(i) of the Act generally provides that any measure specified by the Secretary for use in the REHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, also known as the consensus-based entity (CBE).

The Emergency Care Access & Timeliness eCQM was submitted to the CBE for endorsement review in the Fall 2024 cycle (CBE #4625e), and the CBE endorsed the measure for use in the REHQR Program with conditions on February 12, 2025.[226] The conditions include

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[223] Partnership for Quality Measurement. Emergency Care Capacity and Quality. Available at *https://p4qm.org/measures/4625e*. *Accessed*: *April 30, 2025.*

[224] Yale New Haven Health Services Corporation. (April 2024). Technical Expert Panel (TEP) Evaluation of Measure Emergency Care Capacity and Quality Electronic Clinical Quality Measure (eCQM). Available at *https://mmshub.cms.gov/sites/default/files/ECCQ-TEP-2-Summary-Report.pdf. Accessed: April 30, 2025.*

[225] Yale New Haven Health Services Corporation. (September 2024). Technical Expert Panel (TEP) Evaluation of Measure Emergency Care Capacity and Quality Electronic Clinical Quality Measure (eCQM). Available at *https://mmshub.cms.gov/sites/default/files/ECCQ-TEP-Summary-Report-081624.pdf. Accessed: April 30, 2025.*

[226] Partnership for Quality Measurement. (2025). Fall 2024 Cycle Endorsement and Maintenance (E&M) Technical Report. Available at *https://p4qm.org/sites/default/files/Initial%20Recognition%20and%20Management*

that the measure developer explore: (1) the unintended consequences to patients and providers by engaging with the patient community and accountable entities; and (2) the data elements to identify and address where challenges may persist. If our proposal to adopt the Emergency Care Access & Timeliness eCQM for the REHQR Program is finalized, CMS would closely monitor the effects of this measure in REHs and data as part of the standard measure maintenance.

We believe this measure is appropriate for measuring quality of care under the REHQR Program because ED care is the primary focus of REHs. Furthermore, we believe that this measure meets the selection criteria under section 1861(kkk)(7)(C)(i) of the Act because it is endorsed by the CBE.

The REHQR Program's statute also includes a requirement at section 1861(kkk)(7)(C)(iii) of the Act to consider ways to account for rural emergency hospitals that lack sufficient case volumes when selecting measures to ensure that the performance rates for such measures are reliable. We note that the target population for this measure is comprised of patients of all ages, for all payers, that visit an REH during a 1-year measurement period. As such, we anticipate that the overall number of patients that visit an REH within a given year would be high enough so that there would not be any issues with low case volumes that could undermine the reliability of this measure when used in the REH context. We therefore do not believe the Emergency Care Access & Timeliness eCQM would suffer from low case volumes, and we further believe that we have appropriately considered low case volumes as required by the REHQR statute when selecting this measure.

f. Data Collection, Submission, and Reporting

The Emergency Care Access & Timeliness eCQM is specified in a standard electronic format, utilizing data extracted electronically from EHRs, with all data coming from defined fields in electronic sources. We note that eCQMs allowing for the retrieval of data directly from

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/material/EM-Fall-2024-Initial-Recognition-Final-Project-Report.pdf. Accessed: April 30, 2025.

the EHR will minimize errors due to manual abstraction of data.[227] As discussed in section XVI.C.2.c. of this proposed rule, we propose that REHs would be required to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged Patients measure. We refer readers to section XVI.C.2.c. of this proposed rule for a discussion of proposed eCQM form, manner, and timing of data submission and reporting requirements. If an REH chooses to report the Emergency Care Access & Timeliness eCQM, the REH would report the data using the proposed methods and standards specified in section XVI.C.2. of this proposed rule.

We propose to adopt the Emergency Care Access & Timeliness eCQM into the REHQR Program measure set beginning with the CY 2027 reporting period/CY 2029 program determination. However, as discussed later in section XVI.C.2.c. of this proposed rule, we also propose that the Emergency Care Access & Timeliness eCQM would not be a required measure under the REHQR Program, and that REHs could thus elect to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patients measure for a given reporting period/program determination. Providing REHs with the option to report either of these measures would provide greater flexibility for REHs to implement EHR infrastructure that meets their individual needs while still prioritizing measurement of the variation in access to and the timeliness of emergency care, the goal of promoting interoperability, and reducing burden for REHs in the long term. We note that adoption of this measure does not change the number of mandatory quality measures required to be reported in the REHQR measure set.

The Median Time for Discharged ED Patients measure assesses the time patients spent in the ED before being sent home, also known as ED throughput. We note that this measure is reported quarterly, compared to the Emergency Care Access & Timeliness eCQM, which is less

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[227] Centers for Medicare & Medicaid Services. (2023). Electronic Clinical Quality Measures (eCQMs) Specification, Testing, Standards, Tools, and Community. Available at *https://mmshub.cms.gov/sites/default/files/eCQM-Specifications-Testing-Standards-Tools-Community.pdf*. *Accessed: April 30, 2025.*

burdensome as it is reported annually. We further emphasize that the Emergency Care Access & Timeliness eCQM measures four different ED metric components in a single measure and is more comprehensive than the Median Time for Discharged ED Patients measure which measures one ED metric component.[228] Additionally, the eCQM measures transfer boarding time in the ED and time from arrival to placement in a treatment room, which are not currently captured by the Median Time for Discharged ED Patients measure, or any other measure currently in the REHQR Program measure set.[229]

We refer readers to section XV.B.1. of this proposed rule where we propose adoption of a similar version of this eCQM for the Hospital Outpatient Quality Reporting Program. If CMS finalizes that proposal, adoption of this eCQM in the REHQR Program would also provide greater alignment with HOPD metrics.

We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 49832) for more information on the Median Time for Discharged ED Patients measure.[230]

We intend to publicly report data submitted on the Emergency Care Access & Timeliness eCQM and the Median Time for Discharged ED Patients measure on our Compare tool on Medicare.gov (*https://www.medicare.gov/care-compare/*) or their successor websites after a 30-day preview period. Public reporting for both measures help to provide similar data on timeliness and encourage REHs to implement process improvements and reduce inefficiencies in ED operations, resulting in better quality of care.

We invite public comment on this proposal.

2. Summary of Previously Finalized and Newly Proposed REHQR Program Measure Set for CY 2026 to CY 2031 Program Determinations

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[228] The Median Time for Discharged ED Patients was adopted in the REHQR Program in the CY 2024 OPPS/ASC final rule with comment period (88 FR 49832).

[229] Partnership for Quality Measurement. Emergency care capacity and quality. Available at: *https://p4qm.org/measures/4625e. Accessed: April 30, 2025.*

[230] Partnership for Quality Measurement. Median Time from ED Arrival to ED Departure for Discharged ED Patients. Available at: *https://p4qm.org/measures/0496. Accessed: April 30, 2025.*

Table 85 summarizes the previously finalized and newly proposed REHQR Program measure set for the CY 2026 to CY 2031 program determinations, which would remove the Hospital Commitment to Health Equity (HCHE), Screening for SDOH, and Screen Positive Rate for SDOH measures as discussed in section XIV.C. of this proposed rule and add the Emergency Care Access & Timeliness eCQM as discussed in section XVI.B.1. of this proposed rule.

TABLE 85: PREVIOUSLY FINALIZED AND NEWLY PROPOSED REHQR PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PROGRAM DETERMINATION (PD)

	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	Chart-Abstracted Measures						
None	Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients*	✓	✓	✓	✓	✓	✓
	Claims-Based Measures						
None	Abdomen Computed Tomography (CT) - Use of Contrast Material	✓	✓	✓	✓	✓	✓
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	✓	✓	✓	✓	✓	✓
2687	Risk-Standardized Hospital Visits Within 7 Days After Hospital Outpatient Surgery	✓	✓	✓	✓	✓	✓
	Structural Measures						
None	Hospital Commitment to Health Equity (HCHE)**		Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Process Measures						
None	Screening for Social Drivers of Health (SDOH)***		Voluntary /Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
None	Screen Positive Rate for SDOH***		Voluntary /Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	eCQMs						
4625e	Emergency Care Access & Timeliness eCQM*				Proposed for Optional Reporting	Proposed for Optional Reporting	Proposed for Optional Reporting

✓: Measure is mandatory for the specified program determination year.

* In section XVI.C.2.c. of this proposed rule, we propose that REHs would have the option to report either the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients or the

Emergency Care Access & Timeliness eCQM beginning with the CY 2027 reporting period/CY 2029 program determination.
** Proposed for removal in this proposed rule beginning with the CY 2025 reporting period/CY 2027 program determination.
*** Proposed for removal in this proposed rule beginning with the CY 2025 reporting period.

We refer readers to the QualityNet website at *https://qualitynet.cms.gov/reh/rehqr* for additional information on the reporting periods and submission deadlines for each measure finalized and proposed in the REHQR Program.

3. REHQR Program Measures and Topics for Future Consideration

We refer readers to section XIV.B. of this proposed rule for our cross-program Request for Information on measure concepts regarding well-being and nutrition for consideration in the REHQR Program.

C. Proposed Updates to the Form, Manner, and Timing of REHQR Program Data Submission

We propose to update program policies for introducing eCQMs into the REHQR Program by establishing eCQM data submission and reporting requirements which apply to the proposed Emergency Care Access & Timeliness eCQM.

1. Maintenance of Technical Specifications for Quality Measures

CMS maintains technical specifications for adopted REHQR Program measures. The manuals containing the specifications for adopted measures are on the QualityNet website at *https://qualitynet.cms.gov/reh/specifications-manuals*. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82054) for additional information regarding these specification manuals.

In alignment with the Hospital OQR Program, we propose that the technical specifications for eCQMs for the REHQR Program would be contained in the CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update). The Annual Update and implementation guidance documents are available on the eCQI Resource Center website at *https://ecqi.healthit.gov/*. For eCQMs, we would generally update the measure specifications on an annual basis through the Annual Update which includes code updates, logic corrections,

alignment with current clinical guidelines, and additional guidance for REHs and EHR vendors to collect and submit data on eCQMs from EHRs.

We invite public comment on this proposal.

2. Proposed Data Submission and Reporting Requirements for eCQMs for the REHQR Program Beginning With the CY 2027 Reporting Period/CY 2029 Program Determination

a. Background

Collection and reporting of data through health information technology greatly simplifies and streamlines quality reporting, and automated electronic extraction and reporting of clinical quality data would significantly reduce the administrative burden on REHs for the REHQR Program. Certified EHR technology (CEHRT) could effectively assist REHs in a variety of ways, such as by improving coordination of care with receiving hospitals during transfers, facilitating the types of staffing and personnel models required for REHs, and using eCQMs to improve quality and safety. In response to our request for comments in the CY 2024 OPPS/ASC proposed rule (88 FR 49840 through 49841) on eCQM reporting for the REHQR Program, some commenters recommended that CMS should consider adding eCQMs as optional measures initially (88 FR 82070). REHs have some familiarity and experience with reporting eCQMs when formerly operating as a subsection (d) hospital or CAH participating in the Medicare Promoting Interoperability Program, although we acknowledge that technological, monetary, and staffing barriers may present challenges to eCQM adoption and use in some REHs.

We refer readers to section XVI.B.1. of this proposed rule, where we propose to adopt the Emergency Care Access & Timeliness eCQM into the REHQR Program measure set as an optional measure, beginning with the CY 2027 reporting period/CY 2029 program determination. If finalized, the Emergency Care Access & Timeliness eCQM would be the first eCQM in the REHQR Program measure set. Introducing eCQM reporting to the REHQR Program involves establishing related policies and requirements, such as eCQM certification requirements, data standards and formats, submission methods, and other program-specific

requirements. In the following sections, to reduce reporting burden for REHs, we propose eCQM reporting and submission policies and requirements for the REHQR Program, including reporting of the Emergency Care Access & Timeliness eCQM, that align with those of the Hospital OQR Program, Hospital Inpatient Quality Reporting Program, and Medicare Promoting Interoperability Program.

b. General Data Submission Requirements and Reporting Requirements

(1) Proposed eCQM Certification Requirements for eCQM Reporting

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94418 through 94420), the Hospital OQR Program finalized and codified three requirements relating to eCQM certification for the submission of eCQM data, beginning with the CY 2025 reporting period/CY 2027 payment determination. We propose to adopt the same eCQM certification requirements in the REHQR Program, beginning with the CY 2027 reporting period/CY 2029 program determination, and to likewise codify them by adding new paragraph (h) "Requirements for submission of electronic clinical quality measures (eCQMs) under the REHQR Program" to 42 CFR 419.95. As discussed in section XVI.C.2.c. of this proposed rule, REHs would be required to meet these eCQM requirements beginning with the CY 2027 reporting period/CY 2029 program determination if the REH chooses to submit the Emergency Care Access & Timeliness eCQM rather than the Median Time for Discharged ED Patients measure.

Under this approach, we propose to codify at § 419.95(h)(1) the requirement for REHs to utilize technology certified to Office of the National Coordinator for Health Information Technology's (ONC's) health information technology (IT) certification criteria, as adopted and updated in 45 CFR 170.315, for reporting eCQMs under the REHQR Program. Using the most recent certified health IT, which incorporates updated standards and criteria, is important as it allows the collection of relevant, accurate, and structured electronic data for electronic clinical quality measurement.

We also propose to codify at 42 CFR 419.95(h)(2) the requirement that the health IT used for eCQM reporting by REHs must be certified to all eCQMs (that is, tested and validated on each individual eCQM) available to report under the REHQR Program. Additionally, we propose to codify at § 419.95(h)(3) the requirement that REHs use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at *https://ecqi.healthit.gov/* or another website as designated by CMS. We also propose that certified EHR technology would not need to be recertified each time the eCQMs specifications are updated to a more recent version.

Requiring EHRs to be certified to all available eCQMs under the REHQR Program would produce greater certainty for REHs that their EHR systems are capable of accurately calculating the eCQMs under the REHQR Program because the EHR technology would be up to date and tested on each eCQM. We believe this would reduce burden on REHs by minimizing the need to consult with their EHR and other health information technology vendors each time they report on a new or different eCQM.

Finally, we also propose to codify at § 419.95(h)(4) that the requirements set forth in paragraphs (h)(1) through (3) apply only where an REH opts to report an eCQM.

We invite public comment on these proposals.

(2) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

(a) File Format for EHR Data

Data can be collected in EHRs and health information technology systems using standardized formats to promote consistent representation, interpretation, and allowance for systems to compute data without needing human interpretation. As described in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49701), these standards are referred to as content exchange standards because the standard details how data should be represented and the relationships between data elements. This allows the data to be exchanged across EHRs and health IT systems

while retaining their meaning. Commonly used content exchange standards include the Quality Reporting Document Architecture (QRDA). The QRDA standard provides a document format and standard structure to electronically report quality measure data. We believe electronically reporting data elements formatted according to the QRDA standard can promote consistent representation and more efficient calculation of eCQM measure results.

To utilize the same file format requirements currently applied in the Hospital IQR, OQR, and Medicare Promoting Interoperability Programs (85 FR 58940, 86 FR 42262, and 80 FR 49706, respectively), we propose the file format requirements for the REHQR Program beginning with the CY 2027 reporting period/CY 2029 program determination. Specifically, we propose that REHs: (1) must submit eCQM data via the QRDA Category I (QRDA I) file format;[231] (2) may use third parties to submit QRDA I files on their behalf; and (3) may either use abstraction or pull the data from non-certified sources in order to then input these data into CEHRT for capture and reporting QRDA I. REHs could meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemptions. We discuss the zero-denominator declaration and case threshold exemptions in the subsequent sections. We also refer readers to section XVI.C.1. of this proposed rule where we outline the maintenance of technical specifications including those for eCQMs.

Under this proposal, we expect QRDA I files to reflect data for one patient per file per quarter with five key elements necessary to identify the file: (1) CCN; (2) CMS Program Name; (3) EHR Patient ID; (4) Reporting period specified in the Reporting Parameters Section; and (5) EHR Submitter ID.

(b) Zero Denominator Declarations

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[231] QRDA I is an individual patient-level quality report that contains quality data for one patient for one or more eCQMs. QRDA creates a standard method to report quality measure results in a structured, consistent format and can be used to exchange eCQM data between systems. For further detail on QRDA I, the most recently available QRDA I specifications and Implementation Guides (IGs) can be found at: *https://ecqi.healthit.gov/qrda?qt-tabs_qrda=versions.*

We understand there may be situations in which an REH does not have data to report on a particular eCQM. Therefore, we propose if the REH's EHR is certified to an eCQM, but the REH does not have patients that meet the denominator criteria of that eCQM, the REH could submit a zero in the denominator for that eCQM; submission of a zero in the denominator for an eCQM would qualify as a successful submission for that eCQM.

(c) Case Threshold Exemptions

As a general matter, we understand that in some cases, particularly for REHs, an REH may not meet the applicable case threshold of encounters or discharges for a particular eCQM to reliably calculate performance on the measure. We propose to align with the case threshold exemption from the Medicare Promoting Interoperability Program (77 FR 54080), the Hospital IQR Program (79 FR 50324), and the Hospital OQR Program (86 FR 63869). As stated for the Hospital IQR Program, the case threshold exemption means that for each quality measure where the minimum number of patients that meet the patient population denominator criteria for the relevant reporting period is not met, REHs could declare a "case threshold exemption." Specifically, for the REHQR Program, we propose that beginning with the CY 2027 reporting period/CY 2029 program determination, if an REH's EHR system is certified to report an eCQM and the REH has 5 or fewer outpatient encounters or discharges per quarter or 20 or fewer outpatient encounters or discharges per year (Medicare and non-Medicare combined), as defined by an eCQM's denominator population, that REH would be exempt from reporting on that eCQM. Case threshold exemptions would be able to be entered on the Denominator Declaration screen within the Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal) available during the submission period.[232] The exemption would not have to be used; REHs could report those individual cases if they would like to.

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[232] The Hospital Quality Reporting (HQR) System (formerly referred to as the QualityNet Secure Portal) is the only CMS-approved website for secure communications and healthcare quality data exchange to and within various CMS quality reporting programs. For more information regarding the HQR System, we refer readers to the CMS eCQI Resource Center *(https://ecqi.healthit.gov/tool/hospital-quality-reporting-hqr-system)*.

We invite public comment on these proposals.

(3) Proposed Submission Deadlines for eCQM Data

To align with the Hospital OQR Program, we propose to adopt a policy to require eCQM data submission by May 15 of the following year for the applicable CY reporting period, beginning with the CY 2027 reporting period/CY 2029 program determination. For example, if an REH elects to report the Emergency Care Access & Timeliness eCQM, the first proposed reporting period would run from January 1, 2027 through December 31, 2027, with a submission deadline of May 15, 2028. We note that the submission deadline may be moved to a subsequent day if it falls on a non-working day for federal employees such as weekends or Federal holidays.

We invite public comment on this proposal.

c. Proposed Data Submission and Reporting Requirements for the Emergency Care Access & Timeliness eCQM Beginning With the CY 2027 Reporting Period/CY 2029 Program Determination

In section XVI.B.1. of this proposed rule, we discuss the proposed adoption of the Emergency Care Access & Timeliness eCQM into the REHQR Program beginning with the CY 2027 reporting period/CY 2029 program determination as an option for REHs to report instead of the Median Time for Discharged ED Patients measure. In addition to the general data submission and reporting requirements proposed for eCQMs in section XVI.C.2. of this proposed rule, we also propose requirements for reporting the Emergency Care Access & Timeliness eCQM under the REHQR Program. Specifically, we propose that the Emergency Care Access & Timeliness eCQM would not be required to be reported by REHs under the REHQR Program, but that REHs must elect to report either the Emergency Care Access & Timeliness eCQM or the Median Time for Discharged ED Patients measure to meet program requirements, beginning with the CY 2027 reporting period/CY 2029 program determination. We believe our proposed approach would provide REHs with more flexibility, including the time to plan and budget for the type of EHR infrastructure that meets their needs. Additionally, we

believe this approach could contribute to successful participation in the REHQR Program, while still requiring REHs to report timeliness of ED care metrics. We note that the Median Time for Discharged ED Patients measure is reported quarterly through the HQR system, compared to the Emergency Care Access & Timeliness eCQM, which is reported annually. Sources of the relevant data for the Median Time for Discharged ED Patients measure may include claims forms, electronic health care data, EHRs, or paper records. We refer readers to the CY 2024 OPPS/ASC final rule with comment period (88 FR 82059 through 82062; 88 FR 82074 through 82075) for additional information on reporting the chart-abstracted Median Time for Discharged ED Patients measure.[233]

We propose to report data from the REHQR Program as soon as it is feasible on CMS websites such as the Compare tool on Medicare.gov *(https://www.medicare.gov/care-compare/*) or their successor websites after a 30-day preview period.

We invite public comment on these proposals.

3. Review and Corrections Period for Measure Data Submitted to the REHQR Program

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82075 through 82076), we finalized and codified at § 419.95(c)(3) a review and corrections period for all measure data submitted to the REHQR Program, which runs concurrently with the data submission period. During the review and corrections period, REHs can review, correct, and change these data up until the close of each submission deadline. However, after the submission deadline, REHs are not allowed to change these data. This policy applies to all measure data submitted to the REHQR Program, so this would include eCQM data.

The review and corrections period is from the time the submission period opens to the submission deadline. In the HQR System, REHs can submit QRDA Category I test and production data files and can correct QRDA Category I test and production data files before

[233] For additional information on the Median Time for Discharged ED Patients measure, we refer readers to the specifications manuals for the REHQR Program, located at: *https://qualitynet.cms.gov/reh/specifications-manuals*.

production data is submitted for final reporting. We encourage early testing and the use of pre-submission testing tools to reduce errors and inaccurate data submissions in eCQM reporting. We refer readers to the HQR System website (available at *https://hqr.cms.gov/hqrng/login*) and the CMS eCQI Resource Center (available at *https://ecqi.healthit.gov/tool/hospital-quality-reporting-hqr-system*) for more resources on eCQM reporting.

4. REHQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to section XIV.D. of this proposed rule for our cross-program proposal to codify updates to the Extraordinary Circumstances Exceptions (ECE) policy for the REHQR Program.

XVII. Ambulatory Surgical Center Quality Reporting (ASCQR) Program

A. Background and History of the ASCQR Program

The Ambulatory Surgical Center Quality Reporting (ASCQR) Program is a pay-for-reporting program intended to ensure transparency for quality of care provided at ambulatory surgical centers (ASCs). Section 1833(i)(7)(A) of the Act authorizes the Secretary to reduce any annual increase under the revised ambulatory surgical center (ASC) payment system by 2.0-percentage points for such year that an ASC fails to submit required data on quality measures specified by the Secretary in accordance with section 1833(i)(7)(B) of the Act. Section 1833(i)(7)(B) of the Act states that, except as the Secretary may otherwise provide, several of the statutory provisions governing the Hospital Outpatient Quality Reporting (OQR) Program, specifically sections 1833(t)(17)(B) through (E) of the Act, also apply to the services of ASCs under the ASCQR Program in a similar manner to the manner in which they apply to the services of hospital outpatient departments under the Hospital OQR Program.

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74494) for a detailed discussion of the statutory authority of the ASCQR Program. The ASCQR Program requirements are codified at 42 CFR part 416, subpart H

(§§ 416.300 through 416.330). We refer readers to the CMS website at *https://www.cms.gov/medicare/quality/initiatives/asc-quality-reporting* for general background on the ASCQR Program, as well as the CMS QualityNet ASCQR website at *https://qualitynet.cms.gov/asc* for current program requirements and measure specifications.

B. Proposed Changes to the ASCQR Program Measure Set

We propose to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure (Information Transfer PRO–PM) beginning with voluntary reporting for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination.

We refer readers to section XIV.C. of this proposed rule for a discussion of the following proposed measure removals: (1) the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure, beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) the Facility Commitment to Health Equity (FCHE) measure, beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) the Screening for Social Drivers of Health (SDOH) measure, beginning with the CY 2025 reporting period; and (4) the Screen Positive Rate for SDOH measure, beginning with the CY 2025 reporting period.

1. Proposed Adoption of the Information Transfer PRO–PM Beginning With Voluntary Reporting for the CY 2027 and CY 2028 Reporting Periods Followed by Mandatory Reporting Beginning With the CY 2029 Reporting Period/CY 2031 Payment Determination

a. Background

The volume and complexity of surgical procedures performed in outpatient settings,

including ASCs, have steadily increased for over a decade.[234, 235, 236] As patients can benefit from having a clear understanding of their discharge information to support recovery from such procedures, the communication of discharge information is an important quality of care area for assessing facilities, and this information should be publicly available. A patient's lack of understanding of clinical care instructions provided after a procedure and other aspects of health literacy have been linked to poor adherence to treatment, decreased patient safety, increased return to the emergency department, and lower levels of patient satisfaction; disproportionately increased rates of such adverse effects occur to patients with limited English proficiency and patients over age 65.[237, 238] Research in the hospital setting indicates that information provided to patients that is simpler and more complete is associated with fewer follow-up calls to an associated trauma center and less frequent hospital readmissions.[239, 240] A study comparing discharge instructions provided to patients who had procedures performed in inpatient and ambulatory settings found that discharge instructions from the inpatient setting contained more complete medication lists and pending diagnostic result elements compared to discharge

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[234] DelSole, E. M., Makanji, H. S., & Kurd, M. F. (2019). Current trends in ambulatory spine surgery: a systematic review. *J Spine Surg*. 5(Suppl 2):S124-S132. *https://doi.org/10.21037/jss.2019.04.12*. *Accessed: April 29, 2025.*

[235] Kondamuri, N. S., Miller, A. L., Rathi, V. K., et al. (2020). Trends in Ambulatory Surgery Center Utilization for Otolaryngologic Procedures among Medicare Beneficiaries, 2010-2017. *Otolaryngol Head Neck Surg.* 162(6):873-880 *https://doi.org/10.1177/0194599820914298. Accessed: April 29, 2025.*

[236] Shariq, O. A., Bews, K. A., Etzioni, D. A., et al. (2023). Performance of General Surgical Procedures in Outpatient Settings Before and After Onset of the COVID-19 Pandemic. *JAMA Netw Open*.; 6(3):e231198. Doi:10.1001/jamanetworkopen.2023.1198. *Accessed: April 29, 2025.*

[237] DeSai, C., Janowiak, K., Secheli, B., et al. (2021). Empowering patients: simplifying discharge instructions. *BMJ Open Quality*;10(3)001419. *http://doi.org/10.1136/bmjoq-2021-001419. Accessed: April 8, 2025.*

[238] Malevanchik, L., Wheeler, M., Gagliardi, K., Karliner L., & Shah, S. J. (2021). Disparities After Discharge: The Association of Limited English Proficiency and Postdischarge Patient-Reported Issues, *The Joint Commission Journal on Quality and Patient Safety*, 47(12):775-782. *https://doi.org/10.1016/j.jcjq.2021.08.013. Accessed: April 8, 2025.*

[239] Choudhry, A. J., Younis, M., Ray-Zack, M. D., et al. (2019). Enhanced readability of discharge summaries decreases provider telephone calls and patient readmissions in the posthospital setting. *Surgery.* 165(4):789-794. *https://doi.org/10.1016/j.surg.2018.10.014. Accessed: April 8, 2025.*

[240] Becker, C., Zumbrunn, S., Beck, K., et al. (2021). Interventions to Improve Communication at Hospital Discharge and Rates of Readmission: A Systematic Review and Meta-analysis. *JAMA Netw Open.* 4(8):e2119346. *https://doi.org/10.1001/jamanetworkopen.2021.19346. Accessed: April 8, 2025.*

instructions provided by the hospital ambulatory setting.[241]

b. Measure Overview

The Information Transfer PRO–PM assesses patient understanding of provided discharge information for patients aged 18 years or older who had a procedure (surgical or non-surgical) at an ASC via a 9-item survey.[242] The survey evaluates patient reported understanding of information received across three domains: applicability to patient needs, medication, and daily activities. Survey results provide patient reported outcome (PRO) data measuring ASCs' communication efforts regarding discharge instructions and enable ASCs to reduce future risk of patient harm related to patients not fully understanding their recovery information. The survey was tested and deemed reliable in both English and Spanish versions; for ease of administration, the survey can be completed using a translator, proxy, or caregiver. The measure's testing results are based on data from the hospital outpatient department (HOPD) setting; however, it is reasonably expected that the instrument and methodology apply to the ASC setting regarding patients receiving surgical procedures as both are outpatient surgical settings providing similar services with the supply of discharge instructions. We note that the measure specifications for the Information Transfer PRO–PM require that the survey be administered anonymously to patients, and that the survey instrument does not collect any identifiable patient information.

In monitoring implementation of this measure for the Hospital OQR Program, we discovered that the anonymous administration requirement could potentially limit the hospitals' ability to collect data for their patients without working with a third-party vendor. If the survey is required to be fully anonymous, hospitals fielding the survey themselves would not be able to conduct any targeted follow-up with patients during the 65-day response window or use the

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[241] Downey, E., & Olds, D. M. (2021). Comparison of Documentation on Inpatient Discharge and Ambulatory End-of-Visit Summaries. *J Healthc Qual.* 43(3):e43-e52. *https://doi.org/10.1097/JHQ.0000000000000269. Accessed: April 8, 2025.*

[242] A copy of the survey instrument is available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf.*

information provided to develop more targeted quality improvement efforts.

While anonymous surveys can be valuable for gathering candid feedback, these issues of preventing follow-up, targeted action plans, and deeper investigation of specific issues, as well as leading to less serious or misleading responses have been documented.[243]

We invite public comment on the proposal to utilize this measure as specified with anonymous administration as well as potential data collection options to address the anonymity requirement in both the Hospital OQR and ASCQR Programs, where this measure was previously adopted and is currently proposed for adoption, respectively.

The measure developer conducted pilot testing for this measure in 26 HOPDs in five states and demonstrated that the measure is reliable and meaningful.[244] Reliability of the measure was assessed with the Cronbach alpha score[245] to determine whether the nine survey questions reliably measured the same underlying characteristic; that is, patient's assessment of the clarity and applicability of recovery instructions. The Cronbach alpha score indicated that the survey items are reliable.[246] The measure developer also found the performance scores among facilities in the pilot study to be moderately reliable using a signal-to-noise ratio, which estimated variance among facilities and measured facility-specific standard errors to determine the extent to which

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[243] Murdoch, M., et. Al. (2014). Impact of different privacy conditions and incentives on survey response rate, participant representativeness, and disclosure of sensitive information: a randomized controlled trial. *BMC Med Res Methodol*. Jul 16:14-90.

[244] Centers for Medicare & Medicaid Services. (April 2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure. Available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf. Accessed: April 29, 2025.*

[245] For more information on what the Cronbach alpha score determines and how it is used, we refer readers to: Tavakol, M., & Dennick, R. (2011). Making sense of Cronbach's alpha. *Int J Med Educ*. 27;2: 53- 55. *https://www.ijme.net/archive/2/cronbachs-alpha.pdf. Accessed: April 30, 2025.*

[246] Centers for Medicare & Medicaid Services. (April 2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure. Available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf. Accessed: April 29, 2025.*

variance in facility scores can be attributed to variance in actual performance.[247] More information about the testing, feasibility, scientific acceptability, meaningfulness, and validity of the Information Transfer PRO–PM for the HOPD setting is available at *https://p4qm.org/measures/4210.*

c. Measure Calculation

The measure numerator is the sum of all the individual scores an ASC receives from eligible respondents, which could be patients or their caregivers. Individual scores are calculated for each respondent by taking the sum of items for which the respondent gave the most positive response (either, "Yes" or "Very Clear") and dividing by the number of items the respondent deemed applicable to their procedure or surgery. Applicable items are calculated by subtracting the sum of items for which the respondent selected "Does not apply" from the total number of survey items (nine).[248] The measure denominator is the total number of patients 18 years or older who had a procedure or surgery in an ASC, left the ASC alive, and responded to the survey. The cohort of patients for the Information Transfer PRO–PM is standardized with the OAS CAHPS cohort to minimize provider burden and to harmonize between the two surveys. Only fully completed surveys are included in the measure calculation. For additional details regarding the proposed measure specifications, we refer readers to the CMS QualityNet website.[249]

d. Pre-Rulemaking Measure Review (PRMR)

As required under section 1890A of the Act, the Secretary must establish and follow a pre-rulemaking process for the selection of quality and efficiency measures, including for the

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[247] Centers for Medicare & Medicaid Services. (April 2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure. Available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf. Accessed: April 29, 2025.*

[248] Partnership for Quality Measurement. Submission Tool and Repository Measure Database. *https://p4qm.org/measures/4210. Accessed: April 8, 2025.*

[249] The proposed ASCQR Program measure specifications can be found at *https://qualitynet.cms.gov/asc.*

ASCQR Program. The pre-rulemaking process, which we refer to as the Pre-Rulemaking Measure Review (PRMR), includes a review of measures published on the publicly available list of Measures Under Consideration (MUC List) by one of several committees convened by the consensus-based entity (CBE), with which we contract in accordance with section 1890 of the Act, for the purpose of providing interested parties' input to the Secretary on the selection of quality and efficiency measures under consideration for use in certain Medicare quality programs, including the ASCQR Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94372) for details on the PRMR process, including the voting procedures used to reach consensus on measure recommendations.

The PRMR Hospital Recommendation Group 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 Information Transfer PRO–PM, for potential use.[250, 251] The voting results of the PRMR Hospital Recommendation Group for the proposed Information Transfer PRO–PM for the ASCQR Program were: 5 members recommended adopting the measure; 14 members recommended adoption with conditions; and 8 members voted not to recommend the measure for adoption. No voting category reached 75 percent or greater, including the combination of the recommend and the recommend with conditions categories. Thus, the PRMR Hospital Recommendation Group did not reach consensus and did not recommend including this measure in the ASCQR Program either with or without conditions.

The PRMR Hospital Recommendation Group noted in their deliberations the importance of measuring patient experience and delivering personalized and clear discharge instructions to prevent unnecessary hospital readmissions. However, the PRMR Hospital Recommendation Group members expressed concerns about lack of testing in the ASC setting given differences

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[250] The Information Transfer PRO-PM is identified on the MUC List as MUC2024-073.

[251] Partnership for Quality Measurement. (2025). 2024-2025 Pre-Rulemaking Measure Review (PRMR) Recommendation Group Final Meeting Summary: Hospital Committee. Available at *https://p4qm.org/sites/default/files/2025-02/PRMR-Hospital-Recommendation-Group-Meeting-Summary.pdf. Accessed: April 29, 2025.*

between HOPDs as a hospital setting (where testing of the Information Transfer PRO–PM was conducted) and ASCs. This group also highlighted concerns related to patient survey fatigue; potential overlap with the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey sample population and content; and the risk of low response rates – particularly in small or rural facilities, which could impact scoring.

Although the measure was not pilot tested in the ASC setting with facilities citing resource constraints, we believe that the instrument and methodology reasonably apply to the ASC setting as the measure concept was designed for use in both HOPDs and ASCs and many of the same surgical procedures are performed in both settings.[252] Measure harmonization across the Hospital OQR and ASCQR Programs enables meaningful comparisons of care for patients to assess quality between settings that offer similar services.

Regarding the PRMR Hospital Recommendation Group's concern about potential overlap between the Information Transfer PRO-PM and OAS CAHPS content and target population, the OAS CAHPS survey addresses overall quality of healthcare facility communication but does not assess patient understanding of discharge information related to medication, activity, and applicability/personalization. We believe that both surveys provide valuable insights into different aspects of a patient's experience related to discharge instructions. Additionally, to minimize duplication of patient sampling, resources are available to help facilities align administration of OAS CAHPS with other surveys.[253] In consideration of potential population overlap, we selected a timeframe of 2 to 7 days post-procedure for administration of the Information Transfer PRO–PM's survey to strike a balance between patient

[252] Centers for Medicare & Medicaid Services. (April 2024). Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure. Available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf. Accessed: April 29, 2025.*

[253] OAS CAHPS. (2024). 2024 Introduction to the OAS CAHPS Survey, Self-Paced Training. Available at *https://oascahps.org/Training/Training-Materials. Accessed: April 29, 2025.*

recovery and mitigated overlap with the initial administration of OAS CAHPS.

Regarding concerns about patient survey fatigue and risk of low response rates, the 9-item survey is concise, presenting a low burden for completion. Further, ASCs would not be penalized for patients' decisions to not complete the survey. Payment implications under the ASCQR Program are tied to the successful and timely reporting of required quality measure data, and an ASC that submits data to CMS in the form, manner, and timing specified, regardless of the number of surveys completed by the ASC's patient population, would be considered compliant with the measure requirements.

To review the Hospital Recommendation Group's voting summary, recommendations, and conditions for the Information Transfer PRO–PM please visit *https://p4qm.org/PRMR/Resources*.

e. Measure Endorsement

Under section 1833(i)(7)(B) of the Act, requirements for the development of outpatient measures for the Hospital OQR Program at section 1833(t)(17)(C) of the Act apply to the ASCQR Program, except as the Secretary may otherwise provide. Section 1833(t)(17)(C)(i) of the Act requires measures developed to reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus-based entities (not necessarily the contracted CBE). As we have noted in previous rulemaking, consensus among affected parties can be reflected in ways other than CBE endorsement, including through the measure development process, through broad acceptance and use of the measure(s), and through public comment (76 FR 74494). We have also noted that section 1833(t)(17) of the Act does not require that each measure we adopt for the ASCQR Program be CBE-endorsed (76 FR 74494).

A Technical Expert Panel consisting of interested parties, experts, and consumer advocates contributed to the development of the Information Transfer PRO–PM measure's survey design, measure cohort, and survey implementation, demonstrating a consensus-based

approach to the measure's development.[254]

While we recognize the value of measures undergoing CBE endorsement review and prefer to use endorsed measures, at this time, we find no other CBE-endorsed measures for the ASC setting that address the topic of patients' understanding of clinical information related to their recovery for an outpatient procedure or surgery. We note that we submitted the Information Transfer PRO–PM to the CBE for endorsement review in the Fall 2023 cycle (CBE #4210) for the Hospital OQR Program, and the CBE endorsed the measure on January 29, 2024.[255] The ASC-specific version of the Information Transfer PRO–PM is designed to use the same specifications as the Hospital OQR Program CBE-endorsed measure. We plan to pursue CBE endorsement for the measure's implementation in the ASC setting in a future measure endorsement cycle, and we will continue to monitor implementation of the measure as part of the standard measure maintenance process.

f. Data Collection, Submission, and Reporting

We propose that the Information Transfer PRO–PM would be calculated based on PRO data collected by ASCs directly or through their authorized third-party vendors through the Information Transfer PRO–PM survey instrument[256] distributed to patients or their caregivers by electronic mail or text. We note that the Information Transfer PRO–PM survey is nonproprietary and free to use. We propose that the survey be distributed within 2 to 7 days post-procedure or surgery. This timeframe minimizes the influence of variables related to the surgery or procedure,

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[254] Centers for Medicare & Medicaid Services. (March 22). Methodology Report For Public Comment: Patient Understanding of Key Information Related to Recovery From an Outpatient Surgery or Procedure. Available at *https://www.cms.gov/files/document/methodology-report-public-comment.pdf. Accessed: April 29, 2025.*

[255] Partnership for Quality Measurement. (2024). Fall 2023 Management of Acute and Chronic Events Meeting Summary. Available at *https://p4qm.org/sites/default/files/Management%20of%20Acute%20Events%2C%20Chronic%20Disease%2C%20Surgery%2C%20and%20Behavioral%20Health/material/EM-Acute-Chronic-Events-Fall2023-Endorsement-Meeting-Summary.pdf. Accessed: April 8, 2025.*

[256] A copy of the survey instrument is available at *https://www.cms.gov/files/document/patient-understanding-key-information-related-recovery-after-facility-based-outpatient-procedure-or.pdf*.

such as medications that could affect comprehension, fatigue, or acute pain, while ensuring timely reporting of patient experience related to recovery information.

In the pilot testing conducted by the measure developer using a third-party vendor, patients were sent a reminder to complete the survey 7 days after receipt. The survey remained open until pilot testing was completed; the mean length of time between the procedure date to the survey response date was 65 days. Based on these findings, we propose a 65-day window for patient response to the survey.

We propose to adopt the Information Transfer PRO–PM as a voluntary measure for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination. We would utilize the voluntary period to monitor the implementation and operationalization of the measure. We refer readers to section XVII.C. of this proposed rule for a discussion of the Information Transfer PRO–PM form, manner, and timing of data submission and reporting requirements.

We invite public comment on this proposal.

2. Summary of Previously Finalized and Newly Proposed ASCQR Program Measure Set for CY 2026 to CY 2031 Payment Determinations

Table 86 summarizes the previously finalized and newly proposed ASCQR Program measure set for the CY 2026 to CY 2031 payment determinations. Table 86 reflects our proposals to remove the FCHE, Screening for SDOH, Screen Positive Rate for SDOH, and the COVID-19 Vaccination Coverage Among HCP measures as discussed in section XIV.C. and add the Information Transfer PRO–PM as discussed in section XVII.B.1. of this proposed rule.

TABLE 86: PREVIOUSLY FINALIZED AND NEWLY PROPOSED ASCQR PROGRAM MEASURE SET BY DATA COLLECTION METHOD AND PAYMENT DETERMINATION (PD)

CBE	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	Chart-Abstracted Measures						
None	All-Cause Hospital Transfer/Admission	✓	✓	✓	✓	✓	✓
0658	Endoscopy/Polyp	✓	✓	✓	✓	✓	✓

CBE	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	Surveillance: Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients						
None	Normothermia Outcome	✓	✓	✓	✓	✓	✓
None	Patient Burn	✓	✓	✓	✓	✓	✓
None	Patient Fall	✓	✓	✓	✓	✓	✓
None	Unplanned Anterior Vitrectomy	✓	✓	✓	✓	✓	✓
None	Wrong Site, Wrong Side, Wrong Patient, Wrong Procedure, Wrong Implant	✓	✓	✓	✓	✓	✓
	Claims-Based Measures						
2539	Facility 7-Day Risk-Standardized Hospital Visit Rate After Outpatient Colonoscopy	✓	✓	✓	✓	✓	✓
3357	Facility-Level 7-Day Hospital Visits After General Surgery Procedures Performed at Ambulatory Surgical Centers (ASCs)	✓	✓	✓	✓	✓	✓
3366	Hospital Visits After Urology ASC Procedures	✓	✓	✓	✓	✓	✓
3470	Hospital Visits After Orthopedic ASC Procedures	✓	✓	✓	✓	✓	✓
	National Healthcare Safety Network Measures						
3636	COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP)*	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Patient-Reported Outcomes-Based Performance Measures						
4210	Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measure**				Proposed for Voluntary Reporting	Proposed for Voluntary Reporting	Proposed for Mandatory Reporting
None	Risk-Standardized PRO-PM Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) in the ASC Setting (THA/TKA PRO-PM)***			Voluntary	Voluntary	Voluntary	✓
	Process Measures						
None	Screening for Social Drivers of Health		Voluntary/ Proposed	Proposed for	Proposed for	Proposed for	Proposed for

CBE	Measure Name	CY 2026 PD	CY 2027 PD	CY 2028 PD	CY 2029 PD	CY 2030 PD	CY 2031 PD
	(SDOH)****		for Removal	Removal	Removal	Removal	Removal
None	Screen Positive Rate for SDOH****		Voluntary/ Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Structural Measures						
None	Facility Commitment to Health Equity (FCHE)*****		Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal	Proposed for Removal
	Survey-Based Measures						
None	Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary
None	Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS)	Voluntary	✓	✓	✓	✓	✓

✓Measure is mandatory for the specified payment determination year.
Voluntary**:** Submission of this measure is optional, and ASCs are not subject to a payment reduction for not reporting on the measure.
*Proposed for removal in this proposed rule beginning with the CY 2024 reporting period/CY 2026 payment determination.
**Proposed for adoption in this proposed rule beginning with voluntary reporting in the CY 2027 and CY 2028 reporting periods, followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination.
***Measure is voluntary for the CY 2025, CY 2026, and CY 2027 reporting periods, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2031 payment determination, as discussed in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82028 through 82036).
****Proposed for removal in this proposed rule beginning with the CY 2025 reporting period.
*****Proposed for removal in this proposed rule beginning with the CY 2025 reporting period/CY 2027 payment determination.

We refer readers to the QualityNet website at *https://qualitynet.cms.gov/asc/ascqr* for additional information on the reporting periods and submission deadlines for each measure finalized and proposed in the ASCQR Program.

3. ASCQR Program Measures and Topics for Future Consideration

We refer readers to section XIV.B. of this proposed rule for our cross-program Request for Information on measure concepts regarding well-being and nutrition for consideration in the ASCQR Program.

C. Proposed Updates to the Form, Manner, and Timing of ASCQR Program Data Submission

In this proposed rule, we propose to establish data submission and reporting requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs) for the ASCQR Program, including for the proposed Information Transfer PRO–PM.

1. Proposed Data Submission and Reporting Requirements for PRO–PMs

a. Proposed Data Submission Requirement for PRO-PMs

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82041), we finalized that for the Total Hip Arthroplasty and/or Total Knee Arthroplasty PRO–PM, ASCs must use the Hospital Quality Reporting (HQR) system for data submission as specified for a PRO–PM. In this proposed rule, we propose to apply this submission method to PRO–PMs generally, including the Information Transfer PRO–PM. Specifically, we propose that ASCs must use the HQR system for data submission for any PRO–PM that we adopt for the ASCQR Program measure set. ASCs may choose to: (1) directly submit their PRO–PM data to CMS using the HQR system; or (2) utilize a third-party entity, such as a vendor or registry, to submit their data using the HQR system. The HQR system allows for data submission using multiple file formats (such as .CSV and .XML) or a manual data entry option, allowing ASCs additional flexibility in data submission.

We invite public comment on this proposal.

b. Proposed Data Submission and Reporting Requirements for the Information Transfer PRO–PM

In section XVII.B.1. of this proposed rule, we discuss the proposed adoption of the Information Transfer PRO–PM beginning with voluntary reporting for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination. We propose that the reporting period for this measure would include data collection for procedures performed from January 1 through and including December 31 of the year that is 2 years prior to the applicable payment determination year. Therefore, ASCs would attribute patient survey responses to the CY reporting period during

which the patient's procedure was completed. For example, if a patient undergoes a procedure on December 20, 2027, and their survey response is received on January 4, 2028, that response would be attributed to the CY 2027 reporting period. We refer readers to section XVII.B.1. of this proposed rule, where we propose a 65-day response window for collecting patient survey responses. Under this 65-day response window policy, ASCs may collect survey responses for a reporting period as late as March of the year preceding the applicable payment determination year.

We propose to require ASCs to submit their Information Transfer PRO–PM data in aggregate numerators and denominators by May 15 of the year prior to the applicable payment determination year in the HQR system. As codified at 42 CFR 416.310(f), all deadlines occurring on a Saturday, Sunday, or legal holiday, or on any other day all or part of which is declared to be a non-workday for Federal employees by statute or Executive Order would be extended to the first day thereafter. For example, for the first voluntary reporting period, data collected for the Information Transfer PRO-PM from surgical procedures performed January 1, 2027 through December 31, 2027 would be submitted to CMS's HQR system by May 15, 2028. For the first mandatory reporting period, data collected for the Information Transfer PRO-PM from surgical procedures performed January 1, 2029 through December 31, 2029 would be submitted to CMS's HQR system by May 15, 2030 for the CY 2031 payment determination.

We additionally propose to require ASCs to offer all patients meeting the measure's denominator specifications the opportunity to complete the survey and to report on all completed surveys received. For ASCs that anticipate receiving more than 200 completed surveys, we propose that these facilities would have the option to either: (1) survey and report data on their entire eligible Information Transfer PRO–PM patient population, or (2) randomly sample their eligible Information Transfer PRO–PM patient population to collect and report data from 200 completed surveys. In other words, to reduce burden, facilities with large patient populations would have the choice to randomly sample a sufficient number of patients to yield at least 200

completed surveys in a reporting period. ASCs that are unable to collect 200 completed surveys would not be able to perform random sampling and would instead be required to submit data on survey responses from all completed surveys received.

A minimum random sample size of 200 completed surveys would ensure the reliability of the measure, consistent with what is required for the OAS CAHPS measure for ASCs (86 FR 63908 through 63909). We note that under the Hospital OQR Program, a minimum sample size of 300 is required for the Information Transfer PRO–PM as this is a recommended minimum sample size for a population of 1,500 to provide a 95 percent confidence interval and a 90 percent confidence interval for a population of over 10,000; this is also generally accepted as a minimum sample size for stable population estimates.[257, 258] However, as ASCs are expected to have less varied populations, we believe the sample size of 200 completed surveys, as determined to be sufficient for the OAS CAHPS survey, is appropriate. The 200 surveys would provide the appropriate balance of ensuring sufficient confidence in the results of the Information Transfer PRO–PM survey, while reducing the overall burden of the survey for facilities with large patient populations.

We invite public comment on these proposals.

2. ASCQR Program Extraordinary Circumstances Exception (ECE) Policy

We refer readers to section XIV.D. of this proposed rule for our cross-program proposal to propose and codify updates to the ECE policy for the ASCQR Program.

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[257] Ahmad, H., & Halim, H. (2017). Determining Sample Size for Research Activities. Selangor Business Review, 2(1), 20-34. *https://sbr.journals.unisel.edu.my/ojs/index.php/sbr/article/view/12. Accessed: April 8, 2025.*

[258] Voorhis, C., & Morgan, B. (2007). Understanding Power and Rules of Thumb for Determining Sample Size. Tutorials in Quantitative Methods for Psychology. 3(2), 43-50. www.doi.org/10.20982/tqmp.03.2.p043. *Accessed: April 8, 2025.*

D. Payment Reduction for ASCs That Fail to Meet the ASCQR Program Requirements

1. Statutory Background

We refer readers to the CY 2012 OPPS/ASC final rule with comment period (76 FR 74492 through 74493) for a detailed discussion of the statutory background regarding payment reductions for ASCs that fail to meet the ASCQR Program requirements.

2. Policy Regarding Reduction to the ASC Payment Rates for ASCs That Fail to Meet the ASCQR Program Requirements for a Payment Determination Year

The national unadjusted payment rates for many services paid under the ASC payment system are equal to the product of the ASC conversion factor and the scaled relative payment weight for the APC to which the service is assigned. For CY 2026, the ASC conversion factor is equal to the conversion factor calculated for the previous year updated by the productivity-adjusted hospital market basket update factor. The productivity adjustment is set forth in section 1833(i)(2)(D)(v) of the Act. The productivity-adjusted hospital market basket update was the annual update for the ASC payment system for a 5-year period (CY 2019 through CY 2023), which was extended an additional 2 years (through CY 2025) in the CY 2024 OPPS/ASC final rule with comment period (88 FR 81960). As discussed in section XIII of this proposed rule, we propose to continue using the productivity-adjusted hospital market basket update as the update factor for the ASC payment system for CY 2026. Under the ASCQR Program, in accordance with section 1833(i)(7)(A) of the Act and as discussed in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499), any annual increase in certain payment rates under the ASC payment system shall be reduced by 2.0-percentage points for ASCs that fail to meet the reporting requirements of the ASCQR Program. This reduction applied beginning with the CY 2014 payment rates (77 FR 68500). For a complete discussion of the calculation of the ASC conversion factor and our finalized proposal to update the ASC payment rates using the inpatient hospital market basket update for CYs 2019 through 2023, we

refer readers to the CY 2019 OPPS/ASC final rule with comment period (83 FR 59073 through 59080).

In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68499 through 68500), in order to implement the requirement to reduce the annual update for ASCs that fail to meet the ASCQR Program requirements, we finalized the following policies: (1) to calculate a full update conversion factor and an ASCQR Program reduced update conversion factor; (2) to calculate reduced national unadjusted payment rates using the ASCQR Program reduced update conversion factor that would apply to ASCs that fail to meet their quality reporting requirements for that calendar year payment determination; and (3) that application of the 2.0-percentage point reduction to the annual update may result in the update to the ASC payment system being less than zero prior to the application of the productivity adjustment. The ASC conversion factor is used to calculate the ASC payment rate for services with the following payment indicators (listed in Addenda AA and BB to this proposed rule, which are available via the Internet on the CMS website): "A2," "D2," "G2," "P2," "R2", and "Z2," as well as the service portion of device-intensive procedures identified by "J8" (77 FR 68500). We finalized our proposal that payment for all services assigned the payment indicators listed would be subject to the reduction of the national unadjusted payment rates for applicable ASCs using the ASCQR Program reduced update conversion factor (77 FR 68500).

The conversion factor is not used to calculate the ASC payment rates for separately payable services that are assigned status indicators other than payment indicators "A2", "D2", "G2," "J8", "P2", "R2", and "Z2." These services include separately payable drugs and biologicals, pass-through devices that are contractor-priced, brachytherapy sources that are paid based on the OPPS payment rates, and certain office-based procedures, radiology services, and diagnostic tests where payment is based on the PFS nonfacility PE RVU-based amount, and a few other specific services that receive cost-based payment (77 FR 68500). As a result, we also finalized our proposal that the ASC payment rates for these services would not be reduced for

failure to meet the ASCQR Program requirements because the payment rates for these services are not calculated using the ASC conversion factor and, therefore, are not affected by reductions to the annual update (77 FR 68500).

Office-based surgical procedures (generally those performed more than 50 percent of the time in physicians' offices) and separately paid radiology services (excluding covered ancillary radiology services involving certain nuclear medicine procedures or involving the use of contrast agents) are paid at the lesser of the PFS nonfacility PE RVU-based amounts or the amount calculated under the standard ASC ratesetting methodology. Similarly, in the CY 2015 OPPS/ASC final rule with comment period (79 FR 66933 through 66934), we finalized our proposal that payment for certain diagnostic test codes within the medical range of CPT codes for which separate payment is allowed under the OPPS will be at the lower of the PFS nonfacility PE RVU-based (or technical component) amount or the rate calculated according to the standard ASC ratesetting methodology when provided integral to covered ASC surgical procedures. In the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the standard ASC ratesetting methodology for this type of comparison would use the ASC conversion factor that has been calculated using the full ASC update adjusted for productivity. This is necessary so that the resulting ASC payment indicator, based on the comparison, assigned to these procedures or services is consistent for each HCPCS code, regardless of whether payment is based on the full update conversion factor or the reduced update conversion factor.

For ASCs that receive the reduced ASC payment for failure to meet the ASCQR Program requirements, we have noted our belief that it is both equitable and appropriate that a reduction in the payment for a service should result in proportionately reduced coinsurance liability for beneficiaries (77 FR 68500). Therefore, in the CY 2013 OPPS/ASC final rule with comment period (77 FR 68500), we finalized our proposal that the Medicare beneficiary's national

unadjusted coinsurance for a service to which a reduced national unadjusted payment rate applies will be based on the reduced national unadjusted payment rate.

In the CY 2013 OPPS/ASC final rule with comment period, we finalized our proposal that all other applicable adjustments to the ASC national unadjusted payment rates would apply in those cases when the annual update is reduced for ASCs that fail to meet the requirements of the ASCQR Program (77 FR 68500). For example, the following standard adjustments would apply to the reduced national unadjusted payment rates: the wage index adjustment; the multiple procedure adjustment; the interrupted procedure adjustment; and the adjustment for devices furnished with full or partial credit or without cost (77 FR 68500). We believe that these adjustments continue to be equally applicable to payment for ASCs that do not meet the ASCQR Program requirements (77 FR 68500).

In the CY 2015 through CY 2025 OPPS/ASC final rules with comment period, we did not make any other changes to these policies. We propose to continue applying these policies for the CY 2026 reporting period/CY 2028 payment determination and for subsequent years.

XVIII. Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group

A. Summary

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521), we summarized broad public input received on a Request for Information (RFI) discussing potential methodologic modifications to the Safety of Care measure group within the Overall Hospital Quality Star Rating that is published on the provider comparison tool on Medicare.gov (*https://www.medicare.gov/care-compare/*). The potential modifications discussed in that RFI aimed to emphasize the contribution of the Safety of Care measure group to the Overall Hospital Quality Star Rating. In that RFI, we also noted our intention to potentially issue additional RFIs or undertake rulemaking on this topic in the future.

Patient safety constitutes a fundamental component of the CMS National Quality

Strategy, representing a sustained commitment to fostering optimal health outcomes and ensuring the safest possible care for all patients.[259] As we noted in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521), we believe that increasing the influence of the Safety of Care measure group is a necessary and appropriate methodological change. Patient safety is cornerstone to healthcare delivery and the foundational principle of professional oaths is to "do no harm." Prioritizing safety for both patients and healthcare workers align with this fundamental commitment. Considering the public input received and further internal analyses conducted, we propose to make the following modifications to the Overall Hospital Quality Star Rating methodology: (1) implement a 4-star cap for hospitals in the lowest-performing quartile of the Safety of Care measure group) for the 2026 Overall Hospital Quality Star Rating, and (2) implement a blanket 1-star reduction for hospitals in the lowest-performing quartile of the Safety of Care measure group for the 2027 Overall Hospital Quality Star Rating and thereafter.

B. Background

The Overall Hospital Quality Star Rating provides a summary of certain existing hospital quality information on Medicare.gov[260] based on publicly available quality measure results reported through CMS' hospital quality measurement programs, by assigning hospitals between 1 and 5 stars, a way that is simple and easy for patients to understand (85 FR 86193). The Overall Hospital Quality Star Rating methodology was developed and is maintained according to the guiding principles of scientific validity, maximizing inclusion of hospitals and measure information, accounting for heterogeneity of available measures and hospital reporting, accommodating changes in the underlying measures, aligning with CMS hospital quality measure programs to the extent feasible, transparency of the methodology, and responsiveness to input from stakeholders. The Overall Hospital Quality Star Rating was first introduced and

[259] *https://www.cms.gov/files/document/cms-national-quality-strategy-handout.pdf.*
[260] *https://www.medicare.gov/care-compare/resources/hospital/overall-star-rating.*

reported on our Hospital Compare website in July 2016 (now reported on Care Compare on Medicare.gov) and has been refreshed multiple times.

In the CY 2021 OPPS/ASC final rule with comment period (85 FR 86193), we codified the Overall Hospital Quality Star Rating methodology, including several methodology refinements, intended to improve the simplicity and predictability of measure emphasis within the methodology over time, and comparability of ratings among hospitals. We also finalized the inclusion of Veterans Health Administration (VHA) hospitals and Critical Access Hospitals (CAHs) in the Overall Hospital Quality Star Rating. In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72233), we provided additional information on the previously finalized policy to incorporate VHA hospitals and finalized a proposal to amend 42 CFR 412.190 to revise how we would refresh the Overall Hospital Quality Star Rating annually. In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521) we summarized public input received on the following potential methodological updates to greater emphasize patient safety in the Overall Hospital Quality Star Rating: (1) Reweighting the Safety of Care Measure Group, (2) Policy-based 1-Star Reduction for Poor Performance on Safety of Care, and (3) Reweighting the Safety of Care measure group combined with a Policy-based Star Rating Cap. We refer readers to section XXIV. (Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group: Request for Information (RFI)) of the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521) for additional information.

C. Current Overall Hospital Quality Star Rating Methodology (§ 412.190)

Measures reported on the provider comparison tool on Medicare.gov[261] that meet the criteria for inclusion in the Overall Hospital Quality Star Rating are organized into five conceptually coherent measure groups: Safety of Care, Mortality, Readmission, Patient

[261] *https://www.medicare.gov/care-compare/.*

Experience (all of which include outcome measures), and Timely and Effective Care (which includes a selection of process measures).

The current Overall Hospital Quality Star Rating methodology includes eight general steps. First, measures are selected from those publicly reported on Care Compare on Medicare.gov through certain CMS hospital inpatient and outpatient quality programs. Second, the direction of all included measures that indicate better performance with a lower score are reversed to uniformly reflect that a higher score indicates better performance for all the measures, and all measure scores are standardized to a single, common scale to account for differences in measure score units. Third, measures are arranged into measure groups. Each measure group contains several publicly reported measures to produce a robust measure group score, which is reflective of differences in hospital quality. Fourth, the measure group scores are calculated as a simple average of the measure scores. Measure group scores are then standardized to a common scale, making varying scores comparable. Fifth, the hospital summary score is calculated as a weighted average of the standardized measure group scores. Specifically, each measure group score is multiplied by the assigned weight for that measure group. The weighted measure group scores are then summed up to generate the hospital summary score. If a hospital has no measure scores in a measure group (for example, by not achieving sufficient sample size in any of the measures), the weight is redistributed proportionally across the remaining measure groups. Sixth, minimum reporting thresholds are applied. To receive an Overall Hospital Quality Star Rating, hospitals must report at least three measures in each of at least three measure groups, one of which must be either the Mortality or Safety of Care measure groups. Seventh, peer grouping is applied. Hospitals are grouped into one of three peer groups based on the number of measure groups for which they report at least three measures: a three-measure group peer group, a four-measure group peer group, and a five-measure group peer group. Eighth, a clustering algorithm is applied within each peer group to assign hospital summary scores to Overall Hospital Quality Star Ratings so that 1 star is the

lowest and 5 stars is the highest.

For additional details regarding the current methodology, we refer readers to § 412.190(d) and the Overall Hospital Quality Star Rating Methodology Reports, available at *https://qualitynet.cms.gov/inpatient/public-reporting/overall-ratings/resources*.

D. Proposed Modification to the Overall Hospital Quality Star Rating Methodology

In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521), we presented three options and analyses (utilizing data from the July 2023 refresh of the Overall Hospital Quality Star Rating) for potential methodological updates to emphasize Safety of Care in the Overall Hospital Quality Star Rating and summarized the public comments received. The majority of commenters did not support updating the methodology at that time. While some commenters expressed support for potential changes, there was no consensus on a preferred option (reweighting, the policy-based 1-star reduction, or reweighting combined with the 4-star cap). We refer readers to the CY 2025 OPPS/ASC RFI (89 FR 94514 through 94521), where we detailed the importance of prioritizing Safety of Care within the Overall Hospital Quality Star Rating.

Following the publication of the final rule, we conducted further internal analyses utilizing updated data from the July 2024 refresh of the Overall Hospital Quality Star Rating (the most recent publicly released results as of the writing of this proposal) to reassess the correlation between the Safety of Care measure group and performance in the Overall Hospital Quality Star Rating.

To receive an Overall Hospital Quality Star Rating, hospitals must have at least three measures in each of at least three measure groups, one of which must be Mortality or Safety of Care. However, because the application of minimum reporting thresholds and peer grouping assignment occur strictly after the calculation of measure group scores and overall summary scores, any hospital with at least one measure in any group will have a measure group score for that group – that is, once a hospital meets the Overall Hospital Quality Star Rating reporting

threshold, all measure groups for which it has any measure scores are included in its rating. In other words, a hospital with one or two Safety of Care measures can still receive an Overall Hospital Quality Star Rating if it still has at least three measures in Mortality and in two of the other measure groups; in this case, the hospital would still receive a Safety of Care measure group score based on the one or two measures it does have. Only a hospital qualifying for an Overall Hospital Quality Star Rating with zero Safety of Care measures would not have a Safety of Care measure group score.

There were 2,847 hospitals that met the criteria to receive an Overall Hospital Quality Star Rating in 2024. Among the 2,847 rated hospitals, 2,803 (99 percent) had at least one Safety of Care measure and therefore received a Safety of Care measure group score, while 2,475 (87 percent) had at least three Safety of Care measures. Our analysis showed that hospitals in the lowest-performing quartile of the Safety of Care measure group tended to receive lower Overall Hospital Quality Star Ratings (being more likely to receive 1 or 2 stars and less likely to receive 4 or 5 stars than other hospitals) (Table 87). However, some hospitals performed in the lowest quartile (lowest-performing 25 percent, indicating poor Safety of Care performance relative to other hospitals) of the Safety of Care measure group and still received a 5-star rating. Of the 2,847 hospitals that received an Overall Hospital Quality Star Rating, 695 hospitals scored in the lowest quartile of the Safety of Care measure group, of which 595 hospitals had at least three Safety of Care measures. Of these 595 hospitals, 14 received a 5-star rating, representing 0.5 percent of all rated hospitals (Table 87). These 14 hospitals attained a 5-star rating despite having the lowest quartile Safety of Care measure group performance by achieving high scores across the other measure groups.

TABLE 87: SAFETY PERFORMANCE OF HOSPITALS BY STAR RATING (3+ SAFETY MEASURES)

	Safety Score Range	N	1 Star	2 Stars	3 Stars	4 Stars	5 Stars
Lowest Quartile	-10.06, 0.34	695	156 (22%)	237 (34%)	199 (29%)	86 (12%)	17 (2%)
Lowest Quartile (3+ measures)	-2.94, -0.34	595	136 (23%)	199 (33%)	175 (29%)	71 (12%)	14 (2%)
Quartiles 2-4	-0.33, +2.43	2,152	121 (6%)	358 (17%)	629 (29%)	766 (32%)	381 (17%)
All Hospitals	-10.06, +2.43	2,847	277 (10%)	595 (21%)	828 (29%)	766 (27%)	381 (13%)

As we noted in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94514 through 94521), we believe that a methodological change to increase the importance of the Safety of Care measure group is appropriate. This proposed change is informed by landmark reports on healthcare quality,[262,263] along with the COVID-19 public health emergency, which revealed persistent patient and workforce safety risks and system vulnerabilities.[264] In response, Federal efforts—such as the National Action Alliance to Advance Patient and Workforce Safety and recommendations from the President's Council of Advisors on Science and Technology—are reinforcing patient safety as a national priority, aligned with CMS' initiatives like the National Quality Strategy and the Universal Foundation.[265,266,267] In particular, addressing the issue of hospitals receiving a high Overall Hospital Quality Star Rating despite performing in the lowest quartile of the Safety of Care measure group is critical to achieving CMS' vision of emphasizing and aligning the importance of patient safety across CMS

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[262] Institute of Medicine (US) Committee on Quality of Health Care in America, Kohn, L.T.,Corrigan, J.M., & Donaldson, M.S. (Eds.). (2000). To Err is Human: Building a Safer Health System.National Academies Press (US).
[263] Quality of Health Care in America. (2001). Crossing the Quality Chasm: A New Health System for the 21st Century. National Academies Press (US).
[264] Agency for Healthcare Research and Quality. (February 2021). National Healthcare Quality and Disparities Report chartbook on patient safety.
Rockville, MD. Available at: https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/patientsafety/2019qdr-patientsafety-chartbook.pdf.
[265] AHRQ. (2023). National Action Alliance To Advance Patient and Workforce Safety. https://www.ahrq.gov/cpi/about/otherwebsites/actionalliance.html.
[266] https://www.whitehouse.gov/wp-content/uploads/2023/09/PCAST□Patient-Safety-Report-Sept2023.pdf.
[267] Fleisher, L.A., Schreiber, M., Cardo, D.,Srinivasan, A. (2022). Health Care Safety during the Pandemic and Beyond—Building a System That Ensures Resilience. The New England Journal of Medicine, 386(7): 609–611. DOI: 10.1056/NEJMp2118285.

programs. We therefore propose to make the following two-stage methodologic updates to § 412.190(a)(2) and adding a new paragraph (a)(3)); the first stage would be a narrow but focused transitional step to promptly address the most pressing concern that hospitals in the lowest-performing quartile of the Safety of Care measure group achieve the highest possible Overall Hospital Quality Star Rating while allowing hospitals and stakeholders more time to prepare for the second stage, which will increase the impact of the Safety of Care measure group across all hospitals more broadly.

We also propose changes to paragraphs (b)(1), (e) and (f) to reflect updates to the regulation text uses of Overall Hospital Quality Star Rating and Care Compare on Medicare.gov language. In addition, we propose removing the reference to "as defined in § 400.200 of this chapter".

For the methodologic updates:

Stage 1: Implement a 4-star cap for hospitals in the lowest quartile of the Safety of Care measure group performance beginning in 2026 (§ 412.190(d)(9)(i))

We propose to limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of 4 stars out of 5. The Overall Hospital Quality Star Rating methodology would be unchanged through step eight with the exception of redesignating paragraph (d)(5) as (6), and paragraph (d)(6) as (5) (assignment of star ratings using K-means clustering as described previously in this section), with the cap being applied as a new "step nine": Any hospital that is assigned 5 stars in step eight but has a lowest quartile Safety of Care score (based on at least three Safety of Care measures) would be reassigned to 4 stars.

Using 2024 Overall Hospital Quality Star Rating data, implementing a cap of 4 stars in the lowest quartile of Safety of Care with at least three safety measures would result in 14 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating. This proposed update provides a targeted, direct, and timely solution to the acute concern of hospitals receiving the highest possible 5-star rating despite performing in the lowest quartile of the Safety

of Care measure group. Further, the proposed implementation timeline reflects a deliberate and proactive effort to act swiftly and strategically, reinforcing patient safety as a national priority.

We acknowledge in the CY 2025 OPPS/ASC final rule with comment period that only applying a 4-star maximum to hospitals in the lowest quartile of Safety of Care with at least three safety measures would have less impact than other options discussed in that rule. However, to promptly address the most pressing concern, the proposed 4-star maximum functions as an interim step, allowing hospitals and stakeholders additional time to prepare for Stage 2:

Stage 2: Implement a blanket 1-Star reduction for hospitals in the lowest quartile of Safety of Care measure group performance for the 2027 Overall Hospital Quality Star Ratings and later years (§ 412.190(d)(9)(ii))

We propose to reduce the Overall Hospital Quality Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by 1 star, to a minimum 1-star rating. The Overall Hospital Quality Star Rating methodology would be unchanged through step eight (assignment of star ratings using K-means clustering), with the blanket reduction replacing the 4-star cap in the new step nine: any hospital assigned a 2, 3, 4, or 5-star rating in step eight, but that has a lowest quartile Safety of Care score (based on at least three Safety of Care measures) would be reduced to 1, 2, 3, or 4 stars, respectively.

Using 2024 Overall Hospital Quality Star Rating data, applying a 1-star reduction for all hospitals in the lowest quartile of Safety of Care with at least three safety measures would result in 459 hospitals, out of 2,847 hospitals, receiving a lower Overall Hospital Quality Star Rating. This proposed update would emphasize safety by applying a higher standard for patient safety to hospitals across a broad range of overall performance, rather than limiting it to the few 5-star hospitals in the lowest quartile of Safety of Care (with at least three Safety of Care measures). Since the minimum possible Overall Hospital Star Rating will remain 1 star, hospitals already getting one star would not get a further star reduction and therefore would effectively be exempt from this adjustment consistent with established assignment of ratings between 1-5 whole stars

(85 FR 86193). This approach also aligns with CMS' overarching objective of advancing patient safety and reinforcing our commitment to continuous improvement across the healthcare system.

When determining the quartiles of Safety of Care measure group scores, we will use the distribution from all hospitals with at least 1 Safety of Care measure whether or not they qualify for an Overall Hospital Quality Star Rating, in alignment with the guiding principle of the Overall Hospital Quality Star Rating of inclusiveness of hospital and measure information.

Using the data of the July 2024 Overall Hospital Quality Star Rating, we evaluated the proportion of hospitals that would be impacted by the proposed methodological changes, stratified by various hospital characteristics (Table 88). As previously noted, a larger proportion of hospitals would be impacted by the blanket 1-star reduction (Stage 2 proposed methodological change) compared to the targeted 4-star cap (Stage 1 proposed methodological change). Our simulation revealed that teaching hospitals, non-safety-net hospitals, VHA hospitals, non-CAHs, large hospitals (100+ beds), urban hospitals, and non-specialty hospitals could be somewhat more likely to observe a change in Overall Hospital Quality Star Rating by both Stage 1 and Stage 2 proposed methodological changes than their counterparts. We recognize that with only 14 hospitals experiencing a change in Overall Hospital Quality Star Rating by the Stage 1 proposed methodological change, the generalizability of this observation is limited. In part, this is because these hospitals are more likely to receive an Overall Hospital Quality Star Rating and have three or more Safety of Care measures than their non-teaching, safety-net, non-VHA, CAH, small, rural, and specialty counterparts (Table 88). However, these differences in hospital characteristics are not strongly determinative of a hospital's overall rating, with hospitals of any characteristic being capable of receiving either high or low ratings.

TABLE 88: IMPACT ASSESSMENT OF PROPOSED METHODOLOGICAL ADJUSTMENTS BY HOSPITAL CHARACTERISTICS, JULY 2024 SIMULATION

Characteristic	N (%)	N Rated (Row %)	N Rated & 3+ Safety measures (%)	N Rated & 3+ measures & Q1 Safety (%)	N Capped*^ (%) (Stage 1)	N Blanket 1-Star Reduction* (%) (Stage 2)
All hospitals	4,628 (100%)	2,847 (61.5%)	2,475 (53.5%)	595 (12.9%)	14 (0.30%)	459 (9.9%)
Teaching Status						
Teaching	1,284 (27.7%)	1,234 (96.1%)	1,204 (93.8%)	269 (21.0%)	6 (0.47%)	211 (16.4%)
Non-Teaching	3,177 (68.6%)	1,496 (47.1%)	1,185 (37.3%)	293 (9.2%)	4 (0.13%)	222 (7.0%)
Safety-net Status						
Safety-net	1,199 (25.9%)	468 (39.0%)	383 (31.9%)	115 (9.6%)	2 (0.17%)	83 (6.9%)
Non-Safety-net	3,239 (70%)	2,250 (69.5%)	1,999 (61.7%)	445 (13.7%)	8 (0.25%)	348 (10.7%)
Veterans' hospitals						
VHA hospital	136 (2.9%)	113 (83.1%)	82 (60.3%)	33 (24.3%)	4 (2.94%)	26 (19.1%)
Non-VHA	4,490 (97.0%)	2,734 (60.9%)	2,393 (53.3%)	562 (12.5%)	10 (0.22%)	433 (9.6%)
Critical Access Hospitals						
CAH	1,340 (29.0%)	164 (12.2%)	15 (1.1%)	3 (0.2%)	0 (0%)	2 (0.1%)
Non-CAH	3,286 (71.0%)	2,683 (81.6%)	2,460 (74.9%)	592 (18.0%)	14 (0.43%)	457 (13.9%)
Bed Size						
1-99 Beds	2,511 (54.3%)	854 (34.0%)	535 (21.3%)	139 (5.5%)	5 (0.20%)	116 (4.6%)
100+ Beds	1,942 (42.0%)	1,876 (96.6%)	1,854 (95.5%)	423 (21.8%)	5 (0.26%)	317 (16.3%)
Geographic Location						
Urban	2,060 (44.5%)	1,626 (78.9%)	1,559 (75.7%)	362 (17.6%)	4 (0.19%)	280 (13.6%)
Rural	2,399 (51.8%)	1,104 (46.0%)	830 (34.6%)	200 (8.3%)	6 (0.25%)	153 (6.4%)
Specialty status						
Specialty	122 (2.6%)	32 (26.2%)	27 (22.1%)	4 (3.3%)	0 (0%)	3 (2.5%)
Non-Specialty	4,317 (93.3%)	2,686 (62.2%)	2,355 (54.6%)	556 (12.9%)	10 (0.23%)	428 (9.9%)

*Capped is the number and proportion of hospitals impacted by the proposed 4-star cap for rated hospitals reporting three or more safety measures and performing in the lowest quartile of Safety of Care measure group. Star Reduction is the number and proportion of hospitals impacted by the proposed blanket 1-Star reduction for rated hospitals reporting three or more safety measures and performing in the lowest quartile of Safety of Care measure group.

^ Certain hospital characteristics (teaching status, safety net, status bed size, geographic location) are only available for non-VHA hospitals.

We invite public comment on these proposals.

XIX. Updates to Requirements for Hospitals to Make Public a List of Their Standard Charges

A. Introduction and Overview

1. Statutory Basis and Background

Section 1001 of the Patient Protection and Affordable Care Act (Pub. L. 111-148), as amended by section 10101 of the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), amended Title XXVII of the Public Health Service Act (the PHS Act), in part, by adding a new section 2718(e). Section 2718 of the PHS Act, entitled "Bringing Down the Cost of Health Care Coverage," requires each hospital operating within the United States for each year to establish and update, and make public a list of the hospital's standard charges for items and services provided by the hospital, including for diagnosis-related groups established under section 1886(d)(4) of the Act. Section 2718(b)(3) of the PHS Act requires the Secretary of the Department of Health and Human Services ("Secretary" or "HHS") to issue regulations to enforce the provisions of section 2718 of the PHS Act, and, in so doing, the Secretary may provide for appropriate penalties.

In the final rule that appeared in the November 27, 2019 **Federal Register** (84 FR 65524) titled "Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates: Price Transparency Requirements for Hospitals to Make Standard Charges Public" (hereafter referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. We codified these requirements at 45 CFR part 180. We also explained our belief that these two different methods of making hospital standard charges public are necessary to ensure that such data are available to consumers through data aggregation methods (for example, via integration into price transparency tools, electronic health records, and consumer apps), and direct availability to consumers searching for hospital-specific

charge information. We stated our belief that innovators could use this information to create more useful data products for healthcare consumers to effectively compare prices. Moreover, we believe that employers (that offer or sponsor employee health plans), researchers, policy officials, and similar members of the public could utilize this data to promote competition and choice, ultimately helping to improve healthcare value.

Subsequently, in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941), we strengthened the hospital price transparency (HPT) enforcement process to improve compliance rates and made other updates to the requirements. Specifically, we: (1) increased the penalty amount for noncompliance through the use of a scaling factor based on hospital bed count; (2) deemed State forensic hospitals that meet certain requirements to be in compliance with the requirements of 45 CFR part 180; and (3) prohibited certain actions that we concluded were barriers to accessing the standard charge information, including prohibiting hospitals from designing their MRFs so as to make them inaccessible to automated searches and direct downloads.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82079), we revised several HPT requirements to improve access to, and the usability of, hospital standard charge information; standardize the way hospital charges are presented; align, where feasible, certain HPT requirements and processes with requirements in the Transparency in Coverage (TiC) initiative; and strengthen and streamline our monitoring and enforcement capabilities. Specifically, we finalized: (1) a requirement that hospitals make a good faith effort to ensure standard charge information is true, accurate, and complete, and include a statement affirming this in the MRF; (2) new data elements that hospitals must include in the MRF, as well as a requirement that hospitals encode standard charge information in a CMS template layout; (3) a requirement that hospitals include a .txt file in the root folder that includes a direct link to the MRF and a link in the footer on its website that links directly to the publicly available web page that hosts the link to the MRF; and (4) improvements to our enforcement process by updating our

methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, and publicizing more information about CMS enforcement activities related to individual hospital compliance.

In these final rules, we stated that our policies requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in prices of healthcare services for consumers. We also recognized that the release of hospital standard charge information is not sufficient to achieve our ultimate price transparency goals. We noted that the regulations are, therefore, designed to address some of the barriers that limit price transparency, with a goal of requiring hospitals to make meaningful price information available to patients and employers to support a more competitive, innovative, affordable, and higher quality healthcare system.

On February 25, 2025, the White House issued Executive Order 14221, "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information," to empower patients with clear, accurate, and actionable healthcare pricing information.[268] The Executive Order states, in part, that the Departments of the Treasury, Labor, and HHS (the Departments) shall take action to:

- Require disclosure of actual prices of items and services, not estimates;
- Ensure pricing information is standardized and easily comparable across hospitals and health plans; and
- Update their enforcement policies designed to ensure compliance with transparent reporting of complete, accurate, and meaningful data.

Executive Order 14221 requires HHS to take actions to continue to implement and enforce existing statutory requirements for hospitals to make public a list of standard charges in accordance with guidelines developed by the Secretary. Consistent with the Executive Order and to better attain the goals we have articulated in previous HPT rulemaking - requiring hospitals to

[268] Exec. Order No 14,221 (2025). *https://www.govinfo.gov/content/pkg/FR-2025-02-28/pdf/2025-03440.pdf.*

make meaningful price information available to consumers, employers, policymakers, and others to support a more competitive, innovative, affordable, and higher quality healthcare system, CMS proposes several updates to the regulations at 45 CFR part 180.

In the CY 2020 HPT final rule at § 180.20, we established a definition of "standard charge" as the regular rate established by the hospital for an item or service provided to a specific group of paying patients. In the summary of proposals below, we describe proposed updates to required data elements to improve the comparison of standard charge data to enable more meaningful disclosures to the public.

In the CY 2024 OPPS/ASC final rule with comment period, we established the requirement for each hospital, beginning July 1, 2024, to affirm in its MRF that the hospital has, to the best of its knowledge and belief, included all applicable standard charge information in accordance with the requirements of 45 CFR part 180 and that the information displayed is true, accurate, and complete as of the date indicated in the file. As described in the summary of proposals below, we propose to strengthen this requirement, beginning January 1, 2026, by replacing it with an attestation in the MRF, and that attestation would also contain new specifications (relative to existing affirmation requirements). These specifications would include that the hospital has: (1) included all applicable payer-specific negotiated charges in dollars that can be expressed as a dollar amount and for payer-specific negotiated charges that are not knowable in advance or cannot be expressed as a dollar amount, the hospital has provided in the MRF all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to the specific fee schedule or components referenced in such percentage, algorithm, or formula, and (2) included the name of the hospital's chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data.

In addition, pursuant to section 2718(b)(3) of the PHS Act, we previously have established regulations for enforcing the provisions of this section, including appropriate

penalties. We propose an additional change to encourage faster resolution of HPT civil monetary penalties (CMPs) and to reduce the amount of a CMP, under certain conditions, when the hospital waives its right to an administrative law judge (ALJ) hearing.

2. Summary of Proposals

We propose amendments to the HPT regulations to enhance clarity and standardization in hospital disclosure of standard charges. Specifically, we propose revisions to § 180.20 to add definitions for "tenth (10^{th}) percentile allowed amount," "median allowed amount," and "ninetieth (90^{th} percentile allowed amount," which are values a hospital would encode when a payer-specific negotiated charge is based on a percentage or algorithm, to more accurately reflect the distribution of actual amounts that a hospital has received for an item or service. In tandem with that, we propose revisions to § 180.50 to remove the requirement for hospitals to disclose the estimated allowed amount, and, instead, require hospitals, beginning January 1, 2026, to disclose the 10^{th} percentile, median, and 90^{th} percentile allowed amounts, as well as the count of allowed amounts, in MRFs when payer-specific negotiated charges are based on percentages or algorithms. We also propose to require that hospitals use electronic data interchange (EDI) 835 electronic remittance advice (ERA) transaction data to calculate and encode these values, and we propose to require that hospitals comply with specific instructions regarding the methodology, including the lookback period, that must be used to calculate those amounts. We propose revisions to § 180.50 to require hospitals, beginning January 1, 2026, to attest that in the MRF, the hospital has included all applicable standard charge information in accordance with the requirements of this section and the information encoded is true, accurate, and complete as of the date in the file.

We further propose that hospitals attest in the MRF that the hospital has included all applicable payer-specific negotiated charges as dollars that can be expressed as a dollar amount, and for payer-specific negotiated charges that are not knowable in advance or cannot be expressed as a dollar amount, the hospital has provided in the MRF all necessary information

available to the hospital for the public to be able to derive a dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm, or formula.

We also propose that hospitals encode in the MRF the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data. In addition, to advance the comparability of HPT data with other healthcare data, we propose to require that hospitals encode their National Provider Identifier(s) (NPIs) in the MRFs. Finally, to encourage faster resolution and payment of CMPs, and in exchange for a hospital's admission of having violated HPT requirements, we propose to update § 180.90 to reduce the amount of a CMP by 35 percent, under certain conditions, when a hospital waives its right to an ALJ hearing. These proposed changes aim to improve transparency in hospital pricing, facilitate efficient enforcement of the HPT requirements, and empower consumers with actionable pricing information.

B. Proposal to Modify the Requirements for Making Public Hospital Standard Charges at 45 CFR 180.50

1. Background

a. CY 2024 OPPS/ASC final rule with comment period

This section of the background recites relevant history from the CY 2024 OPPS/ASC final rule with comment period, and all references pertain to it.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82083, 82097, 82184), we indicated we understand that hospitals establish payer-specific negotiated charges in many ways, ranging from basic fee schedules (in which dollar amounts for specific items and services are known) to grouper methodologies (in which a base rate in dollars has been established but may then be modified depending on other factors like transfers or outliers), to "percent of billed charges" schemes (in which the dollar amount varies from person to person and is not known until the services are performed). We demonstrated in Figure A in the CY 2024

OPPS/ASC final rule with comment period (88 FR 82098) the components of an MS-DRG algorithm. An example of how Figure A may translate into an algorithm encoded in the MRF may be: base rate multiplied by the MS-DRG weight; outlier payment of $4303 per diem when length of stay is greater than 2 times the average length of stay. Based on our experiences reviewing MRFs since the finalization of the CY 2024 OPPS/ASC rule, we have observed factors included in algorithms such as, but not limited to: weights based on resources required, mix of services provided within an episode of care, and thresholds or caps on the overall price of services billed within an episode of care. Therefore, we reiterate our stance outlined in the CY 2024 OPPS/ASC final rule that not all hospitals can produce a payer-specific negotiated charge in dollars that meets the definition of a 'standard charge'.

As indicated in the CY 2024 OPPS/ASC final rule with comment period, we finalized a requirement for hospitals to display an estimated allowed amount which would provide needed context, in dollars, for instances where the hospital's standard charge is based on a percentage or algorithm for a specified payer's plan. We defined a new data element, the "estimated allowed amount," at § 180.20, as the average dollar amount that the hospital has historically received from a third party payer for an item or service.

We noted that we had heard from interested parties that, when a hospital has negotiated a payer-specific negotiated charge that is based on an algorithm, an estimate displayed in dollars within the MRF is useful, particularly for making comparisons across hospitals (88 FR 82099). We stated, for example, that an estimate displayed in dollars would permit users to make price comparisons across hospitals when, regarding the same procedure and payer/plan, one hospital has established a payer-specific negotiated charge as an algorithm and a second has established a payer-specific negotiated charge as a dollar amount. After considering what additional data could be required in the MRF to provide further needed context for a payer-specific negotiated charge that is expressed as an algorithm or a percentage, we finalized the estimated allowed amount as a new data element at § 180.20. We also required at § 180.50(b)(2)(ii)(C) that hospitals calculate

and encode an estimated allowed amount, in dollars, when hospitals have established a payer-specific negotiated charge that is based on a percentage or an algorithm. We stated that the estimated allowed amount is the average reimbursement in dollars that the hospital has received from the payer in the past. We further stated that the estimated allowed amount is therefore not prospective and is also not based on the hospital's chargemaster, which, as we understand it, contains only gross charges for itemized items and services, or claims submitted to the payer. As we explained (88 FR 82099 through 82100), because the estimated allowed amount data element is meant to provide an estimate of what the algorithm produces in dollars, across the universe covered by a particular payer's plan, such an amount should reflect the amount the hospital expects to be reimbursed for the item or service (or service package), on average. As such, it is not the final exact amount in dollars that an individual would pay for an item or service. Even so, we stated that we believe this information provides context to the public that is necessary to compare payer-specific negotiated charges across hospitals and is a valuable benchmark that innovators can use to develop price estimator tools to estimate an individual's personalized out-of-pocket costs. We stated that we believed this information, when paired with the algorithm encoded in the MRF, would promote greater transparency of hospital standard charges that can be useful to MRF users.

b. Background subsequent to the CY2024 OPPS/ASC final rule with comment period

Since the CY2024 OPPS/ASC final rule with comment period was finalized, we have continued to gain experience with the implementation of the estimated allowed amount data element and received public feedback and questions requesting that we further clarify its calculation. Based on our observations through comprehensive audits and feedback from users of the data, and consistent with Executive Order 14221, we propose to revise the HPT regulations to recast the estimated allowed amount data element to better require, through new data elements, disclosure of dollar amounts for items and services in hospital MRFs, which we believe would enhance transparency and comparability of payer-specific negotiated charges

across hospitals. Specifically, and as further discussed later in this section, we propose to require hospitals to report four new data elements when a standard charge is based on a percentage or algorithm – the median allowed amount (which would replace the estimated allowed amount data element), the 10th percentile and 90th percentile allowed amounts, and the count of allowed amounts used to calculate the median, 10th, and 90th percentile allowed amounts.

2. Definitions

At § 180.20, we propose to add definitions for three new data elements, the "median allowed amount," the "tenth (10th) percentile allowed amount," and the "ninetieth (90th) percentile allowed amount." These data elements would be defined as follows:

- "Median allowed amount" would be defined as the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.

- "Tenth (10th) percentile allowed amount" would be defined as the 10th percentile of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.

- "Ninetieth (90th) percentile allowed amount" would be defined as the 90th percentile of total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

We discuss these proposed definitions in more detail in the following sections.

3. Proposal to Replace the Estimated Allowed Amount with the Allowed Amounts Data Elements and the Count of Allowed Amounts Data Element

a. Background on Encoding Payer-Specific Negotiated Charges As Dollar Amounts

As noted in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82099), we have learned that most commercial contracting methods allow a hospital to identify and display as a dollar figure the payer-specific negotiated charges they have established with third party payers. Accordingly, we expect that, for most contracting scenarios, a hospital's payer-specific negotiated charges can also be expressed as a dollar amount.

Hospitals and MRF users have indicated in inquiries to CMS that they are confused about our current requirements for encoding payer-specific negotiated charges, so we are clarifying our current policy. If a dollar amount can be derived from a hospital's payer-specific negotiated charge, it must be encoded as a dollar value in the MRF. For items and services encoded in the MRF with a "standard charge methodology" of "case rate," "per diem," or a known "fee schedule," we expect that hospitals will be able to encode a "payer-specific negotiated charge: dollar amount." We recognize that there may be situations where the payer-specific negotiated charge is a percentage of a fee schedule that is not available to the hospital. In such instances, under our existing policies, the hospital must encode a "payer-specific negotiated charge: percentage" and an estimated allowed amount (which would be replaced with the median allowed amount should our proposal be finalized) and may indicate in the additional notes data element the type of fee schedule. We note that hospitals encoding a case rate or per diem as the standard charge methodology must encode the dollar amount for the service package base rate, which may be coupled with a "payer-specific negotiated charge: algorithm" and an estimated allowed amount (which would be replaced with the median allowed amount should our proposal be finalized) if necessary. We encourage readers to review the scenarios and examples on the

CMS Hospital Price Transparency – Data Dictionary GitHub Repository website for examples of how to encode standard charge data,[269] and additional guidance on CMS' HPT website.[270]

b. Replacing the Estimated Allowed Amount with the Median Allowed Amount

We propose to revise § 180.50(b)(2)(ii)(C) to require, at new § 180.50(b)(2)(ii)(C)(2), that, beginning January 1, 2026, if a payer-specific negotiated charge is based on a percentage or algorithm, the hospital must calculate and encode the median allowed amount in dollars for that item or service. As noted above, we propose to define "median allowed amount" in § 180.20 as the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the MRF. Should the calculated median fall between two observed allowed amounts (in other words, where the total count, *n*, is an even number), we propose that the median allowed amount would be the next highest observed value. As discussed in more detail below, we believe that requiring hospitals to encode the median allowed amount in the circumstances described in proposed § 180.50(b)(2)(ii)(C), rather than the estimated allowed amount, would improve the public's ability to better understand, and, therefore, more meaningfully use, payer-specific negotiated charges, and would make such charges more comparable across hospitals.

Currently, § 180.50(b)(2)(ii)(C) states that if the payer-specific negotiated charge is based on a percentage or algorithm, the MRF must also describe the percentage or algorithm that determines the dollar amount for the item or service and calculate and encode an estimated allowed amount in dollars for that item or service. This data element is intended to improve the public's ability to understand the actual price of care, particularly when making comparisons across hospitals. In § 180.20, we define "estimated allowed amount" as the average dollar amount that the hospital has historically received from a third party payer for an item or service.

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[269] CMS, (2024, June), *Hospital-Price-Transparency Examples,* Hospital Price Transparency, GitHub. *https://github.com/CMSgov/hospital-price-transparency/tree/master/examples*.

[270] CMS, (2025, May), *Resources*, Hospital Price Transparency website *https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/resources.*

Since finalizing the CY 2024 OPPS/ASC final rule with comment period, we have received feedback from interested parties requesting clarity on how, and the appropriate data source and lookback period from which, to calculate this additional contextual data element.

As indicated in the CY 2024 OPPS/ASC final rule with comment period, we believe that having a contextual data element displayed in dollars would improve users' ability to make price comparisons across hospitals when, with respect to the same procedure and payer/plan, one hospital has established a payer-specific negotiated charge as an algorithm and a second as a dollar amount. In addition, we agree with interested parties that have noted that data points with dollar amounts are necessary to support a better understanding of the costs of care, especially given the complexities of hospital contractual arrangements with third party payers.

On February 25, 2025, the President issued Executive Order 14221 requiring that HHS act to require disclosure of actual prices and ensure pricing information is easily comparable across hospitals. Consistent with the Executive Order and the feedback we have received from interested parties, we have considered ways to improve the requirement for hospitals to make public actual dollar amounts in the MRF to further transparency and comparability of hospital pricing information. Specifically, we have further considered the usefulness of the estimated allowed amount, as defined at § 180.20, in providing necessary context for the payer-specific negotiated charge and in facilitating comparisons across hospitals. We now believe that the payer-specific negotiated charge should be better contextualized and more precisely encoded to improve the MRF users' ability to understand and use hospital standard charges.

As set forth in § 180.20, the "estimated allowed amount" means the *average* dollar amount that the hospital has historically received from a third party payer for an item or service. While we believe that the estimated allowed amount provides useful additional context and enhances transparency and comparability of hospital standard charges, we acknowledge, as indicated in the CY 2024 OPPS/ASC final rule with comment period, that these average dollar amounts do not necessarily represent the actual dollar amount an individual would pay for an

item or service. Thus, we propose to revise § 180.50(b)(2)(ii)(C) to require hospitals to encode, beginning January 1, 2026, the median allowed amount, rather than the estimated allowed amount, if a payer-specific negotiated charge is based on an algorithm or percentage. As noted above, we propose to define the median allowed amount as the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the MRF. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.

TABLE 89: Allowed Amount Outlier Example

Rank	Claim Remittance Value
1	$10,000
2	$11,000
3	$12,000
4	$15,000
5	$18,000
6	$20,000
7	$22,000
8	$25,000
9	$26,000
10	$26,000
11	$200,000

For example, in the scenario detailed in Table 89 the mean of the claim remittances amounts is $35,000, which exceeds all the other values except for the $200,000 outlier and would not reasonably reflect the allowed amount for most patients. By contrast, the $20,000 median would be a more accurate reflection of the allowed amount for many patients and the amount a hospital typically would be reimbursed for an item or service. Requiring the median rather than the average is consistent with generally accepted statistical principles for assessing the central point of a distribution when there are outliers.[271] We recognize there are different methodologies that can be used to calculate a specific percentile when there is no single value. In

[271] Cooksey RW. Descriptive Statistics for Summarising Data. Illustrating Statistical Procedures: Finding Meaning in Quantitative Data. 2020 May 15:61–139.

this context, however, we believe that the need to identify an actual dollar value instead of an average of the two amounts outweighs the use of this accepted methodology and justifies the deviation. This methodology would only be applicable in cases, as we stated, when the percentile falls between two different integers. MRF users would be able to identify cases in which the methodology has been applied by looking at the 'count of allowed amounts' data element, which is described below.

We believe that requiring the median allowed amount would provide greater context and clarity with respect to the payer-specific negotiated charge and would better enable price estimator tools to develop and estimate an individual's personalized out-of-pocket cost, enabling MRF users to more easily compare such standard charges across hospitals.

c. Proposal to Add the 10th and 90th Percentile Allowed Amounts

We propose to revise § 180.50(b)(2)(ii)(C) to require at new § 180.50(b)(2)(ii)(C)(2) that, beginning January 1, 2026, if a payer-specific negotiated charge is based on a percentage or algorithm, the hospital must calculate and encode a 10th and a 90th percentile allowed amount in dollars for that item or service. We propose to define "tenth (10th) percentile allowed amount" in § 180.20 as the 10th percentile of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the MRF. If the calculated percentile falls between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value. We propose to define "ninetieth (90th) percentile allowed amount" in § 180.20 as the 90th percentile of total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the MRF. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

Research demonstrates that healthcare prices for a service can vary widely even within one insurer, and are not uniformly distributed.[272] However, requiring a hospital to post every possible value and the frequency of those values would be highly burdensome to hospitals and would produce unmanageably large data files that are difficult to access and interpret. Therefore, our proposals for hospitals to encode 10th and 90th percentile allowed amounts, if a payer-specific negotiated charge is based on a percentage or algorithm, is to provide MRF users with useful information about the distribution of allowed amounts as simply and directly as possible. We considered removing outlier allowed amounts to provide MRF users a range of expected allowed amounts that are not distorted by unusually low or high claims, which are common in healthcare data (for example, we considered the 1st, 5th, and 99th percentile). Along with the median (which is the 50th percentile), the 10th and 90th percentiles convey information about the likelihood, based on the distribution, of the allowed amounts that the hospital has actually received for an item or service as, by definition, 80 percent of observations fall between the 10th and 90th percentile values. We believe that requiring the display of the 10th and 90th percentile allowed amounts provides a means to better convey the potential range of values for an item or service while reducing volatility and wide ranges of price dispersion as demonstrated in Table 89. For example, in Table 89, the hospital would report $26,000 as the 90th percentile allowed amount. If we had asked for the 95th percentile or the 99th percentile the hospital would report the maximum observed value of $200,000. To identify appropriate statistics for our proposal, we examined academic research that analyzed price transparency data containing negotiated rates for in-network services and allowed amounts for out-of-network services required by the Transparency in Coverage final rule (85 FR 72158) for payer and group health plans. We observed that these

[272] Whaley C., Radhakrishnan, N., Richards, M., Simon, K., Chartock, B. (2025) Understanding health care price variation: evidence from Transparency-in-Coverage data. *Health Affairs Scholar, 3*(2). *https://pmc.ncbi.nlm.nih.gov/articles/PMC11798183/*.

research studies on payer negotiated rates commonly use the 10th and 90th percentile as the lower and upward bound of their claim and cost analyses.[273,274,275,276,277,278,279,280]

In the CY2024 OPPS/ASC final rule with comment period (88 FR 82100), we stated that we agreed with commenters that the display of a maximum allowed amount could provide some clarity about the highest dollar amount a consumer might be obligated to pay (once the consumer calculates their own potential out-of-pocket obligation based on the displayed maximum allowed amount). For example, suppose, with respect to a particular payer and plan, the maximum allowed amount for an item or service was displayed as $1,500, the plan featured a 20 percent coinsurance requirement, and the individual had already met any applicable annual deductible. In such a scenario, the individual would likely not be required to pay more than $300 (20 percent of $1,500) for the indicated item or service.[281]

At that time, however, we elected not to adopt commenters' suggestions to require hospitals to encode the maximum allowed amount because, as we stated, a maximum dollar value derived from past remittances or other data sources could include outliers, thereby potentially misrepresenting an individual's required payment for an item or service. The display of the maximum allowed amount could be skewed to the point where it would not present useful information to consumers or the public. As opposed to the maximum allowed amount, however,

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[273] Xiao, R., Ross, J., Gross, C. P., & et al. (2022). Hospital-administered cancer therapy prices for patients with private health insurance. *JAMA Internal Medicine, 182*(6), 603–611.
[274] Jiang, J., Makary, M., & Bai, G. (2022). Commercial negotiated prices for CMS-specified shoppable radiology services in U.S. hospitals. *Radiology,* 302(3):625-626.
[275] Baker Institute for Public Policy. (2024). *Price versus costs: Unpacking hospital profits*.
[276] Rochlin, D. H., Rizk, N. M., Matros, E., Wagner, T. H., & Sheckter, C. C. (2024). Negotiated rates for surgical cancer care in the era of price transparency—Prices reflect market competition. Annals of Surgery, 279(3), 385–391.
[277] Oseran, A. S., et al. (2023). Price transparency and cardiovascular spending: An important but incomplete first step. *Journal of the American Society of Echocardiography, 36*(6), 578–580.
[278] Stanton, E. W., Pedreira, R., Rizk, N., Swaminathan, A., & Sheckter, C. (2024). Burn care funding in the era of price transparency—Does verification signal bargaining power? *Journal of Burn Care & Research, 45*(5), 1117–1123.
[279] Lee J.Y., Muratov S., Tarride J-E., & Holbrook A.M. Managing high-cost healthcare users: the international search for effective evidence-supported strategies. (2018). *Journal of the American Geriatrics Society*, *66*(5):1002–8.
[280] Hu, L., Li, L., Ji, J. & et al. Identifying and understanding determinants of high healthcare costs for breast cancer: a quantile regression machine learning approach. (2020) *BMC Health Serv Res* 20, 1066.
[281] We note that this scenario is slightly different than we had portrayed at 88 FR 81540, 82101 that, in retrospect, we realized was erroneous with respect to the deductible.

the 90th percentile of the total allowed amounts for an item or service would be more representative of the dollar amount the individual might be responsible for paying, less subject to extreme outliers, and would provide an additional data point to contextualize the dollar value when the payer-specific negotiated charge for an item or service is a percentage or algorithm. Similarly, we believe that setting a threshold based at the 10th percentile would exclude outliers on the low end, and, when combined with the other data elements, provide MRF users with a better understanding of the realistic range of standard charges.

As with the proposal to require the median allowed amount, we believe the proposed 10th and 90th percentile allowed amount data elements would help MRF users to develop patient-level solutions to aid in patient financial planning and decision-making. The availability of a range of reference points, including a lower (10th percentile), median (50th percentile), and upper (90th percentile) allowed amounts, would better enable healthcare consumers to compare cost information across hospitals, empowering them to better be able to manage budgets, avoid unexpected financial burdens, and make more fully informed and value-conscious health care choices. Likewise, researchers, innovators, policy officials, employers, and others MRF users would be able to use the information to improve data analysis and develop more accurate predictive models, better and more precisely model healthcare costs and cost estimation algorithms, provide insights into healthcare pricing dynamics, and gain a deeper understanding of price dispersion across contracts that might provide a basis for negotiation and advocacy to more effectively bargain with healthcare providers and payers to yield more competitive pricing.

Furthermore, the 90th percentile allowed amount would be helpful for assessing financial risk and identifying cases where costs exceed typical ranges. This information could assist researchers and innovators in refining cost predictions and contribute to better risk management strategies.

We believe that requiring only the median allowed amount may not be sufficient to provide innovators, researchers, and other MRF users with a clear basis from which to calculate

potential out-of-pocket obligations. We believe that for consumers with insurance plans that include coinsurance and deductibles, the 10th percentile allowed amount and the 90th percentile allowed amount would provide critical potential lower and upper reference points for estimating out-of-pocket expenses. Therefore, by virtue of our proposal to require hospitals to provide these two additional data points, MRF users would have more meaningful statistics from the actual distribution of real prices, which we believe would help to further contextualize the standard charge data that is encoded as a percentage or algorithm, and additional data points that innovators can use to provide more meaningful context when creating data products for healthcare consumers to effectively compare prices.

We note that, in many cases, the 10th percentile allowed amount, median allowed amount, and 90th percentile allowed amount would fall between two actual prices; in other words, where the total count *n* would be an even number. We recognize that there are different methodologies that can be used to calculate a specific percentile when there is no single value. In such instances, we propose the hospital should identify and display the next highest value for the 10th percentile, median (50thpercentile), and 90th percentile allowed amounts, which would ensure that the value encoded in these allowed amount data elements is an actual dollar amount received by the hospital.

TABLE 90: Allowed Amount Data Element Calculation Example

Rank	Claim Remittance Value
1	$10,000
2	$11,000
3	$12,000
4	$15,000
5	$18,000
6	$20,000
7	$22,000
8	$25,000
9	$26,000
10	$26,000
11	$50,000
12	$200,000

In the scenario detailed in Table 90, the hospital would calculate the median allowed amount to be $21,000 and then would select the next highest observed value, $22,000, to encode in the median allowed amount data element. Similarly, the hospital would calculate the 10th percentile to be $11,100 and select the next highest observed value, $12,000, to encode in the 10th percentile allowed amount data element. Finally, the hospital would calculate the 90th percentile to be $47,600 and select the next highest observed value, $50,000, to encode in the 90th percentile allowed amount data element.

We solicit comment on our proposed revision to § 180.50(b)(2)(ii)(C) requiring hospitals to calculate and encode the 10th percentile, median (50th percentile), and 90th percentile allowed amounts in dollars when the payer-specific negotiated charge is based on a percentage or algorithm, as well as our proposed definition at § 180.20 of "tenth (10th) percentile allowed amount," "median allowed amount," and "ninetieth (90th) percentile allowed amount."

d. Calculation of Allowed Amounts

(1) Determining the "Total Allowed Amount"

We note that, under the proposed definition of "median allowed amount," "10th percentile allowed amount," and "90th percentile allowed amount" at § 180.20, hospitals would calculate the allowed amount considering the "total allowed amount" for an item or service. The "total allowed amount" dollar figure would be derived from the gross charge minus contractual adjustments and consist of the portion billed to a payer for a particular plan and the portion, if any, billed to the patient. As with the estimated allowed amount in the current rule, and as we explained in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82101), the amount should reflect the total amount the hospital was reimbursed for the item or service (or service package). We believe defining the "total allowed amount" this way would help to enhance consistency in how hospitals calculate this contextual data element, increasing comparability across hospitals. As described in more detail later in this section, hospitals would determine the "total allowed amount" from EDI 835 ERA transaction data, which includes information about

what the hospital was reimbursed by the plan, any secondary or other payer payment, and the patient's cost sharing responsibility for an item or service.

(2) Data Source for Calculating the Allowed Amounts

In the CY 2024 OPPS/ASC final rule with comment period, we stated our belief at the time that hospitals should retain flexibility, in the interest of reducing burden, to determine the best data source(s) for calculating the estimated allowed amount data element, though we agreed with commenters that using information from EDI 835 ERA transaction data would appear to meet our requirements (88 FR 82101). To enhance the consistency of hospital standard charge information and the comparability of the median allowed amount, and the 10th percentile and the 90th percentile allowed amounts, and in accord with what commenters had earlier suggested, we propose to require that hospitals only use EDI 835 ERA transaction data to calculate and encode the allowed amounts. As we had indicated, EDI 835 ERA transaction data, the electronic transaction data that provides claim payment information that hospitals use to track and analyze their claims and reimbursement patterns, including any adjustments made to the claim such as denials, reductions, or increases to the amount charged, and expected patient co-pays, co-insurance or secondary coverage, would meet the requirement to calculate an allowed amount (88 FR 82100 through 82101). We seek comment on the proposal to require that hospitals only use EDI 835 ERA transaction data to calculate and encode the allowed amounts. We also seek comment on whether there are instances where a hospital would not have access to EDI 835 ERA transaction data and whether there are alternative data sources we should consider requiring hospitals to use to calculate the allowed amounts and count of allowed amounts.

(3) Lookback Period for Calculating the Allowed Amounts

In the CY 2024 OPPS/ASC final rule with comment period, we also declined to specify a lookback period for hospitals when calculating the estimated allowed amount. This flexibility was intended to reflect the variations in frequency and timing with which hospitals negotiate contracts with payers. The estimated allowed amount was intended to reflect the average

reimbursement in dollars a hospital received. Our expectation was that hospitals would calculate the historical amount they received from a payer for an item or service based on the most recent reimbursement under that negotiated algorithm or percentage.

However, we have come to understand that if hospitals use substantially different lookback periods, particularly across multiple years, it could distort the allowed amounts, for example, because of pricing changes over time such as inflation, efficiencies, or the introduction of new products or services. Additionally, hospitals using varied lookback periods reduces comparability across MRFs.

As such, to help ensure that all hospitals calculate the allowed amount data elements consistently and calculate them based on the most recent reimbursements, we propose to require that hospitals base the median allowed amount, the 10th and 90th percentile allowed amounts, and the count of allowed amounts (discussed in a later section) on EDI 835 ERA transaction data from no longer than 12 months prior to posting the MRF. We propose that if the negotiated percentage or algorithm associated with the allowed amounts was only used for a portion of the 12-month time period prior to posting the MRF, the hospital would encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the portion of time that the percentage or algorithm was used. We propose that if the negotiated percentage or algorithm associated with the allowed amounts was used for the entire 12-month time period prior to posting the MRF, the hospital would encode the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts) from the EDI 835 ERA transaction data for the entire 12-month time period prior to posting the MRF. A hospital may therefore need to use different lookback periods to calculate the allowed amounts for each payer, depending on when a contract was negotiated. We acknowledge that there may be situations where the EDI 835 ERA transaction data is not yet final or may change after the allowed amounts are encoded in the MRF due to additional

adjustments being applied to a claim(s), and so we clarify that the allowed amounts should be based on the EDI 835 ERA transaction data available at the time the MRF is updated.

We considered the efficacy of various lookback periods to calculate and encode the allowed amount data elements, and looked to research to help us gauge potential lookback periods for generating price data based on historic claims remittances.[282,283] As we discuss below, we considered a 3- or 6-month lookback period, and requiring hospitals to use a rolling 12-month period prior to when the MRF posted.

While a shorter lookback period (3- or 6-month) could be useful for accounting for recent healthcare trends and identifying quick changes in allowed amounts, with respect to less frequently provided items and services, we acknowledge that hospitals may not have any claims remittance data from such a short time period from which to derive the allowed amount data elements, which would result in numerous blanks in the MRF. Additionally, timely filing limits for claims vary by state and payer, with a typical range of 30 days to 12 months from the date of service, with some longer claim periods.[284,285,286,287,288,289] Therefore, using a 3-month or 6-month lookback period to derive the median, 10th, and 90th percentile allowed amounts, and count of allowed amounts, could result in numerous blanks in the MRF for some items and services and would not accomplish our goal of providing MRF users with meaningful and comparable price data.

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[282] National Academy for State Health Policy Palliative Care in Medicaid Costing Out the Benefit: Actuarial Analysis of Medicaid Experience, December 17, 2022 *https://nashp.org/palliative-care-in-medicaid-costing-out-the-benefit-actuarial-analysis-of-medicaid-experience/*.

[283] Xie, Q. Y., Schreier, G., Hoy, M., Liu, Y., Neubauer, S., Chang, D. C. W., Redmond, S. J., & Lovell, N. H. (2016). Analyzing health insurance claims on different timescales to predict days in hospital. Journal of Biomedical Informatics, 60, 187–196. *https://www.sciencedirect.com/science/article/pii/S1532046416000034.*

[284] National Academy for State Health Policy. Palliative Care in Medicaid Costing Out the Benefit: Actuarial Analysis of Medicaid Experience, December 17, 2022 *https://nashp.org/palliative-care-in-medicaid-costing-out-the-benefit-actuarial-analysis-of-medicaid-experience/*.

[285] Xie, Q. Y., Schreier, G., Hoy, M., Liu, Y., Neubauer, S., Chang, D. C. W., Redmond, S. J., & Lovell, N. H. (2016). Analyzing health insurance claims on different timescales to predict days in hospital. Journal of Biomedical Informatics, 60, 187–196. *https://www.sciencedirect.com/science/article/pii/S1532046416000034.*

[286] Washington State Office of the Insurance Commissioner. What medical providers need to know about health insurance. *https://www.insurance.wa.gov/what-medical-providers-need-know-about-health-insurance.*

[287] Texas Department of Insurance. (Last Updated on March 25, 2025) Prompt Pay FAQ. *https://www.tdi.texas.gov/hprovider/ppsb418faq.html*.

[288] Centers for Medicare & Medicaid Services (CMS). (2011) Transmittal 2140: Changes to the Time Limits for Filing Medicare Fee-For-Service Claims*. https://www.cms.gov/regulations-and-guidance/guidance/transmittals/downloads/r2140cp.pdf.*

[289] 42 C.F.R. § 447.45(d)(1). *https://www.ecfr.gov/current/title-42/part-447/section-447.45#p-447.45(d)(1).*

After considering these alternative options, we propose that the lookback period for the median allowed amount (and 10th and 90th percentile allowed amounts, and count of allowed amounts, discussed in a later section) be based on EDI 835 ERA transaction data from no longer than 12 months prior to posting the MRF. As discussed previously, we propose that if the negotiated percentage or algorithm associated with the allowed amounts was only used for a portion of the 12-month time period prior to posting the file, the hospital would encode the median allowed amount (and 10th and 90th percentile allowed amounts and count of allowed amounts) from the EDI 835 ERA transaction data for the portion of time that the percentage or algorithm was used. We believe that limiting the lookback period to no more than 12 months prior to posting the MRF would be consistent with section 2718(e) of the Public Health Service Act that refers to "for each year," and our regulations that require the MRF to be updated at least annually (42 CFR 180.50(e) and 180.60(e)). Additionally, for most items and services, it would allow hospitals the ability to amass sufficient claims remittance data at the payer and plan level to encode a price. Where a hospital's payer contracts were initiated or renegotiated in a lesser period than the previous 12 months, with respect to those contracts we propose that a hospital would apply whatever period of applicability existed. As noted above, hospitals may need to employ different lookback periods for payers and plans, depending on when a contract was negotiated. Should it be finalized as proposed, this approach would, we believe, help achieve the purpose of Executive Order 14221 to require disclosure of a real price and help achieve our goal of ensuring pricing information is standardized and easily comparable across hospitals when a hospital's payer-specific negotiated charge is based on a percentage or algorithm. We also would carefully monitor its implementation and effectuation by hospitals to ensure that is the case and may in the future consider alternative or additional proposals should we observe weaknesses or flaws.

We solicit comment on our proposal to require hospitals, beginning January 1, 2026, to use EDI 835 ERA transaction data to calculate and encode the median allowed amount, the 10th

and 90th percentile allowed amounts (and count of allowed amounts, discussed in the next section). We seek comment on any instances where a hospital would not have access to EDI 835 ERA transaction data and whether there are alternative data sources we should consider requiring hospitals to use to calculate the allowed amounts and count of allowed amounts. Finally, we solicit comment on our proposal to require that the lookback period for the median allowed amount, the 10th and 90th percentile allowed amounts (and count of allowed amounts) be based on EDI 835 ERA transaction data from no longer than 12 months prior to posting the MRF.

4. Proposal for Hospitals to Encode the Count of Allowed Amounts

Because the percentage or algorithm reported by a hospital is based on the contract a hospital has with a particular payer for a particular plan, the median allowed amount would be calculated as the median of the total allowed amounts (after all adjustments and payments on the claim) for an item or service under a particular plan, and the 10th and 90th percentile allowed amounts would be calculated as the 10th percentile and the 90th percentile of the total allowed amounts (after all adjustments and payments on the claim) for an item or service under a particular plan. As part of our proposal to require hospitals to encode the median, 10th percentile, and 90th percentile allowed amounts if a hospital's payer-specific negotiated charge is based on an algorithm or percentage, we also propose to require hospitals to encode the count of allowed amounts that were used to calculate the median, 10th percentile, and 90th percentile allowed amounts when the standard charge is based on a percentage or algorithm. We propose that the same count of allowed amounts would be used to calculate the median, 10th percentile, and 90th percentile allowed amounts. By providing additional context regarding the number of values used to calculate the median, 10th, and 90th percentile allowed amounts—because more price volatility might reasonably be anticipated with respect to a less frequently performed service—the count of allowed amounts in the EDI 835 ERA transaction data would help MRF users determine whether those are reasonably good approximations of what typically would be generated by the payer-specific negotiated charge percentage or algorithm. Knowing the number

of claims used to derive the allowed amounts allows the MRF user to assess how representative the median, 10th and 90th percentile allowed amounts are of the overall price distribution for the item or service. For example an MRF user may question the reliability of the encoded median, 10th and 90th percentile allowed amounts for a smaller sample of allowed amounts and may feel greater reassurance that these values are more statistically valid if a large number of allowed amounts was used to derive them. We believe this data element would also help drive understanding of the accuracy and completeness of the file as, where applicable, we also propose that hospitals would be required to disclose why they are unable to calculate a median allowed amount based on a lack of EDI 835 ERA transaction data.

We propose requiring hospitals to encode this data element based on the actual number of allowed amounts within the EDI 835 ERA transaction data utilized to calculate the allowed amount data elements, except that we also propose that hospitals exclude zero-dollar claims from the count of allowed amounts. Zero-dollar claims are healthcare claims submitted by the hospital to a payer organization where the payment amount is zero, and they arise because of payer contractual situations where a service is not reimbursed for reasons including, but not limited to: when provided with a mix of other services, if the service was performed more than a specified number of times within a specified time period, lack of prior authorization for services, pre-existing condition exclusions, services deemed not medically necessary, and patients not having yet met their deductibles. Hospitals submit claims that result in no payment for some items and services because they provide information for the payer to calculate and process payment for the mix of services furnished, not because it results in a separate payment for that item or service. We propose to exclude them because they would result in misleading and skewed calculation of the median, 10th, and 90th percentile allowed amounts. The count of allowed amounts should be based on the number of allowed amounts used to calculate the allowed amounts. For example, if 184 allowed amounts were used to derive the median, 10th, and 90th percentile allowed amounts for a particular item or service, the hospital would encode “184” as the value for the count of

allowed amounts. If a hospital only had 1 allowed amount within the EDI 835 ERA transaction data for an item or service, the hospital would encode a "1" as the value for the count of allowed amounts.

We also acknowledge that, in certain situations (for example, in the case of a new hospital, or a hospital contracting with a new payer organization or a newly renegotiated contract), a hospital may have no historical claim remittance history from which to derive a median, 10th, or 90th percentile allowed amount for a payer and plan. Should a hospital have a "0" count of allowed amounts from the most recent 12-month time period from which to derive the allowed amounts for a particular item or service, we propose that it would encode "0" as the value for the count of allowed amounts for a specific payer and plan and may leave the median, 10th, and 90th percentile allowed amounts in the MRF blank. In such cases, we propose to require hospitals to encode information to explain the hospital's insufficient claim remittance history in the additional notes data element. In particular, should a hospital have no claims with the payer because it is a new or revised payer contract, we propose that a hospital should encode "new or recently revised payer contract" in the additional notes data element. We also note that nothing would preclude a hospital from updating its MRF when it has one or more remittances for an item or service.

We considered proposing an alternative approach of requiring hospitals to provide the range, or categories, of the count of allowed amounts, for example less than 10, 10-49, 50-99, 100-149, 150-199, 200-499, and 500 and over. Requiring hospitals to report ranges for the count of allowed amounts would have similarly met the objective of providing the needed context to the allowed amounts and helped inform users of the volatility of the price, and providing standard ranges could have improved the ability to compare across MRFs without the variability of individual counts. Although we believe the policy that we elected to propose offers greater precision and information value, we nevertheless believe that such an alternative approach still would have achieved our goal of providing clarity and context about the encoded price, as well

as providing standard range values that can be used for comparison across MRFs. We seek comment on whether knowing a precise count of allowed amounts is helpful to determine the volatility of the price encoded in allowed amount data elements, or if knowing that allowed counts fell within a particular range is sufficient.

We also seek comment on particular range criteria, and, were we to finalize this alternative approach as opposed to our proposed approach, we might incorporate commenter feedback to provide more guidance on how the ranges would be encoded and the valid values required in the CMS Hospital Price Transparency – Data Dictionary GitHub Repository website. For example, were a hospital to base the allowed amount data elements on 184 allowed amounts within the EDI 835 ERA transaction data, the hospital would select a predetermined range, such as 150-199 allowed amounts.

We solicit comment on our proposed revision to § 180.50(b)(2)(ii)(C) to require hospitals to calculate and encode the count of allowed amounts used to calculate the median, 10th, and 90th percentile allowed amounts, as well as on our proposal that hospitals encode this data element with the actual number of allowed amounts used within the EDI 835 ERA transaction data. We also solicit comment on the alternative we considered of encoding the count of allowed amounts using a standardized range of the number of allowed amounts used within the EDI 835 ERA transaction data, rather than the actual number of allowed amounts, and seek comment on standardized range values of counts of allowed amounts that would be useful.

5. Proposal to Modify the MRF Affirmation Statement

We propose to supplant the existing affirmation requirement by, instead, specifying at new § 180.50(a)(3)(iii) that, beginning January 1, 2026, hospitals would be required to attest in their MRFs to the following statement: “The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific

negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula." We also propose at new § 180.50(a)(3)(iv) that, beginning January 1, 2026, the hospital must encode within the MRF the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate and complete data as directed in § 180.50(a)(3)(iii).

We propose to adopt this attestation to make clear to hospitals, MRF users, and to the public our expectations that the hospital should accurately and completely encode all available standard charge information, and if the hospital established a standard charge as a dollar amount, the hospital would display the standard charge as a dollar amount, and if the hospital is unable to display standard charges as a dollar, the hospital would be required to provide all information necessary to derive a dollar amount. We intend this public declaration to establish for MRF users and for CMS actionable certainty on the accuracy and completeness of the standard charge information displayed. We also intend that this public declaration would increase hospital accountability to the MRF users that the data is complete as of the date indicated in the file. We believe demonstrating our strengthened expectations will result in the public display by hospitals of more meaningful data for MRF users.

Since the proposed new attestation requirements at § 180.50(a)(3)(iii)-(iv) would supplant, with significantly stronger provisions, certain existing requirements, we believe those particular existing requirements would become superfluous and propose to remove them. Provisions that we propose to remove, effective December 31, 2025, include the affirmation requirement now at § 180.50(a)(3)(ii) and the requirement at § 180.50(a)(3)(i), which states, beginning January 1, 2024, that each hospital must make a good faith effort to ensure that the

standard charge information encoded in the MRF is true, accurate, and complete as of the date indicated in the MRF. Specifically, we believe the attestation requirement that we propose would not only incorporate those concepts, but, in fact, would mandate significantly heightened hospital recognition of their responsibilities than what we presently require. We believe that our proposed attestation requirements, if finalized as proposed, would reduce public confusion related to whether all standard charges for hospital items and services, where possible, are included within the MRF as dollar amounts. Additionally, should our proposal be finalized as proposed, it would establish that the hospital has provided all available information to enable the public to derive a dollar amount, including, but not limited to, the specific fee schedule or components referenced in a percentage, algorithm or formula. We believe this would provide the necessary reassurance that hospitals have provided in their MRFs meaningful, accurate information to MRF users about their standard charges for health care items and services in order for those users to fully realize the intended use of the MRFs as expressed in the CY 2020 HPT final rule—that is, for enhancing the public's ability to use the data in, for example, innovator developed consumer tools and in EHRs at the point of care for value-based referrals, or to aggregate and use the data to increase competition.

We stated in the CY 2024 OPPS/ASC final rule with comment period that we believed an affirmation in the hospital's MRF, which we finalized in that rulemaking, would lessen public confusion related to the accuracy and completeness of the data in the file and improve CMS' ability to assess both the completeness and accuracy of the MRF, and that by improving assessment of compliance, CMS would improve its enforcement capabilities. Through rulemaking and during subsequent public engagement and outreach, CMS has received numerous comments and inquiries from the public and interested parties leading us to question the sufficiency of the current affirmation requirement. For example, we have heard from MRF users that they were unsure whether the absence of standard charge information meant that the hospital had not established a standard charge or if the hospital had not complied with the

requirement to disclose those charges in the MRF. We have heard from MRF users that they questioned whether hospitals have included all items and services they offer or if they included all payer and plan combinations for the payer-specific standard charges they have established. We have received complaints that hospitals are obfuscating standard charge dollar amounts and instead only encoding payer-specific standard charges as percentages and algorithms. We have also received questions regarding our assessment of the accuracy and completeness of the standard charge information displayed by hospitals in their MRFs. We also noted in the 2024 OPPS/ASC final rule with comment period that, while we believe enforcement of HPT requirements is CMS's role, the law places responsibility on hospitals to establish and make public complete and accurate standard charge information.

We also have received comments from MRF users since the effective date of the 2024 OPPS/ASC final rule with comment period indicating that requiring hospitals to make a good faith effort did not go far enough to convey CMS' intent that all standard charge information available must be encoded in the MRF, with commenters suggesting our requirement to allow a good faith estimate may actually deter hospitals from providing fully complete and accurate standard charge data in their MRF. MRF users have also questioned hospitals' inability to encode dollar amounts for the payer-specific negotiated charge data elements, and, relatedly, whether the notion that hospitals and payers use complex contracting methodologies really means the amount for an item or service could only be expressed as an algorithm or formula and not a dollar amount. Similarly, MRF users have questioned why specific contract methodologies, when coupled with an algorithm, preclude a hospital from specifying a dollar amount, with these MRF users also indicating they were unsure that all the hospital standard charge data was, in fact, fully encoded in the MRF. We do not find it surprising that MRF users, upon finding only a consumer-unfriendly algorithm, may be unable to easily compare pricing information across hospitals; efforts to rectify that give rise to some of our proposals here. We also provided clarification in the 2024 OPPS/ASC final rule with comment period, (88 FR 82096) and

reiterated in recently issued guidance, that if a hospital can derive a dollar amount for a hospital's payer-specific negotiated charge, it must encode that dollar value in the MRF's "payer-specific negotiated charge: dollar amount" data element.[290] Nevertheless, we acknowledge that we do not believe that all hospitals, in all instances, can produce a payer-specific negotiated charge in dollars that meets the definition of a "standard charge." Thus, we clarify that a hospital may display a payer-specific negotiated charge as a standard algorithm to the extent a standard algorithm is the manner by which the hospital establishes its standard charges with third party payers, and in such instances, as provided at § 180.50(b)(2)(ii)(C), the MRF must also describe the percentage or algorithm that determines the dollar amount for the item or service. In the 2024 OPPS/ASC final rule with comment period (88 FR 82098), we provided direction for hospitals on how to encode standard charges as an algorithm, stating that descriptions for algorithms could include, for example, a link to the algorithm used, a descriptor of a commonly understood algorithm, or a list of factors that would be used to determine the individualized allowed amount in dollars. Our expectation is that hospitals will encode the necessary information to enable MRF users to have all the factors of the algorithm required to be able to derive a price.

To provide CMS actionable and enforceable certainty, and MRF users additional assurance, including in situations where the hospital's payer-specific negotiated charge is based on a contractual algorithm, percentage, or formula by which a hospital genuinely cannot specify a dollar amount, we propose at § 180.50(a)(3)(iii) to require that a hospital attest in its MRF to the accuracy and completeness of the data, and at § 180.50(a)(3)(iv) to require that a hospital include the name of the hospital chief executive, president, or other senior official designated by the hospital's leadership to maintain true, accurate, and complete MRF data, to establish that the data was reviewed and verified by the hospital's leadership. Requiring an individual's name be

[290] Updated Hospital Price Transparency Guidance Implementing the President's Executive Order "Making America Healthy Again by Empowering Patients with Clear, Accurate, and Actionable Healthcare Pricing Information," May 22, 2025, *https://www.cms.gov/files/document/updated-hpt-guidance-encoding-allowed-amounts.pdf*.

specified would also, we believe, expedite our ability to quickly identify an individual at the hospital to obtain, where necessary, further clarity regarding the MRF data. In connection with this proposed requirement, we propose to add a new general data element, attester name, and should the proposal be finalized as proposed, we would provide, on the CMS Hospital Price Transparency – Data Dictionary GitHub Repository website, instruction on how to encode this data element.

We acknowledge that, at § 180.50(d)(6)(i)(D), we already require hospitals to include in their .txt files a hospital point of contact. But, that existing requirement was added as part of our efforts to improve the automated accessibility of MRFs (88 FR 82111). This point of contact was generally intended to identify for the MRF users who used the .txt requirement to retrieve hospitals MRF urls an individual capable of answering technical questions about a hospital's MRF. We noted in the CY 2024 OPPS/ASC final rule with comment period that the designation of a primary point of contact to address technical questions regarding the MRF per that requirement would not in itself assure accuracy or completeness of an MRF (88 FR 82116). Thus, we believe that existing requirement is distinct from our proposed requirement here that a hospital specifically encode within the MRF file itself the name of a senior official designated by the hospital's leadership to maintain true, accurate, and complete MRF data, but we seek comment on whether our current requirement at § 180.50(d)(6)(i)(D) adequately assures all MRF users of the accuracy and completeness of the data encoded within the hospitals' MRF.

We appreciate the need the public has expressed, as conveyed by their feedback to us, for greater assurance that MRF standard charge information is true, accurate, and complete, which is, in part, why we propose that hospitals include this revised attestation statement in the MRF. We believe that strengthening this attestation about the veracity of the MRF data, in lieu of the existing good faith effort requirement, would better assure us and MRF users that the data encoded is accurate and complete. Such greater assurance would not, however, diminish CMS's role as the hospital price transparency enforcer or alter our view that the False Claims Act is

outside the scope of this proposed rule just as we expressed at 88 FR 82086 that it was outside the scope of that final rule with comment period, and attestations will not alter our use of the regulatory alternatives outlined at § 180.70 to monitor and enforce hospital compliance with our requirements.

In the 2024 OPPS/ASC final rule with comment period, at § 180.70(a)(2)(iv), we extended our compliance authority to require, upon our request, an authorized hospital official to submit to CMS a certification as to the accuracy and completeness of the standard charge information posted in the MRF. Independent of our proposal here, we continue to believe that it is necessary for CMS to have the authority, as part of our monitoring processes, to require a formal certification by an authorized hospital official to resolve any specific questions related to the standard charges displayed by a hospital and the items and services for which the hospital has established a standard charge. As part of that existing authority, we may also require further assurance that within the hospital's MRF, any payer-specific negotiated standard charges that cannot be expressed as a dollar amount in the MRF are based on a contractual algorithm, percentage, or formula that precludes the provision of a dollar amount. We expect that the authorized hospital official who is named as the Attester in the MRF is the same authorized hospital official who would submit to CMS a certification to the accuracy and completeness of the MRF data. In the 2024 OPPS/ASC final rule with comment period, we also finalized at § 180.70(a)(2)(v) that we will require hospitals to submit to us, upon our request, additional documentation as may be necessary to make a determination of hospital compliance. In response to a request from CMS, a hospital must supply sufficient source documentation to satisfy CMS that the hospital has met the regulatory requirements. We believe our attestation proposal here complements the authority finalized in the 2024 OPPS/ASC final rule with comment period to provide CMS with adequate documentation to determine the accuracy and completeness of a hospital's price transparency files.

We considered several alternatives to altering the required affirmation within the MRF. First, we considered proposing that hospitals would be required to submit their MRF attestation directly to CMS, using a CMS-developed template that would provide evidence of the accuracy and completeness of the MRF. We did not propose such an alternative because we believe that the attestation statement and the name of the authorized hospital official should remain within the MRF to streamline our compliance process and reassure users of the MRF about the accuracy and completeness of the information. This alternative would also, we believe, be duplicative of the CMS's existing authority at § 180.70(a)(2)(iv). In the 2024 OPPS/ASC final rule with comment period, we noted that many other CMS programs require the submission of an attestation; for brevity we do not repeat them here, but refer the reader to that discussion at 88 FR 82085. Though we did not mention it there, we note that the CMS-1500, the standard claim form used by non-institutional providers and suppliers to bill Medicare and other payers, and CMS-1450, the standard claim form used by institutional healthcare providers to bill for services, also both contain certification provisions.

We seek comment on whether CMS should require hospitals to post, on their publicly available websites that host the hospital MRF, a standalone attestation document that would be signed by a hospital senior official. We viewed such an alternative as less useful than what we have proposed because MRF users, innovators, researchers, employers, other policy makers, and CMS, frequently access hospitals' MRFs from hospital websites in an automated fashion, and where an attestation would consist of a separate standalone document it would not "travel" inside the MRF like the current affirmation statement, potentially hindering effective automated retrieval. Moreover, we stated in the CY 2024 OPPS/ASC proposed rule that requiring hospitals to add the then-proposed affirmation directly in their MRF would make it clear to the public that it relates directly to that MRF and would mitigate the potential for confusion if we only required that the affirmation appear on a website that links to the hospital's MRF, especially if that website also links to other hospital MRFs. In short, we believe that separating the attestation

from the MRF could add complexity to existing automation processes, introduce more public confusion about the intent of the attestation, and defeat one of our primary objectives of having hospitals better assure the public of the accuracy and completeness of hospitals' MRFs. However, we acknowledge that MRFs are not necessarily particularly healthcare consumer friendly and frequently are very large files, so there may be merit to requiring a separate, easily retrieved attestation document. We seek comment on this alternative.

We seek comment on our proposal to add § 180.50(a)(3)(iii) which, beginning January 1, 2026, would require hospitals to include in their MRFs the following attestation: "The hospital has included all applicable standard charge information in accordance with the requirements of § 180.50, and the information encoded is true, accurate, and complete as of the date in the file. The hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the MRF or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula." We also seek comment on our proposal, in § 180.50(a)(3)(iv), to require, beginning January 1, 2026, that hospitals include a data element in the MRF to encode the name of the hospital chief executive officer, president, or senior official designated to oversee the encoding of true, accurate, and complete data as directed in § 180.50(a)(3)(iii). Finally, we seek comment on our proposal to remove, as superseded and rendered unnecessary by virtue of these stronger proposed requirements, effective January 1, 2026, § 180.50(a)(3)(i), which states that beginning January 1, 2024, a hospital must make a good faith effort to ensure that the standard charge information encoded in the MRF is true, accurate, and complete as of the date indicated in the MRF, and the affirmation statement at § 180.50(a)(3)(ii).

6. Proposal to Report Hospital National Provider Identifier (NPI) Information in the Machine Readable File

We propose to revise § 180.50(b)(2)(i)(A) to require hospitals, beginning January 1, 2026, to report a unique identifier, specifically their NPI(s), in their MRFs. We believe that having hospitals add their NPI(s) to the MRF would improve the comparability of HPT and other healthcare data, including health plan transparency data from the Transparency in Coverage (TiC) MRFs. Below, we explain the details of this proposal, including how we propose that hospitals would encode their NPI(s) in their MRFs.

An NPI is a unique 10-digit number used to identify healthcare providers and organizations, including hospitals.[291] All healthcare providers that are Health Insurance Portability and Accountability Act (HIPAA)-covered entities must obtain an NPI. [292] Healthcare providers who are individuals are assigned a Type 1 NPI and healthcare providers that are organizations are assigned a Type 2 NPI (69 FR 3440). Type 2 NPIs are also known as organizational NPIs. "Subparts" of organizations – which are components of the same organization that may be separately licensed or identified[293] – may also obtain a Type 2 NPI (69 FR 3441) if they conduct HIPAA standard transactions separately[294] from the main organization (45 CFR 162.410(a)(1)). Entities and individuals maintain NPIs unless they are deactivated upon request, death, or dissolution (45 CFR 162.408(c)), and NPIs do not change if provider name, EIN, or state licensure changes (69 FR 3441). There are several internet-based NPI lookup tools available online, including CMS's National Plan & Provider Enumeration System (NPPES) NPI registry.[295] NPIs are commonly used in other CMS systems for financial transactions, and for other health care data sets, including claims, utilization, and quality data sets.

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[291] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/nationalprovidentstand*.
[292] Ibid.
[293] Guidance on NPI Enumeration; 45 CFR 162.412(b). *https://www.cms.gov/files/document/guidance-national-provider-identifier-npi-enumeration-pdf.pdf*.
[294] *https://www.cms.gov/regulations-and-guidance/administrative-simplification/nationalprovidentstand/downloads/medsubparts01252006.pdf*.
[295] CMS's NPPES registry is available online at the following website address: https://npiregistry.cms.hhs.gov/.

In the CY 2020 HPT final rule (84 FR 65555), we stated that, by ensuring accessibility to all hospital standard charge data for all items and services, these data would be available for use by the public in price transparency tools, to be integrated into electronic health records (EHRs) for purposes of clinical decision making and referrals, or to be used by researchers and policy officials to help bring more value to healthcare. Similarly, in the TiC final rule (85 FR 72160), we indicated that the release of standard charge data would strengthen America's health care system by giving health care consumers, researchers, regulators, lawmakers, health innovators, and other interested parties in health care the information they need to make or assist others in making informed decisions about health care purchases. In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82027), we further advanced standardization of the MRF to reduce data coding inconsistencies that hindered the machine-readability of the data in the files, which at the time presented a barrier to the intended use of the data and reinforced our goal to advance the utility of the MRF data. With this proposal, we take additional steps to remove barriers to effective use of this data.

Under the current HPT regulations at § 180.50, hospitals must provide identifying information, including hospital name, address, license number, and the Employer Identification Number (EIN) either in the MRF file name or the file itself. While these elements help to identify the hospital, interested parties have told us that they are inadequate to facilitate comparing hospital MRF data with other datasets that include hospital-related information and that a standard identifier would bolster these efforts. In particular, we are told that the MRF's lack of a standard identifier hinders efforts to compare standard charge data across MRFs and limits opportunities to automate the comparison and analysis of HPT and TiC MRF data. Innovators, researchers and other MRF users have stressed to us the importance of including standard identifiers to streamline data and reduce the complexity of analyzing numerous and different disclosures. The currently required hospital license number is useful to help crosswalk the name of the hospital with the state license number, but because it differs from the identifier

required in the TiC files, innovators and researchers have noted that they find it difficult to compare across files. We also note that EINs, while required as part of the naming convention for the hospital MRF and included in the TiC MRF, are generally not included in CMS datasets or other public financial and claims datasets. Therefore, we believe it is important to propose to require hospitals to report a standard identifier, specifically the NPI, which is used in other CMS systems such as the Provider Enrollment, Chain, and Ownership System (PECOS), and the TiC MRFs, to maximize comparability across data and files.

Moreover, Executive Order 14221 requires HHS to ensure that pricing information is standardized and easily comparable across hospitals and health plans.[296] To this end, we believe it is important to align the HPT MRF and the TiC identifier data element. Under the TiC final rule (85 FR 72158), and as described in the TiC GitHub schemas for the "In-Network File," "Out-Of-Network Allowed Amount File," and the optional "Provider Reference File," most group health plans and health insurance issuers must post pricing information, and such pricing information must be associated with a provider's NPI to ensure that consumers have reliable data and can make informed healthcare purchasing decisions.[297] We believe that aligning the NPI across the HPT and TiC MRFs would support improved cross-comparison among hospital data and health plan data, providing users of both MRFs further context about hospital standard charges.

We believe this proposal would increase data researchers' ability to automate research as they would be better able to match on a common hospital numeric unique identifier across multiple datasets. Additionally, inclusion of the NPI(s) in the MRF could enable the development of products that combine price, claims, and quality data to stimulate additional hospital price competition. Including identifiers used for financial transactions (like the Type 2 NPI(s)) in the MRF would also make it easier for key participants in price negotiations (for

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[296] *https://www.whitehouse.gov/presidential-actions/2025/02/making-america-healthy-again-by-empowering-patients-with-clear-accurate-and-actionable-healthcare-pricing-information/*.
[297] *https://github.com/CMSgov/price-transparency-guide*.

example, employers and payers) to programmatically identify hospitals in their internal financial databases, such as claims databases, enabling them to better conduct in-depth payment and volume analyses to support contract negotiations and potentially reduce healthcare costs for consumers. A standard identifier could also help CMS, researchers, and innovators reduce dependence on manual processes for identifying a hospital and hospital locations and increase opportunities for automated processes.

We specifically propose to require, beginning January 1, 2026, that hospitals report, in a newly created general data element in the MRF, any Type 2 NPI(s) that has a primary taxonomy code starting with '28' (indicating hospital) or '27' (indicating hospital unit) and that is active as of the date of the most recent update to the standard charge information. We propose to limit the Type 2 NPI(s) that hospitals would report to only those that meet this taxonomy criteria, because while hospitals may have more NPIs beyond these criteria for other departments or units, these taxonomy codes limit the number of NPIs to only those indicating hospital or hospital unit. In the case that hospitals have more than one NPI that meet the proposed criteria above, we propose that hospitals would be required to report in the general data element all active Type 2 NPIs meeting the criteria. Should the proposal be finalized as proposed, we would include additional technical instructions in the CMS data dictionary and JSON schema in the Hospital Price Transparency – Data Dictionary GitHub Repository available at *https://github.com/CMSgov/hospital-price-transparency*. We seek comment on our proposal and any additional taxonomy codes that would be necessary or helpful to consider.

We considered, as an alternative, that should a hospital have multiple NPIs, it would be required to report only one NPI. With this alternative, MRF users could crosswalk the NPI to identify additional NPIs. A review of the publicly available January 2025 data from PECOS, the online Medicare enrollment system, found that only approximately 10 percent of hospital

enrollment applications reported multiple NPIs.[298] This data was cross-walked with NPPES data to find the provider taxonomy code (a 10-digit code that designates classification or specialization), whether the NPI was still active in the system, and whether an NPI was classified as an organization subpart. The majority of reported NPIs for applications with multiple NPIs were active. Some applications reported as many as 27 NPIs with a hospital or hospital unit taxonomy. However, the median number of NPIs with a hospital or hospital unit taxonomy was 2 and the average number of NPIs with a hospital or hospital unit taxonomy was 1.9. For this reason, we believe that requiring hospitals to include NPIs that meet our proposed criteria would not pose a significant burden or, for most hospitals, significantly increase the amount of data stored in the MRFs.

We also considered proposing to require that hospitals include in the MRF a Place of Service code and the Taxpayer Identification Number (TIN), as the TiC final rule also requires them. Place of Service Codes are used on professional claims to indicate the setting where an item or service was rendered. Because the HPT requirements already require hospitals to indicate the setting of the item or service in the MRF, we do not believe the Place of Service Codes would provide any additional information that is not already included in the MRF. Similarly, we do not believe there would be a benefit to requiring hospitals to encode their TIN within the MRF; rather, we believe that would be duplicative since the HPT MRF naming convention already requires the EIN (typically a hospital's TIN), thus innovators and researchers could extract it from the naming convention.

We also considered proposing to require that hospitals include other identifiers in their MRF, such as the CMS Certification Number (CCN). CCNs are assigned by CMS and used to identify health care facilities participating in the Medicare Part A and Medicaid programs.[299,300]

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[298] CMS Hospital Enrollments and Hospital Additional NPIs datasets *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-enrollments*.

[299] *https://www.cms.gov/files/document/provider-enrollment-certification-roadmap.pdf*.

[300] *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c10.pdf*.

Hospitals primarily have assigned CCNs as entities, but CCNs can also be used to identify specific hospital locations or units, especially when those units operate under the same organizational umbrella but at different sites. CCNs do not change when hospital ownership changes, but hospital mergers, acquisitions, and consolidations can result in CCN changes. We elected not to propose to require that hospitals encode CCNs because CCNs are limited to Medicare- or Medicaid-participating hospitals, while the HPT regulations apply to all hospitals in the United States (with exceptions listed at § 180.30(b)), and, also, the inclusion of CCNs would not align with the TiC provider identifier requirements.

We seek comment on our proposal, as well as any additional, or alternative, taxonomy codes that commenters believe would be necessary or helpful to consider. We also seek comment on other standard identifiers that may be useful in providing needed context and streamlining the alignment of price transparency data.

C. Proposal to Improve and Enhance Enforcement

1. Background

In the CY 2020 HPT final rule (84 FR 65524), we established actions that would address hospital noncompliance with the requirements under §§ 180.50 and 180.60, which may include issuing a written warning notice, requesting a CAP, and imposing CMPs on noncompliant hospitals and publicizing these penalties on a CMS website. In the CY 2022 OPPS/ASC final rule with comment period (86 FR 63941), we increased the amount of CMP to which a hospital could be subject to a minimum total penalty of $300/day that applies to smaller hospitals with a bed count of 30 or fewer, and a penalty of $10/bed/day for hospitals with a bed count greater than 30, not to exceed a maximum daily dollar amount of $5,500.

In the CY 2024 OPPS/ASC final rule with comment period (88 FR 82113), we finalized several improvements to our enforcement process by updating our methods to assess hospital compliance, requiring hospitals to acknowledge receipt of warning notices, working with health system officials to address noncompliance issues in one or more hospitals that are part of a health

system, and publicizing more information about CMS enforcement activities related to individual hospital compliance. We also finalized revisions to § 180.70(a)(2) to add activities that CMS may use to monitor and assess for compliance. Specifically, we revised § 180.70(a)(2)(iii) to indicate that we may conduct an audit and comprehensive compliance review of a hospital's standard charge information posted on a publicly available website. We stated that we believed that provision was necessary to clarify the methods we may use to determine a hospital's compliance with HPT requirements. In addition, we added new provisions at § 180.70(a)(2)(iv)-(v), to require, upon our request, an authorized hospital official to submit to CMS a certification as to the accuracy and completeness of the standard charge information posted in the MRF, and to require submission of additional documentation as may be necessary to determine hospital compliance. Further, we finalized at § 180.70(b)(1) a requirement that a hospital submit an acknowledgement of receipt of a warning notice in the form and manner, and by the deadline, specified in the notice of violation issued by CMS to the hospital (88 FR 82117, 82185), which requirement we thought was necessary to provide an appropriate compliance contact earlier in the enforcement process.

We also, in the CY 2024 OPPS/ASC final rule with comment period (88 FR 82119, 82185), finalized at § 180.70(d) that CMS may publicize on its website information related to CMS' assessment of a hospital's compliance; any compliance action(s) taken against a hospital, the status of such compliance action(s), or the outcome of such compliance action(s); and notifications sent to health system leadership. We indicated that, should CMS decide to publicize this information on its website, it would apply uniformly to all hospitals. We further noted that, similar to other such assessments, the information we make public would only be relevant as of the date indicated and should not be taken to suggest any ongoing state of compliance or noncompliance. We stated that we believed such information: (1) would improve the public's understanding of CMS' enforcement process by allowing interested parties to view compliance actions and determinations made by CMS, increasing transparency; (2) might reduce repetitive

complaints to CMS regarding a hospital's compliance assessment;[301] and (3) might increase the likelihood that hospitals would more quickly come into compliance due to public scrutiny.

We are aware that there are still instances of egregious violations of the HPT requirements, such as failure to post an MRF or a shoppable services file. Over a 3-year period, as shown in Table 91, violations related to not having posted an MRF and/or a shoppable service file accounted for nearly 20 percent of all enforcement actions (including warning notices, CAP request letters, and all other).[302]

In a fact sheet, "Hospital Price Transparency Enforcement Updates" (*https://www.cms.gov/newsroom/fact-sheets/hospital-price-transparency-enforcement-updates*), that we posted on April 26, 2023, we provided updates we have implemented regarding our enforcement process, including streamlining the process to no longer issue a warning notice to a hospital that has not posted an MRF or shoppable services list/price estimator tool. This was intended to incentivize hospitals to more quickly comply with our HPT requirements, and especially the basic HPT requirements to post an MRF and a consumer-friendly display of shoppable services. Consistent with Executive Order 14221, we continue to believe that it is critically important that all hospitals subject to the HPT regulations be compliant with them. As CMS identifies hospitals without an MRF and/or shoppable services file, we will continue to prioritize those cases for immediate compliance by sending them a CAP request letter.

[301] Information on enforcement actions as a result of CMS' assessment of a hospital's compliance with the HPT regulations may be found here *https://data.cms.gov/provider-characteristics/hospitals-and-other-facilities/hospital-price-transparency-enforcement-activities-and-outcomes*.

[302] Data is gathered from the CMS Hospital Price Transparency database and encompasses compliance actions from August 29, 2022, through March 10, 2025.

TABLE 91: Number Of Violations By Type, 2022-March 2025; Number of Compliance Actions by Violation Type, 2022-2025

Violation Type (No MRF, No Consumer-friendly Display, and Other)	Number of Compliance Actions	Compliance Actions as a Percent of Total
No MRF	266	11.8%
No Consumer-friendly Display	72	3.2%
No MRF and No Consumer-friendly Display	37	1.6%
Violations Unrelated to missing MRF and/or Consumer-friendly Display (all other cases)	1871	83.3%
Total Compliance Actions	2246	100.0%

2. Civil Money Penalties: Waiver of Hearing, Automatic Reduction of Penalty Amount

In prior HPT rulemaking,[303] we issued regulations that established processes to enforce the HPT requirements, including issuance of CMPs when a noncompliant hospital fails to respond to our request to submit a corrective action plan (CAP) or comply with the requirements of the CAP (§ 180.90(a)). The HPT regulations set forth the criteria we use to determine the CMP amount (§ 180.90(c)) and permit hospitals to appeal a CMP imposed by us within 30 days of issuance of the notice of imposition of a CMP (§§ 180.100 and 180.110). As of May 2025, we have issued CMP notices to 27 hospitals, 20 of which have exercised their right to appeal the CMP to an administrative law judge (ALJ).[304] Hospitals may elect to mount an appeal for many reasons, including disagreeing with our assessment of the law or facts underlying our determination, seeking to protect their reputation and/or avoid other civil or state regulatory actions, or other reasons.

We are aware that some other CMS enforcement programs offer entities subject to CMPs the ability to waive appeal rights in exchange for a 35 percent discount in the amount of the CMP owed.[305] For example, in the FY 2024 Skilled Nursing Facility Prospective Payment System

[303] The CY 2020 HPT final rule, CY 2022 OPPS/ASC final rule, and CY 2024 OPPS/ASC final rule with comment period.
[304] CMS (2025, June) *Enforcement Actions. https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions*.
[305] *See*, *for example,,* 42 CFR 488.1245(c)(2)(ii) (Hospice); 42 CFR 488.845(c)(2)(ii) (Home Health Agency); 42 CFR 488.436(b) (Long-Term Care (LTC) Facility).

final rule (88 FR 53200, 53326), we discussed our experience over the years with the CMP reduction pertaining to LTC facilities. We noted there how, between CYs 2016 and 2022 (but for CY 2017 that was not referenced), around 80 percent of LTC facilities submitted waivers, with the figure rising to 91 percent in CY 2021 but retreating to 81 percent in CY 2022, while also a considerable percentage of the remaining facilities did not submit a waiver but also not did not contest the penalty and its basis. Most significantly, throughout the period only between 2 to 6 percent of facilities availed themselves of the full hearing process.

Given respondents' widespread invocation of the LTC facility enforcement appeal waiver provision, we considered whether offering hospitals the opportunity to receive a reduced penalty—in some circumstances, and in exchange for their acknowledging their HPT noncompliance—could expedite timely payment of CMPs. Among our considerations, we believe that hospitals that might elect such a waiver opportunity pursuant to such a proposal would be demonstrating their acceptance of responsibility for HPT noncompliance, and, concomitantly, their corresponding commitment to timely achieving future compliance, which would be key to helping us achieve our overarching HPT goal of ensuring this information, in compliant form, is accessible to healthcare consumers.

We therefore propose at new § 180.90(c)(4), and subject to the exceptions discussed below, that the amount of a CMP would be reduced by 35 percent should a hospital submit to CMS a written notice requesting to waive its right to a hearing under § 180.100 within 30 calendar days of the date of the notice of imposition of the CMP. We also propose that if a hospital waives its right to appeal a CMP and receives a 35 percent reduction in accordance with § 180.90(c)(4), the hospital: (1) *would not* be eligible to receive a 35 percent reduction under § 180.90(c)(4) on any CMPs issued under § 180.90(f) that result from the same instance(s) of noncompliance (that is, continuing violations); and (2) *would* waive its right to appeal CMPs for any such continuing violations. As discussed above, and if our proposal is finalized as proposed, in waiving its right to appeal and receiving a 35 percent reduction with respect to the initial

CMP, we believe a hospital would be demonstrating acceptance of responsibility for HPT noncompliance and a commitment to achieving future compliance; as such, we do not believe it would be necessary or appropriate to provide further appeal rights or CMP reductions for continuing violations.

At § 180.90(c)(4), we propose that, in certain situations, CMS would decline to make available to hospitals the opportunity to have a CMP amount reduced. First, we propose that, should a hospital not affirmatively waive its right to a hearing in accordance with the procedures specified at proposed § 180.90(c)(4), a CMP amount would not be reduced. We believe the proposed timeframe (within 30 calendar days of the date of notice of imposition of the CMP) would provide a hospital ample opportunity to elect whether to exercise its option to waive a hearing. Second, we propose that, should CMS impose upon a hospital a CMP for HPT noncompliance going to the core of the HPT requirements—for example, failing to make public either an MRF as required in § 180.40(a) or any shoppable services in a consumer-friendly format (either in the form of a shoppable services file or an internet price estimator tool) as required in § 180.40(b)—the hospital would be ineligible to avail itself of such an opportunity. As reflected in Table 91, through the compliance review process CMS has encountered instances where hospitals have not made public an MRF and/or a consumer-friendly list of shoppable services (either a shoppable services file or internet price estimator tool). We believe that a hospital that fails to abide by such core HPT requirements—effectively entirely depriving the public access to these important tools—would forfeit the opportunity to avail itself of a penalty reduction and would be required to pay in full a CMP. For example, should CMS impose upon a hospital a CMP for failing to make public an MRF as required by § 180.40(a), even if it did have a shoppable services file or internet price estimator tool as required by § 180.40(b), such hospital would not be eligible for a reduction to its CMP by waiving its appeal rights (and the same would pertain were a hospital to have an MRF as required by § 180.40(a), but not a shoppable services file or internet price estimator tool as required by § 180.40(b)). We believe this

exception would be appropriate given that we finalized, and codified at 42 CFR part 180, the requirement that hospitals make public their standard charges in two ways (as an MRF and in a consumer-friendly format), effective beginning January 1, 2021; in other words, hospitals have been subject to this requirement for more than 4 years. We believe that excluding hospitals that fail to make public either an MRF or a consumer-friendly list of standard charges from the opportunity to avail themselves of a CMP reduction would incentivize hospitals to abide by our requirements to appropriately post such files.

We note that our proposal would not preclude a hospital, so long as it did not seek a waiver, from requesting a hearing, nor would waiving the right to a hearing remove from the hospital's record the fact of its HPT noncompliance. Rather, should our proposal be finalized as proposed, should a hospital choose to waive its right to a hearing, it would accept CMS' determination that it was noncompliant. Significantly, whether or not a hospital would elect to waive the right to a hearing, it would still be required to achieve compliance to avoid the potential imposition of additional CMPs pursuant to § 180.90(f). We expect that this proposal, if finalized as proposed, would benefit both CMS and the hospital by reducing or eliminating the time, resources, expenses, and other potential burden otherwise attributable to prosecuting or defending the administrative appeals processes.

Finally, we also propose to make conforming revisions to § 180.90(d)(1) and to add a new § 180.90(d)(2) to take into account the proposed provisions at § 180.90(c)(4), which would allow for a reduction to the CMP amount were certain criteria to be met, as discussed above. We propose to redesignate current § 180.90(d)(2) and (3) as § 180.90(d)(3) and (4), respectively.

We solicit comment on these proposals.

XX. Proposed Market-Based Medicare Severity-Diagnosis Related Groups (MS-DRG) Relative Weight Data Collection and Change in Methodology for Calculating MS-DRG Relative Weights under the Inpatient Prospective Payment System

A. Overview

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58873 through 58892), we discussed the need for Medicare to reduce its reliance on the hospital chargemaster and develop market-based approaches to payment under the Medicare FFS system. We continue to believe this is the case.

In that rulemaking (85 FR 58891), we adopted a policy that required hospitals to report on the Medicare cost report the median payer-specific negotiated charge that the hospital had negotiated with all of its Medicare Advantage Organizations (MAOs), by MS-DRG, effective for cost reporting periods ending on or after January 1, 2021. In the same final rule, we adopted the use of the median payer-specific negotiated charge by MS-DRG for MAOs in the market-based MS-DRG relative weight methodology finalized for relative weight calculations beginning in FY 2024. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45319), we repealed both the collection of market-based rate information on the Medicare cost report and the market-based MS–DRG relative weight methodology and stated that we would continue to evaluate and consider the usefulness and appropriateness of market-based data for ratesetting purposes. After further consideration, as discussed in section XX.C. of this proposed rule, we once again propose, with modifications (as discussed in section XX.C.2), to require that hospitals report on the Medicare cost report, beginning January 1, 2026, the median[306] of the payer-specific negotiated charges (hereinafter referred to as the "median payer-specific negotiated charge") that the hospital has negotiated with all of its MAOs, by MS-DRG, for use in a market-based MS-DRG relative weight methodology, effective for the relative weights calculated for FY 2029.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58885), we discussed our authority for adopting a market-based MS-DRG relative weight data collection and MS-DRG relative weight methodology. Sections 1815(a) and 1833(e) of the Act provide authority to collect data for purposes of determining the amount of payments due to a provider under the Medicare program.

[306]More precisely as discussed later in this section, the weighted median MAO payer-specific negotiated charges where the MAO payer-specific negotiated charges are weighted by the number of inpatient discharges for each of those payers that occurred during the cost reporting period. We simply refer to the median for ease of discussion.

Specifically, sections 1815(a) and 1833(e) of the Act state that no Medicare payments will be made to a provider unless it has furnished information requested by the Secretary to determine payment amounts due under the Medicare program and pertain to CMS's authority to collect information on the Medicare cost report. We also discussed CMS' authority under section 1886(d)(4) of the Act to assign and update MS-DRG weighting factors to reflect relative resource use. In particular, section 1886(d)(4)(B) of the Act requires that for each diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups, and section 1886(d)(4)(C)(i) of the Act requires that the weighting factors be adjusted at least annually to reflect changes in treatment patterns, technology, and other factors which may change the relative use of hospital resources.

In this proposed rule, we propose for cost reporting periods ending on or after January 1, 2026, to collect on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MAOs, by MS-DRG. We propose to utilize this data within a proposed methodology for calculating the IPPS MS-DRG relative weights to reflect relative market-based pricing, effective in FY 2029. This proposal reflects certain modifications to the policy as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58873 through 58892), as discussed further in section XX.C. of this proposed rule. As stated previously, we continue to believe there is a need for Medicare to reduce its reliance on the hospital chargemaster and develop market-based approaches to payment under the Medicare FFS system. We discuss in further detail in this section our evaluation and reconsideration of the usefulness and appropriateness of market-based data for ratesetting purposes since the FY 2022 IPPS/LTCH PPS final rule. As discussed in greater detail in section XX.C.2. of this proposed rule, this proposal provides instruction on how hospitals would calculate the median of the payer-specific negotiated charges for an MS-DRG using data from the machine-readable file (MRF) that hospitals are required to disclose under the hospital price transparency regulations at 45 CFR

Part 180. This proposal also addresses circumstances when hospitals use something other than MS-DRGs as a basis for reporting under those hospital price transparency requirements.

As described further in section XX.C.2. of this proposed rule, we specifically propose that for the purposes of reporting the data on the cost report, hospitals would report the median of the payer-specific negotiated charges for an MS-DRG that the hospital has disclosed for all of its MAOs on the most recent version of the MRF that the hospital is required to disclose under 45 CFR 180.40(a). If the hospital disclosed the payer-specific negotiated charge for an MS-DRG as a dollar amount, the hospital would use the dollar amount disclosed on its MRF under 45 CFR 180.50(b)(2)(ii)(C) in determining the median of the payer-specific negotiated charges to be reported on its Medicare cost report, as discussed further in section XX.C.2. If the hospital disclosed the payer-specific negotiated charge as a percentage or algorithm on the MRF , we propose that the hospital would instead use the proposed "median allowed amount" (as proposed in section XIX. of this proposed rule) to calculate the median of the payer-specific negotiated charges.[307] The hospital would then report the median payer-specific negotiated charge on its Medicare cost report, as also discussed further in section XX.C.2. of this proposed rule. We believe this proposed approach of utilizing data required for disclosure on the MRF under 45 CFR 180.50(b)(2)(ii)(C) in determining the median of the payer-specific negotiated charges would help streamline requirements for hospitals and result in less administrative burden overall because hospitals would already be required to calculate and disclose these data in compliance with the hospital price transparency requirements. For additional details on hospital price transparency requirements, including MRF requirements and the proposed modifications to the hospital price transparency requirements, we refer readers to section XIX. of this proposed rule and *https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/hospitals*.

[307] As discussed further in section XX.C.2. of this proposed rule, if CMS does not finalize to amend 45 CFR 180.50(b)(2)(ii)(C), hospitals would use the "estimated allowed amount" as required under the current hospital price transparency regulations for purposes of calculating the median payer-specific negotiated charge that is reported on the cost report.

As described in greater detail in section XX.C. of this proposed rule, the median payer-specific negotiated charges as reported on the Medicare cost report would be used in a proposed market-based methodology to calculate IPPS MS-DRG relative weights beginning in FY 2029 to reflect the relative hospital resources used to provide inpatient services to patients. The use of the median payer-specific negotiated charges would replace the current use of gross charges that are reflected on a hospital's chargemaster and cost information from Medicare cost reports for the development of the IPPS MS-DRG relative weights.

B. Factors Considered

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58873 through 58892), to reduce the Medicare program's reliance on the hospital chargemaster and to support the development of a market-based approach to payment under the Medicare FFS system, we finalized our proposal to require that hospitals report certain market-based payment rate information on their Medicare cost report for cost reporting periods ending on or after January 1, 2021. In that same rulemaking, we also adopted a market-based MS–DRG relative weight methodology using that information. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45319), we repealed both the collection of market-based rate information on the Medicare cost report and the market-based MS-DRG relative weight methodology and stated that we would continue to evaluate and consider the usefulness and appropriateness of market-based data for ratesetting purposes.

As noted in the FY 2022 IPPS/LTCH PPS rulemaking, we have continued to consider the use of market-based rate information for purposes of the IPPS relative weight methodology, including for the reasons discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58874 through 58875) regarding reducing the Medicare program's reliance on the hospital chargemaster and supporting the development of a market-based approach to payment under the Medicare FFS system, as well as additional factors since the repeal of the prior policies.

For example, in the FY 2021 IPPS/LTCH PPS proposed rule we described research that chargemasters are usually highly inflated and that these inflated charges have been used to secure higher payments from Medicare and private payers (85 FR 32790). We indicated that some hospitals' charges do not reflect market rates. Hospital bills that are generated off these chargemaster rates can be inherently unreasonable when judged against prevailing market rates. We stated that recognizing that chargemaster (gross) rates rarely reflect true market costs, we believed that by reducing our reliance on the hospital chargemaster we could adjust Medicare payment rates so that they reflect the relative market value for inpatient items and services. As part of our efforts since the FY 2022 repeal, we have examined more recent research on hospital chargemasters, which is generally consistent with the discussion in the FY 2021 rulemaking regarding whether hospital chargemasters reflect true market costs. Recent research by Linde and Egede[308] concluded that higher chargemaster markups are associated with higher hospital profitability. They delineated four potential causal pathways that may connect chargemaster markups to hospital profitability. First, chargemaster prices are commonly billed to uninsured patients and therefore may increase profits via higher payments (or payment settlements) with uninsured patients. Second, higher chargemasters may yield higher payments from insured individuals that seek care out-of-network, or who receive care at in-network facilities but are cared for by out-of-network providers. Third, chargemaster prices do in many cases serve as reference prices for the contractual payments between private insurers and hospitals. As such, higher chargemaster prices may yield increased profits by increasing payments from private payors. Fourth, higher chargemaster prices may allow hospitals to increase the cost-saving value of liabilities that end up being written off as bad debt, and therefore increased hospital profits.

We have also continued to consider the available research comparing Medicare, MAO, and commercial payment rates since the repeal. As discussed in the FY 2021 IPPS/LTCH PPS

[308] Linde S, Egede LE. Do Chargemaster Prices Matter?: An Examination of Acute Care Hospital Profitability. Med Care. 2022 Aug 1;60(8):623-630.

final rule (85 FR 58874 through 58877), we reviewed available literature to compare Medicare FFS and MAO payment rates and how those MAO rates may reflect the relative hospital resources used within an MS-DRG differently than our current cost-based methodology.

As discussed in the FY 2021 rulemaking, Berenson et al.[309] surveyed senior hospital and health plan executives and found that MA plans nominally pay only 100 to 105 percent of traditional Medicare rates and, in real economic terms, possibly less. Respondents broadly identified three primary reasons for near payment equivalence:

- Statutory and regulatory provisions that limit out-of-network payments to traditional Medicare rates,
- De facto budget constraints that MA plans face because of the need to compete with traditional Medicare and other MA plans, and
- A market equilibrium that permits relatively lower MA rates as long as commercial rates remain well above the traditional Medicare rates.

As also discussed in the FY 2021 rulemaking, Baker et al.[310] used data from Medicare and the Health Care Cost Institute (HCCI) to identify the prices paid for hospital services by FFS Medicare, MA plans, and commercial insurers in 2009 and 2012. They calculated the average price per admission, and its trend over time, in each of the three types of insurance for fixed baskets of hospital admissions across metropolitan areas. After accounting for differences in hospital networks, geographic areas, and case-mix between MA and FFS Medicare, they found that MA plans paid 5.6 percent less for hospital services compared to FFS Medicare. For the time period studied, the authors suggest that at least one channel through which MA plans paid lower prices was by obtaining greater discounts on types of FFS Medicare admissions that were known to have very short lengths-of-stay. They also found that the rates paid by commercial

[309] Berenson RA, Sunshine JH, Helms D, Lawton E. Why Medicare Advantage plans pay hospitals traditional Medicare prices. *Health Aff (Millwood).* 2015;34(8):1289-1295.
[310] Baker LC, Bundorf MK, Devlin AM, Kessler DP. Medicare Advantage plans pay less than traditional Medicare pays. *Health Aff (Millwood).* 2016;35(8):1444-1451.

plans were much higher than those of either MA or FFS Medicare, and that this differential was growing. At least some of this difference they indicated came from the much higher prices that commercial plans paid for certain service lines.

Maeda and Nelson[311] also analyzed data from the HCCI in their research. They compared the hospital prices paid by MA organizations and commercial plans with Medicare FFS prices using 2013 claims from the HCCI. The HCCI claims were used to calculate hospital prices for private insurers, and Medicare's payment rules were used to estimate Medicare FFS prices. The authors focused on stays at acute care hospitals in metropolitan statistical areas (MSAs). They found MA prices to be roughly equal to Medicare FFS prices, on average, but commercial prices were 89 percent higher than FFS prices. In addition, commercial prices varied greatly across and within MSAs, but MA prices varied much less. Although they noted that they used slightly different methods to calculate Medicare FFS prices, the authors considered their results generally consistent with the Baker et al. study findings in that hospital payments by MA plans were much more similar to Medicare FFS levels than they were to commercial payment levels.

In their study, Maeda and Nelson also examined whether the ratio of MA prices to FFS prices varied across DRGs to assess whether there were certain DRGs for which MA plans tended to pay more or less than FFS. They ranked the ratio of MA prices to FFS prices and adjusted for outlier payments. The authors found that "there were some DRGs where the average MA price was much higher than FFS and there were some DRGs where the average MA price was a bit lower than FFS." For example, for the time period in question, on average, MA plans paid 129 percent more than FFS for rehabilitation stays (DRG 945), 33 percent more for depressive neuroses (DRG 881), and 27 percent more for stays related to psychoses (DRG 885). But MA plans paid an average of 9 percent less than FFS for stays related to pathological

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[311] Maeda JLK, Nelson L. How Do the Hospital Prices Paid by Medicare Advantage Plans and Commercial Plans Compare with Medicare Fee-for-Service Prices? *The Journal of Health Care Organization, Provision, and Financing.* 2018;55(1-8).

fractures (DRG 542) and wound debridement and skin graft (DRG 464) (see Online Appendix Table 5 from their study). The authors state these results suggest that there may be certain services where MA plans pay more than FFS possibly because the FFS rates for those services are too low, but that there may be other services where MA plans pay less than FFS possibly because the FFS rates for those DRGs are too high (Maeda, Nelson, 2018 p. 5).

In addition to this research discussed in the FY 2021 rulemaking, we have also considered more recent research comparing Medicare FFS rates, MAO rates, and rates of other commercial payers, some of which used data that was made public under the provisions of the Hospital Price Transparency regulations. Meiselbach et al.[312] used 2022 price information disclosed by hospitals to examine the ratio of commercial-to-MA prices negotiated by the same insurer and found that median prices were two to three times higher for commercial plans than MA plans in the same hospital for the same service. They attributed the relatively lower MA prices to the same reasons outlined by Berenson et al. Based on price transparency data from 22 dyads of large hospitals and insurers, Randall and Duffy[313] found that, for a market basket of inpatient services, prices for health insurance exchange plans were 143.3 percent of those for MA organizations and about 89 percent of those for commercial group insurance plans.

This more recent research does not directly address the relationship between payer-specific charges negotiated between hospitals and MAOs and Medicare IPPS payment rates, but it is generally consistent in other respects to the earlier research we cited in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58876 through 58877) indicating that hospital payments by MAOs are much more similar to Medicare FFS levels than they are to commercial payment levels. We continue to believe that payer-specific charges negotiated between hospitals and MAOs and Medicare IPPS payment rates are generally well-correlated. In the FY 2022

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[312] Meiselbach MK, Wang Y, Xu Jianhui, Bai G, Anderson GF. Hospital Prices for Commercial Plans Are Twice Those For Medicare Advantage Plans When Negotiated By The Same Insurer. *Health Aff.* 2023;42(8):1110-1118.
[313] Randall S, Duffy EL. Insurers Negotiate Lower Hospital Prices for HIX Than for Commercial Groups. *The American Journal of Managed Care.* 2022;28(9): e347-e350.

IPPS/LTCH PPS final rule we indicated that we agreed with commenters that we needed to further consider the questions raised by commenters regarding the ability of the payer-specific charges negotiated between hospitals and MAOs to represent market-based pricing given the relationship between Medicare FFS and MAO rates. After considering this issue further since the FY 2022 rulemaking, we do not believe that the current general correlation between the two precludes the ability of this data over time to reflect market-based pricing for at least some services. As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58883), MA rates to MA contracted inpatient hospitals are not required to be the same as (or based on) Medicare FFS rates; the Medicare statute only requires MAOs to pay FFS rates to a health care provider for services furnished to an MA enrollee when the MAO does not have a contract with the health care provider. We believe that to the extent hospitals and MAOs over time negotiate different relative relationships for some services than the relationships that exist under the IPPS, this information adds value to the IPPS and should be incorporated. For example, in the FY 2021 IPPS final rule we stated that we believe the rates that hospitals negotiate with MAOs capture the relative resource use to provide services to patients in order to maximize profits (or, in the case of not-for-profit hospitals, net income), subject to market constraints and conditions (supply and demand, community benefit requirements, etc.). Therefore, we stated we believed that payer-specific negotiated charges provide greater insight into the resource use of a hospital (85 FR 58886). After further consideration, recognizing that there is currently general correlation between the Medicare FFS and MAO rates, we believe that the ability of the payer specific negotiated charges to provide these insights over time still holds true.

Another factor that we considered in our current proposal is the experience hospitals have gained through the process of disclosing the payer-specific negotiated charge information for the purpose of the hospital price transparency requirements. In calculating the median payer-specific negotiated charges to be reported on the Medicare cost report for use in the proposed market-based relative weight methodology, hospitals would use the same payer-specific negotiated

charge information that hospitals are required to disclose under the requirements (45 CFR 180.40(a)) that we initially finalized in the Hospital Price Transparency final rule (84 FR 65524), beginning January 1, 2021. Over the last four years, hospitals have become increasingly familiar with the hospital price transparency requirements and procedures necessary to disclose payer-specific negotiated charges. CMS has also taken enforcement actions against hospitals that have failed to comply with the price transparency requirements.[314] We believe that this increased familiarity, experience, and enforcement has improved the data integrity of this information, simplified the initial administrative burden in disclosing this data, and means that this data is now more robust for Medicare ratesetting purposes than it was when we repealed the prior market-based policies.

An additional factor we considered was the ending of the COVID-19 public health emergency (PHE). To the extent commenters previously raised concerns regarding the need for additional flexibilities as hospitals continue to recover from the COVID-19 PHE, as summarized in the FY 2022 IPPS/LTCH final rule (86 FR 45319), the COVID-19 PHE expired on May 11, 2023.

Taking into account these factors, we propose to require that hospitals report on the Medicare cost report the median payer-specific negotiated charge that the hospital has negotiated with all of its MAO payers, by MS-DRG, effective for cost reporting periods ending on or after January 1, 2026, and to use this data in a new market-based MS-DRG relative weight methodology, beginning in FY 2029.

If finalized, we would intend to make our analysis of this market-based data available for public review prior to the proposed effective date of this market-based relative weight methodology in FY 2029, including the estimated potential payment impact on the MS-DRG relative weights. As under the current methodology, the impact of any MS–DRG relative weight

[314] For example, see *https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/enforcement-actions*.

changes on an individual hospital would depend on the mix of services provided by that particular hospital.

C. Market-Based MS-DRG Relative Weight Estimation

1. Overview

Section 1886(d)(4)(A) of the Act states that the Secretary shall establish a classification of inpatient hospital discharges by diagnosis-related groups and a methodology for classifying specific hospital discharges within these groups. Section 1886(d)(4)(B) of the Act states that for each such diagnosis-related group the Secretary shall assign an appropriate weighting factor which reflects the relative hospital resources used with respect to discharges classified within that group compared to discharges classified within other groups. For the reasons previously discussed, we believe the use of median payer-specific negotiated charge data for a hospital's MAOs, to be collected on the Medicare cost report, may support the development of an appropriate market-based approach to payment under the Medicare FFS system by incorporating such data into the estimation of the relative hospital resources used with respect to discharges classified within a single MS-DRG compared to discharges classified within other MS-DRGs, as required by statute.

As discussed, since the FY 2022 IPPS/LTCH PPS final rule, we have continued to evaluate and consider the usefulness and appropriateness of market-based data for ratesetting purposes. Based on this review, we believe it would be appropriate to propose the use of hospitals' median payer-specific negotiated charges for MAOs, to be collected on the Medicare cost report as described previously, within a proposed new methodology for calculating the MS-DRG relative weights to reflect a more market-based approach, using our authority under sections 1886(d)(4)(A), 1886(d)(4)(B), and 1886(d)(4)(C) of the Act.

2. Proposed Market-Based Data Collection

In order to support the development of a relative market-based payment methodology under the IPPS, we propose to collect market-based payment rate data on the Medicare cost

report for cost reporting periods ending on or after January 1, 2026. This proposed data collection is similar to the market-based data collection as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 558873 through 58892), with additional modifications to use the payer-specific negotiated charges from the hospital's most recent MRF published prior to the submission of its cost report, to reflect proposed revisions to the hospital price transparency regulations at 45 CFR 180, and to better address when the payer-specific negotiated charge is based on a percentage or algorithm, in response to previous concerns (85 FR 58884).

Specifically, we propose that hospitals would report on their cost report the median of the payer-specific negotiated charges that the hospital negotiated with its MAOs, by MS-DRG, beginning with cost reporting periods ending on or after January 1, 2026. Sections 1815(a) and 1833(e) of the Act provide that no Medicare payments will be made to a provider unless it has furnished the information, as may be requested by the Secretary, to determine the amount of payments due to the provider under the Medicare program. We require that providers follow reasonable cost principles under section 1861(v)(1)(A) of the Act when completing the Medicare cost report. Under the regulations at 42 CFR 413.20 and 413.24, we define adequate cost data and require cost reports from providers on an annual basis. As previously discussed, the collection of this market-based data on the Medicare cost report would allow for the adoption of a market-based strategy to determine the appropriate weighting factors to reflect the relative hospital resources used with respect to hospital discharges, as required under sections 1886(d)(4)(B) and 1886(d)(4)(C) of the Act.

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58877), Medicare certified providers, such as Medicare certified hospitals, are required to submit an annual cost report to their Medicare Administrative Contractor (MAC). The Medicare cost report contains provider information such as facility characteristics, cost and charges by cost center, in total and for Medicare, Medicare settlement data, and financial statement data. The cost report must be submitted in a standard (ASCII) electronic cost report (ECR) format. CMS maintains the cost

report data in the Healthcare Cost Report Information System (HCRIS) data set. The HCRIS data supports our payment policymaking, congressional studies, legislative health care reimbursement initiatives, Medicare profit margin analysis, and relative weight updates. As such, data from hospital cost reports beginning on or after May 1, 2010 is reflected on the HCRIS dataset, and available for public access and use.

If we were to finalize this proposal to collect the proposed market-based information (specifically, the median payer-specific negotiated charges negotiated between a hospital and all its MAOs, by MS–DRG) on the cost report, this data would become publicly accessible on the HCRIS dataset in a de-identified manner and would be usable for analysis by third parties. The data would, by definition, be de-identified since we propose that the hospital calculate the median rate (that is, the specific rate that is negotiated between a hospital and a specific MAO for an MS-DRG would not be reported and need to be de-identified). For more information or to obtain HCRIS data we refer readers to *https://www.cms.gov/data-research/statistics-trends-and-reports/cost-reports/cost-reports-fiscal-year*.

We propose that the hospital would determine the weighted median of the payer-specific negotiated charges that the hospital negotiated with its MAOs, by MS-DRG, as follows:

Step 1. Using the hospital's most recent MRF as of the hospital's cost report filing date identify the following information: (a) each MAO payer-specific negotiated charge under 45 CFR 180.50(b)(2)(ii) that the hospital has negotiated with its MAOs for inpatient items or services (for example, discharges), and (b) the code under 45 CFR 180.50(b)(2)(iv)(A) for each payer-specific negotiated charge. If the payer-specific negotiated charge is based on a percentage or algorithm, the hospital would identify and substitute the dollar amount in the MRF required under 45 CFR 180.50(b)(2)(ii)(C) for the percentage or algorithm. Exclude any payer-specific negotiated charges that represent capitated payment.

Step 2. For the cost reporting period, sum the number of inpatient discharges for each MAO for each MS-DRG. Exclude inpatient discharges where payment was made on a capitated basis.

Step 3. For each MS-DRG, list each MAO payer-specific negotiated charge (from Step 1) the number of times as there were inpatient discharges that occurred during the cost reporting period for that MAO (from Step 2).

Step 4. For each MS-DRG, compute the median[315] of the MAO payer-specific negotiated charge in the list from Step 3. To compute the median, using the list in Step 3, order the list in Step 3 from the lowest MAO payer-specific negotiated charge to the highest; if the list contains an odd number of charges the median is the middle value in the list, or if the list contains an even number of charges the median is the mean of the two middle values. For each MS-DRG, this median is the weighted median MAO payer-specific negotiated charge for that MS-DRG.

As we discussed in the FY 2021 rulemaking, we recognize that the payer-specific negotiated charges negotiated between MAOs and hospitals may in some cases be based on a system other than MS-DRGs. If there are codes identified in (b) of Step 1 that are not MS-DRG codes, or discharges in Step 2 that are not classified to MS-DRGs, the hospital would crosswalk those codes or classify those discharges to MS-DRGs. Hospitals can utilize the CMS GROUPER and associated definitions manual for this purpose. Hospitals have access to the publicly available version of the CMS Grouper used to group ICD-10 diagnosis and procedure codes to MS-DRGs.[316] This software and associated definitions manual can be used to crosswalk the code(s) in the MRF or classify the discharge to an MS-DRG code.

We note that, in section XIX. of this proposed rule, we propose to amend the regulations at 45 CFR 180 as they relate to a standard charge that is based on a percentage or algorithm.

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[315] The middle number; found by ordering all data points and selecting the one in the middle (or if there are two middle numbers, taking the mean of those two numbers).

[316] *https://www.cms.gov/medicare/payment/prospective-payment-systems/acute-inpatient-pps/ms-drg-classifications-and-software.*

Specifically, we propose in section XIX. of this proposed rule, that, beginning January 1, 2026, hospitals would be required to report a new data element, the "median allowed amount," instead of the "estimated allowed amount" reported at present, and that the median allowed amount would be defined as the median of the total allowed amount that the hospital has historically received from a third-party payer (including MAOs) for an item or service. We also propose in section XIX. of this rule that if a payer-specific negotiated charge is based on a percentage or algorithm, the hospital's MRF would have to describe the percentage or algorithm that determines the dollar amount for the item or service and the hospital would have to calculate and encode the median allowed amount in dollars for that item or service. We propose in section XIX. of this rule that, to calculate the 'median allowed amount,' hospitals would be required to use electronic remittance advice transaction data, and that the dollar amount would reflect no longer than a 12-month time period prior to the posting of the most recent MRF. We refer readers to section XIX. in this proposed rule for more information regarding the specific proposal. Accordingly, the dollar amount in the MRF required under 45 CFR 180.50(b)(2)(ii)(C) for the percentage or algorithm in Step 1 would be the "median allowed amount" if this proposed amendment is finalized. If CMS does not finalize changes to 45 CFR 180.50(b)(2)(ii)(C), the dollar amount would be the "estimated allowed amount" under the current regulations.

A simplified example for the purpose of illustrating this process is as follows:

For its cost reporting period ending on September 30, 2026, a hospital had MAO payer-specific negotiated charges for MS-DRG 123 for five MAOs: MA1, MA2, MA3, MA4, and MA5.

The hospital filed its cost report on February 28, 2027.

The hospital made available to the public its MRF on January 1, 2027. This MRF did not contain MAO payer-specific negotiated charges for MA5 because the hospital stopped contracting with MA5 and began contracting with a new MAO, MA6.

Step 1. The hospital identified the following MAO payer-specific negotiated charge information for MS-DRG 123 from its January 1, 2027 MRF:

- MA1: $7,400
- MA2: $7,200
- MA3: $7,500

- MA4: $7,300 (algorithm-based)
- MA6: $7,400

Note, as the payer-specific negotiated charge for MA4 was based on an algorithm, the hospital substituted the dollar amount in the MRF required under 45 CFR 180.50(b)(2)(ii)(C) for the algorithm.

Step 2. The hospital summed the number of inpatient discharges that occurred during the cost report period ending September 30, 2026, for each MAO for MS-DRG 123.

- MA1: 2 discharges
- MA2: 1 discharge
- MA3: 1 discharge
- MA4: 3 discharges
- MA5: 2 discharges

Step 3. The hospital listed each MAO payer-specific negotiated charge (from Step 1) the number of times as there were inpatient discharges that occurred during the cost reporting period for that MAO (from Step 2).

- MA1: $7,400, $7,400
- MA2: $7,200
- MA3: $7,500
- MA4: $7,300, $7,300, $7,300

For example, the $7,400 MA1 charge from Step 1 was listed two times because there were two discharges for MS-DRG 123 that occurred during the cost report period ending September 30, 2026, for MA1; the MRF charge of $7,200 for MA2 was listed once because there was one discharge; the MRF charge of $7,500 for MA3 was listed once because there was one discharge; the MRF charge of $7,300 for MA4 was listed three times because there were three discharges, there is no MRF charge for MA5 as the hospital no longer contracted with that MAO, and the MRF charge of $7,400 for MA6 was not listed as there were no discharges during the cost reporting period for that MAO.

Step 4. The median charge for MS-DRG 123 is $7,300 because that is the median of the charges in the list from Step 3.[317] (Note that if the list had contained an even number of charges, the median would have been the mean of the two middle numbers).[318]

- $7,200 - MA2
- $7,300 - MA4
- $7,300 - MA4
- $7,300 - MA4
- $7,400 - MA1
- $7,400 - MA1
- $7,500 - MA3

[317] Ordering the payer-specific negotiated charges from Step 3 from lowest to highest as {$7,200, $7,300, $7,300, $7,300, $7,400, $7,400, $7,500} the median, or middle, charge in that list is the fourth charge of $7,300.
[318] For example, if the list had been {$7,300, $7,300, $7,400, $7,500} the median would have been $7,350, the mean of $7,300 and $7,400 (the two middle values are the second and third charges of $7,300 and $7,400.)

For purposes of this calculation, we propose to define the term ‘‘payer-specific negotiated charge’’ as the charge that a hospital has negotiated with a MAO for an item or service. We propose to use this definition of payer-specific negotiated charge because it would capture the charges that are negotiated between hospitals and MAOs and be able to provide the data needed to support the use of market-based information for payment purposes within the MS-DRG relative weight calculation. For consistency, the definition of "payer-specific negotiated charge" that we propose here is the same as the definition at 45 CFR 180.20 for purposes of our requirements for hospitals to make their standard charges available to the public. We also propose to define ‘‘items and services’’ as all items and services, including individual items and services and service packages, that could be provided by a hospital to a patient in connection with an inpatient admission for which the hospital has established a standard charge.[319] (With respect to service packages, we note that an MS-DRG, as established by CMS under the MS-DRG classification system, is a type of service package consisting of items and services based on patient diagnosis and other characteristics.) We propose this definition of "items and services" because we believe it captures the types of items and services, including service packages, that a hospital would use to calculate and report the median payer-specific negotiated charge for each MS-DRG to support the use of market-based rate information by MS-DRG within the MS-DRG relative weight calculation. For purposes of this calculation, an MAO is defined as in 42 CFR 422.2 and means a public or private entity organized and licensed by a State as a risk-bearing entity (with the exception of provider-sponsored organizations receiving waivers) that is certified by CMS as meeting the MA contract requirements. We note that these proposed definitions are the same as those finalized in the FY 2021 IPPS/LTCH PPS final rule.

[319] Our proposed definition here of "items and services" is the same as the definition at 45 CFR 180.20, but for the examples included there and omitting the reference to outpatient department visits, as here we would not require hospitals to calculate the median of their payer-specific negotiated charges for items and services provided in the hospital outpatient setting.

As finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58888), we propose that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. We note that hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this proposed data collection. Examples of subsection (d) hospitals that only receive non-negotiated payment rates include hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act or federally owned and operated facilities. We note that this proposed data collection requirement would apply to a smaller subset of hospitals as compared to the public reporting requirements under the hospital price transparency regulations. We recognize that Critical Access Hospitals (CAHs) may, in some instances, negotiate payment rates; however, because CAHs are not subsection (d) hospitals and are not paid on the basis of MS-DRGs, CAHs would not be subject to this proposed data collection requirement. We also note that rural emergency hospitals would not be subject to this proposed data collection requirement given that they do not provide inpatient services.

On March 12, 2025, CMS announced the intention to end the Maryland Total Cost of Care Model.[320] We propose that hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, would be exempted from this data collection requirement during the performance period of that Model. Following the end of the performance period of the Maryland Total Cost of Care Model, Maryland hospitals would no longer be exempt from this data collection requirement.

Further instructions for the reporting of this proposed market-based data collection requirement on the Medicare cost report will be discussed in a forthcoming new Information Collection Request, which is currently under development.

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[320] *https://www.cms.gov/priorities/innovation/innovation-models/md-tccm*.

We believe that the administrative burden for this proposal is reduced by utilizing data that hospitals would disclose under existing and proposed hospital price transparency requirements relative to if hospitals did not already have this data compiled. Please refer to section XXII.E. of this proposed rule where we discuss the estimated burden for hospitals as a result of this proposed policy.

We also propose to amend 42 CFR 413.20(d)(3) to reflect this proposed requirement. Specifically, we propose to amend § 413.20(d)(3) to require hospitals to report the median payer-specific negotiated charge by MS-DRG for MAOs on the Medicare cost report. We propose to capture this proposed data collection requirement in regulation at § 413.20(d)(3)(i)(B). This proposed requirement would be effective for cost reporting periods ending on or after January 1, 2026.

3. Proposed Market Based MS-DRG Relative Weight Methodology

As previously discussed, we propose a new market-based methodology for estimating the MS-DRG relative weights, beginning in FY 2029. We note that this proposed market-based MS-DRG relative weight methodology would be the same market-based MS-DRG relative weight methodology that was initially adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58879 through 58881). Specifically, we propose to implement a methodology for calculating the MS-DRG relative weights using the median payer-specific negotiated charge for MAOs for each MS-DRG, as described in this section and reported on the cost report. For the reasons discussed in section XX.B. of this proposed rule, based on our further review, we believe that using the median payer-specific negotiated charge for MAOs within the MS-DRG relative weight calculation would allow for a more market-based approach to determining Medicare FFS reimbursement.

Below is a description of the steps for a proposed MS-DRG relative weight methodology change using the payer-specific negotiated charge data. We refer readers to the FY 2021

IPPS/LTCH PPS final rule (85 FR 58880 through 58881) for additional discussion of the finalized methodology which we are reproposing.

● *Step One: Standardize the Median Payer-Specific Negotiated Charges*: In order to make the median payer-specific negotiated charges from the cost reports more comparable among hospitals, we would standardize the median payer-specific negotiated charges reported on the cost report by removing the effects of differences in area wage levels, and cost-of living adjustments for hospital claims from Alaska and Hawaii, in the same manner as under the current MS-DRG relative weight calculation for those effects.

● *Step Two: Create a Single Weighted Average Standardized Median MAO Payer-Specific Negotiated Charge by MS-DRG Across Hospitals*: For each MS-DRG, we would create a single weighted average across hospitals of the standardized median payer-specific negotiated charges. We would weight the standardized payer-specific negotiated charge for each MS-DRG for each hospital using that hospital's Medicare transfer-adjusted case count for that MS-DRG, with transfer adjusted case counts calculated the same way as under the current MS-DRG relative weight methodology. We note that, as discussed in the FY 2025 IPPS/LTCH PPS final rule (89 FR 69109), the current MS-DRG relative weight methodology does not include MA cases as discharges for Medicare beneficiaries enrolled in a MA managed care plan are excluded from the relative weight methodology. We believe that using the Medicare transfer-adjusted case counts would be a reasonable approach to combining the data across hospitals because it would reflect relative volume and transfer activity (that is, larger hospitals responsible for more discharges would be weighted more heavily in the calculation, hospitals that transfer more often would be weighted less heavily).

● *Step Three: Create a Single National Weighted Average Standardized MAO Payer-Specific Negotiated Charge Across all MS-DRGs*: We would create a single national weighted average across MS-DRGs of the results of Step Two, where the weights are the national Medicare transfer adjusted case counts by MS-DRG.

- *Step Four: Calculate the Market-based Relative Weights*: For each MS-DRG, the market-based relative weight would be calculated as the ratio of the single weighted average standardized median MAO payer-specific negotiated charge for that MS-DRG across hospitals from Step Two to the single national weighted average standardized median MAO payer-specific negotiated charge across all MS-DRGs from Step Three.

- *Step Five: Normalize the Market-based Relative Weights*: We note that as under the current cost-based MS-DRG relative weight methodology, the market-based relative weights would be normalized by an adjustment factor so that the average case weight after recalibration would be equal to the average case weight before recalibration. As under the current cost-based relative weight estimation methodology, the normalization adjustment is intended to help 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 believe initially there would be minimal impacts to the relative weights calculated under this proposed market based MS–DRG relative weight methodology (which would utilize the median payer-specific negotiated charge data negotiated between hospitals and their MAOs) beginning in FY 2029, given the relationship between the MAO rates and Medicare FFS rates (as evidenced by feedback from commenters as discussed in the FY 2021 IPPS/LTCH PPS final rule and the results of our literature review). If finalized, we would expect, for some period of time following implementation of this proposed market-based MS-DRG relative weight methodology, to continue to estimate and publicly provide, for informational purposes, the MS-DRG relative weights as calculated using our current cost-based estimation methodology.

In addition, similar to our discussion in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58886 through 58887), if finalized, we would intend to provide additional opportunity for the public to review the MAO median payer-specific negotiated charge data received prior to the utilization of this data in the market-based MS-DRG relative weight methodology beginning in FY 2029. We continue to believe this would allow for additional discussions, public review, and

conversation about utilizing this market-based data in the MS-DRG relative weight methodology.

We seek comment on all elements of this proposed market-based data collection for cost reporting periods ending on or after January 1, 2026, and market-based methodology for estimating the MS-DRG relative weights beginning in FY 2029. We also seek comments on potential unintended consequences of this proposal, if any, including special considerations if needed to mitigate those potential consequences for certain hospitals. We also seek comment on how these or other market-based strategies could be utilized in additional Medicare FFS payment systems and the benefits of these market-based approaches.

XI. Graduate Medical Education Accreditation

A. Executive Order 14279

Executive Order 14279 (April 23, 2025), entitled "Reforming Accreditation to Strengthen Higher Education," directs the Attorney General, in consultation with the Secretary of Health and Human Services, to "investigate and take appropriate action to terminate unlawful discrimination by American medical schools or graduate medical education entities that is advanced by the Liaison Committee on Medical Education or the Accreditation Council for Graduate Medical Education or other accreditors of graduate medical education, including unlawful 'diversity, equity, and inclusion' requirements under the guise of accreditation standards."[321] The Executive Order further directs that standards for training doctors should focus solely on providing the highest quality care, and should not require or encourage educational institutions to discriminate unlawfully on the basis of race.

The Accreditation Council for Graduate Medical Education ('ACGME') is the primary organization in the United States that currently conducts accreditation for Graduate Medical Education ('GME') Programs. While ACGME accreditation is a voluntary process, programs

[321] 90 FR 17529. *https://www.federalregister.gov/documents/2025/04/28/2025-07376/reforming-accreditation-to-strengthen-higher-education.*

that are not accredited by the ACGME generally do not receive Medicare funding from CMS for Direct Graduate Medical Education (DGME) and Indirect Medical Education (IME). Additionally, if the ACGME withdraws accreditation, residents generally must receive assistance to continue their education from other ACGME-accredited programs.[322]

For a number of years, the ACGME has identified 'diversity, equity, and inclusion' as a primary value of the organization and a central component of its vision for graduate medical education.[323] The ACGME's Common Program Requirements require that institutions "must engage in practices that focus on mission-driven, ongoing, systematic recruitment and retention of a diverse and inclusive workforce of residents, fellows (if present), faculty members, senior administrative staff members," and that organizations' "programs implement, policies and procedures related to recruitment and retention of individuals underrepresented in medicine and medical leadership."[324] In practice, many such diversity, equity, and inclusion programs unlawfully discriminate against Americans on the basis of race. In *Students for Fair Admissions v. President and Fellows of Harvard College (2023)*, the U.S. Supreme Court held that race-based admissions policies, even when focused on the goal of diversity, violate the Equal Protection Clause of the Fourteenth Amendment unless they satisfy strict scrutiny.[325] While the ruling applies specifically to admissions decisions at institutions of higher education, its broader reasoning—especially the requirement that any use of race be narrowly tailored to a compelling interest—strongly suggests that race-conscious elements in Diversity, Equity, and Inclusion (DEI) initiatives in federally funded education programs are generally impermissible. These programs raise particular concerns in the medical context, where patients and the larger society

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[322] *https://www.acgme.org/about/acgme-frequently-asked-questions/*.
[323] ACGME, *Policies and Procedures*, February 2, 2025. *https://www.acgme.org/globalassets/pdfs/ab_acgmepoliciesprocedures.pdf.*
[324] ACGME, *Guide to the Common Program Requirements*, March 2024, *https://www.acgme.org/globalassets/pdfs/guide-to-the-common-program-requirements-residency.pdf?utm_source=chatgpt.com*.
[325] *Students for Fair Admissions, Inc. v. President and Fellows of Harvard College*, June 2023. *https://www.supremecourt.gov/opinions/22pdf/20-1199_hgdj.pdf.*

have a compelling need for medical education to be focused primarily on excellence and delivering the best possible care to patients.

B. Definition of "Approved Medical Residency Programs"

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 CMS 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. 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, 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 nonprovider sites, when applicable) to the number of inpatient hospital beds.

Hospitals may receive direct GME and IME payments for residents in "approved medical residency training programs." Section 1886(h)(5)(A) of the Act defines an "approved medical residency training program" as "a residency or other postgraduate medical training program

participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary."

The regulations at § 413.75(b) define an "approved medical residency program" for purposes of direct GME payment as a program that meets one of four criteria: (1) is approved by one of the national organizations specified in the regulations at § 415.152; (2) may count towards certification of the participant in a specialty or subspecialty listed in the current edition of certain publications specified in the regulations; (3) is approved by the ACGME as a fellowship program in geriatric medicine; or (4) is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that involves induced abortions, regardless of whether the standard provides exceptions or exemptions. The regulations at § 412.105(f)(1)(i) define an "approved teaching program" similarly for purposes of IME payment.

The regulations at § 415.152 define an "approved graduate medical education program" as a residency program approved by one of the following national organizations (or their predecessors): The Accreditation Council for Graduate Medical Education (ACGME), the American Osteopathic Association (AOA), the Commission on Dental Accreditation (CODA) of the American Dental Association, and the Council on Podiatric Medical Education (CPME) of the American Podiatric Medical Association. Thus, in general, under §§ 413.75(b) and 412.105(f)(1)(i), an "approved" program can be a program that is accredited by one of these national organizations, or one that leads toward board certification by the American Board of Medical Specialties (ABMS).

The statute gives CMS authority to specify additional criteria for approved GME programs. Therefore, to ensure that accreditation for approved medical residency programs is in compliance with applicable laws related to race-based admission policies and to improve the accreditation process, the agency proposes that accreditors may not require as part of accreditation, or otherwise encourage institutions to put in place, diversity, equity, and inclusion programs that encourage unlawful discrimination on the basis of race or other violations of

Federal law. The effective date of this proposal would be January 1, 2026. Additionally, we note that the Secretary may recognize other organizations that meet or exceed Medicare's requirements as accreditors to increase the potential for competition in the accreditation space and improve the quality of the accreditation process.

This proposal is intended to ensure that accreditors of academic medical institutions are focused on the mission of ensuring excellence in graduate medical education, of improving the potential for competition in the accreditation space, and of eliminating unlawful and discriminatory DEI programs. We welcome commenters' feedback on this proposal.

XXII. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. ICRs for the Hospital Outpatient Quality Reporting (OQR) Program

1. Background

In sections XIV. and XV. of this proposed rule, we discuss the proposed requirements for the Hospital OQR Program. The Hospital OQR Program is generally aligned with the CMS quality reporting program for hospital inpatient services known as the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94522 through 94530) for detailed discussions of the previously finalized Hospital OQR Program ICRs which are currently approved under OMB control number 0938-1109 (expiration date January 31, 2026).

In this proposed rule, we propose to: (1) remove the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) remove the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) remove the Screening for Social Drivers of Health (SDOH) measure beginning with the CY 2025 reporting period; (4) remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period; (5) modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) eCQM (Excessive Radiation eCQM) from mandatory reporting beginning with the CY 2027 reporting period to continue voluntary reporting in the CY 2027 reporting period and subsequent years; (6) adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) with voluntary reporting for the CY 2027 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination; (7) remove the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2028 reporting period/CY 2030 payment determination; and (8) remove the Left Without Being Seen (LWBS) measure beginning with the CY 2028 reporting period/CY 2030 payment determination.

In section XIV.D. of this proposed rule, we also propose to update our Extraordinary Circumstances Exception (ECE) Policy for the Hospital OQR Program. This proposed update

would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

In the CY 2025 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the Hospital OQR Program by utilizing the Bureau of Labor Statistics (BLS) mean hourly wage rate for Medical Records Specialists (89 FR 94522 through 94523). Specifically, we used the industry-specific wage for Medical Records Specialists working in "general medical and surgical hospitals," as this categorization aligns the closest with the Hospital OQR Program care setting. The most recent data from BLS' May 2024 National Occupational Employment and Wage Estimates reflects a median hourly wage of $27.53 per hour for Medical Records Specialists working in "general medical and surgical hospitals" (SOC 29-2072).[326] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is 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 ($27.53 × 2 = $55.06) to estimate total cost burden is reasonably accurate. Accordingly, unless otherwise specified, we calculate cost burden to hospitals using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this proposed rule for the Hospital OQR Program.

In the CY 2025 OPPS/ASC final rule with comment period, our burden estimates assumed that approximately 3,200 hospital outpatient departments (HOPDs) would report data to the Hospital OQR Program (89 FR 94523). For this proposed rule, based on the most recent available data from the CY 2024 Hospital OQR Program payment determination, we estimate

[326] U.S. Bureau of Labor Statistics. (2025). Occupational Outlook Handbook, Medical Records Specialists. Available at: *https://data.bls.gov/oes/#/industry/622100. Accessed: April 8, 2025.*

that 3,200 HOPDs would report data to the Hospital OQR Program for the CY 2026 reporting period/CY 2028 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the COVID–19 Vaccination Coverage Among HCP Measure Beginning with CY 2024 Reporting Period/CY 2026 Payment Determination

As discussed in section XIV.C.1. of this proposed rule, we propose to remove the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The information collection burden associated with this measure is currently approved under OMB control number 0920-1317. To report this measure, HOPDs 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 HOPD requires between 40 minutes (0.67 hours) to upload a CSV file and 45 minutes (0.75 hours) monthly to enter the data manually. CDC assumes that manual data entry would be completed by a Microbiologist with a wage rate of $58.60/hour and uploading of a CSV file would be completed by an Information Technologist with a wage rate of $56.50/hour. Therefore, we estimate that this proposal would result in a decrease in burden of between 25,600 hours (0.67 hours x 12 months x 3,200 HOPDs) at a savings of $1,446,400 (25,600 hours x $56.50/hour) and 28,800 hours (0.75 hours x 12 months x 3,200 HOPDs) at a savings of $1,687,680 (28,800 hours x $58.60/hour) annually across all 3,200 HOPDs under OMB control number 0920-1317.

3. Information Collection Burden Estimate for the Proposed Removal of the HCHE Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

As discussed in section XIV.C.2. of this proposed rule, we propose to remove the HCHE measure beginning with the CY 2025 reporting period/CY 2027 payment determination. The information collection burden associated with this measure is currently approved under OMB control number 0938-1109. The currently approved information collection burden estimate for

this measure assumes HOPDs spend approximately 10 minutes (0.167 hours) annually to report measure data. Therefore, for all participating HOPDs, we estimate removal of this measure would decrease burden by approximately 533 hours (0.167 hours x 3,200 HOPDs) at a savings of $29,347 (533 hours x $55.06/hour).

4. Information Collection Burden Estimate for the Proposed Removal of the Screening for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screening for SDOH measure beginning with the CY 2025 reporting period. 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 have previously estimated 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.

We determine the cost for patients (or their representative) to complete the screening using a post-tax wage of $25.63/hour based on assumptions from the report ‘‘Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,’’ which identifies an approach for valuing time when individuals undertake administrative and other tasks on their own time.[327] 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.[328] 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,[329] resulting in the post-tax hourly wage rate of $25.63/hour. Unlike our State and

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[327] Office of the Assistant Secretary for Planning and Evaluation. (2017). Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. Accessed: June 24, 2025.*

[328] Bureau of Labor and Statistics. (2025). Usual Weekly Earnings of Wage and Salary Workers, Fourth Quarter 2025. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf. Accessed: March 3, 2025.*

[329] Guzman, G. & Kollatr, M. (2024). Income in the United States: 2023. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf. Accessed: June 24, 2025.*

private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs because the individuals' activities, if any, would occur outside the scope of their employment.

Under OMB control number 0938-1109, we estimate 206,325,645 HOPD visits annually that will result in screening once the measure becomes mandatory. Therefore, for all participating HOPDs, we estimate removal of this measure would decrease burden for voluntary reporting for the CY 2025 reporting period by approximately 1,719,380 hours for 51,581,411 patients (0.033 hours x 206,325,645 patients x 50 percent response rate x 50 percent of HOPDs) at a savings of $44,067,709 (1,719,380 hours x $25.63/hour). For mandatory reporting beginning with the CY 2026 reporting period, we estimate a decrease in burden of 6,877,522 hours (206,325,645 patients x 0.033 hours per patient) at a savings of $176,270,889 (6,877,522 hours x $25.63/hour). With regard to measure reporting, we estimate a decrease in burden of 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPD) at a savings of $14,701 (267 hours × $55.06/hour) for voluntary reporting for the CY 2025 reporting period and 533 hours annually (0.167 hours x 3,200 HOPDs) at a savings of $29,347 (533 hours x $55.06/hour) for mandatory reporting beginning with the CY 2026 reporting period.

5. Information Collection Burden Estimate for the Proposed Removal of the Screen Positive Rate for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period. For this measure, HOPDs are required to report on an annual basis the number of patients who screen positive for one or more of the five SDOH domains divided by the total number of patients screened (reported as five separate rates). We previously estimated each HOPD requires 10 minutes (0.167 hours) annually to report this measure. Therefore, we estimate removal of this measure would decrease burden by 267 hours (3,200 HOPDs × 50 percent of HOPDs × 0.167 hours per HOPD) at a savings of $14,701 (267 hours × $55.06/hour) for voluntary reporting for the CY 2025 reporting period and

533 hours annually (0.167 hours x 3,200 HOPDs) at a savings of $29,347 (533 hours x $55.06/hour) for mandatory reporting beginning with the CY 2026 reporting period.

6. Information Collection Burden Estimate for the Proposed Adoption of the Emergency Care Access & Timeliness eCQM with Voluntary Reporting for the CY 2027 Reporting Period, Followed by Mandatory Reporting Beginning with the CY 2028 Reporting Period/CY 2030 Payment Determination

As discussed in section XV.B.1. of this proposed rule, we propose to adopt the Emergency Care Access & Timeliness eCQM beginning with voluntary reporting for the CY 2027 reporting period, followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination. Similar to the information collection burden for the Appropriate Treatment for ST-Segment Elevation Myocardial Infarction (STEMI) and Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults eCQMs currently approved under OMB control number 0938-1109, we assume a Medical Records Specialist would require 10 minutes (0.167 hours) to submit the data required per quarter for each HOPD or 40 minutes (0.67 hours; 10 minutes x 4 quarters) annually. For voluntary reporting for the CY 2027 reporting period, HOPDs would be able to voluntarily submit at least one quarter and up to four quarters of data. For estimation purposes, similar to the assumptions previously used for the STEMI and Excessive Radiation Dose or Inadequate Image Quality for Diagnostic CT in Adults eCQMs, we estimate 20 percent of HOPDs would voluntarily report one quarter of data for the measure in the CY 2027 reporting period, with 100 percent of HOPDs reporting the measure as required in subsequent years (86 FR 63962 and 63963, and 88 FR 82134). For voluntary reporting for the CY 2027 reporting period, we estimate an annual burden for voluntarily participating HOPDs of 107 hours (3,200 HOPDs × 20 percent × 0.167 hours × 1 quarter) at a cost of $5,891 (107 hours × $55.06/hour). Beginning with the CY 2028 reporting period, we estimate the annual burden for all participating HOPDs to be 2,133 hours (0.67 hours x 3,200 HOPDs) at a cost of $117,443 (2,133 hours x $55.06/hour). With respect to any costs/burdens

unrelated to data submission, we refer readers to the Regulatory Impact Analysis in section XXV. of this proposed rule.

7. Information Collection Burden Estimate for the Proposed Removal of the Median Time from ED Arrival to ED Departure for Discharged ED Patients Measure Beginning with the CY 2028 Reporting Period/CY 2030 Payment Determination

As discussed in section XV.B.2. of this proposed rule, we propose to remove the Median Time from ED Arrival to ED Departure for Discharged ED Patients measure beginning with the CY 2028 reporting period/CY 2030 payment determination, when reporting for the Emergency Care Access & Timeliness eCQM is proposed to become mandatory. The information collection burden associated with this measure is currently approved under OMB control number 0938-1109. The currently approved information collection burden estimate for this measure assumes an average of 289 cases are reported annually per HOPD, and HOPDs require approximately 2.9 minutes (0.049 hours) per case to perform the necessary chart abstraction and report measure data. Therefore, we estimate removal of this measure would decrease burden by approximately 14.2 hours (0.049 hours x 289 cases) at a savings of $782 per HOPD (14.2 hours x $55.06/hour). Therefore, for all participating HOPDs, we estimate a decrease in annual burden of 45,440 hours (14.2 hours per HOPD x 3,200 HOPDs) at a savings of $2,501,926 (45,440 hours x $55.06/hour).

8. Information Collection Burden Estimate for the Proposed Removal of the Left Without Being Seen Measure Beginning with the CY 2028 Reporting Period/CY 2030 Payment Determination

As discussed in section XV.B.2. of this proposed rule, we propose to remove the Left Without Being Seen measure beginning with the CY 2028 reporting period/CY 2030 payment determination, when reporting for the Emergency Care Access & Timeliness eCQM is proposed to become mandatory. The information collection burden associated with this measure is currently approved under OMB control number 0938-1109. The currently approved information collection burden estimate for this measure assumes HOPDs spend approximately 10 minutes (0.167 hours) annually to report measure data. Therefore, for all participating HOPDs, we

estimate removal of this measure would decrease burden by approximately 533 hours (0.167 hours x 3,200 HOPDs) at a savings of $29,347 (533 hours x $55.06/hour).

9. Information Collection Burden Estimate for the Proposal to Modify the Excessive Radiation eCQM from Mandatory Reporting Beginning with the CY 2027 Reporting Period to Continue Voluntary Reporting in the CY 2027 Reporting Period and Subsequent Years

As discussed in section XV.B.3. of this proposed rule, we propose to modify the reporting requirements for the Excessive Radiation eCQM by maintaining voluntary reporting instead of mandatory reporting of the measure, beginning with the CY 2027 reporting period. The information collection burden associated with this measure is currently approved under OMB control number 0938-1109 and estimates HOPDs spend approximately 10 minutes (0.167 hours) per quarter annually to report measure data. In the CY 2024 OPPS/ASC final rule, where we adopted the Excessive Radiation eCQM beginning with voluntary reporting in the CY 2026 reporting period, we estimated that 20 percent of hospitals would voluntarily report one quarter of data for the measure and 100 percent of hospitals would report data for the measure once mandatory reporting began with the CY 2027 reporting period/CY 2029 payment determination. We also finalized to gradually increase the number of quarters of data hospitals would be required to report on the measure starting with two self-selected quarters for the CY 2027 reporting period/CY 2029 payment determination, and all four quarters for the CY 2028 reporting period/CY 2030 payment determination (88 FR 82134).

Because 80 percent of HOPDs would no longer be required to report this measure under the proposed modification to extend voluntary reporting beginning with the CY 2027 reporting period, we estimate the revised data submission burden would be 107 hours (3,200 HOPDs × 20 percent × 0.167 hours × 1 quarter) at a cost of $5,891 (107 hours x $55.06/hour) annually. This updated burden estimate is a decrease of 960 hours [(3,200 HOPDs × 0.167 hours × 2 quarters) - (3,200 HOPDs × 20 percent × 0.167 hours × 1 quarter)] at a savings of $52,858 (960 hours x $55.06) for the CY 2027 reporting period, and a decrease of 2,027 hours [(3,200 HOPDs × 20

percent × 0.167 hours × 3 quarters) + (3,200 HOPDs × 80 percent × 0.167 hours × 4 quarters)] at a savings of $111,607 (2,027 hours x $55.06/hour) annually beginning with the CY 2028 reporting period.

In addition, for this measure as described under OMB control number 0938-1109, participating HOPDs must follow the process for running their chosen vendor's translation software prior to sending data to its EHR for measure calculation and reporting. We estimate participating HOPDs spend approximately 15 minutes (0.25 hours) annually to conduct these activities prior to data submission. Therefore, for all participating HOPDs, we estimate removal of this measure would decrease annual burden associated with these activities by approximately 640 hours (0.25 hours x 80 percent x 3,200 HOPDs) at a savings of $35,238 (640 hours x $55.06/hour) beginning with the CY 2027 reporting period.

10. Summary of Proposed Information Collection Burden Estimates for the Hospital OQR Program

Tables 92 through 96 summarizes the information collection burden changes under OMB control number 0938-1109 (expiration date January 1, 2026). We estimate that the proposals in this proposed rule would result in a decrease in information collection burden of 6,924,988 hours at a savings of $178,884,367 annually for all 3,200 program-eligible HOPDs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2028 reporting period/CY 2030 payment determination. We also estimate that the proposals in this proposed rule would result in a decrease in information collection burden of between 25,600 hours at a savings of $1,446,400 and 28,800 hours at a savings of $1,687,680 under OMB control number 0920-1317. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1109. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section XXVI.A. of this proposed rule).

We invite public comments on the information collection requirements and whether our estimated burden is a reasonable estimate.

TABLE 92: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove HCHE measure	10	1	3,200	1	0.167	0	533	-533
Remove Screening for SDOH measure (Patient Screening)	2	1	1,600	32,238	1,075	0	1,719,380	-1,719,380
Remove Screening for SDOH measure (Reporting)	10	1	1,600	1	0.167	0	267	-267
Remove Screen Positive for SDOH measure	10	1	1,600	1	0.167	0	267	-267
	Total Change in Information Collection Burden Hours: -1,720,447							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-1,720,447) = **-$44,126,458**							

TABLE 93: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove HCHE measure	10	1	3,200	1	0.167	0	533	-533
Remove Screening for SDOH measure (Patient Screening)	2	1	3,200	64,477	2,149	0	6,877,522	-6,877,522
Remove Screening for SDOH	10	1	3,200	1	0.167	0	533	-533

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2026 Reporting Period							
measure (Reporting)								
Remove Screen Positive for SDOH measure	10	1	3,200	1	0.167	0	533	-533
	Total Change in Information Collection Burden Hours: -6,879,121							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (**-6,879,121**) = **-$176,358,930**							

TABLE 94: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Adopt Emergency Care Access & Timeliness eCQM	10	1	640	1	0.167	107	0	+107
Remove HCHE measure	10	1	3,200	1	0.167	0	533	-533
Remove Screening for SDOH measure (Patient Screening)	2	1	3,200	64,477	2,149	0	6,877,522	-6,877,522
Remove Screening for SDOH measure (Reporting)	10	1	3,200	1	0.167	0	533	-533
Remove Screen Positive for SDOH measure	10	1	3,200	1	0.167	0	533	-533
Modify Excessive Radiation eCQM (Data Submission)	10	1	640	1	0.167	107	1,067	-960
Modify Excessive Radiation eCQM (Login and	15	1	640	1	0.25	160	800	-640

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2027 Reporting Period							
Run Software)								
	Total Change in Information Collection Burden Hours: -6,880,614							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (**-6,880,614**) = **-$176,441,135**							

TABLE 95: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per quarter**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Adopt Emergency Care Access & Timeliness eCQM	10	4	3,200	1	0.67	2,133	0	+2,133
Remove Median Time from ED Arrival to ED Departure for Discharged ED Patients measure	2.9	1	3,200	289	14.2	0	45,440	-45,440
Remove Left Without Being Seen measure	10	1	3,200	1	0.167	0	533	-533
Remove HCHE measure	10	1	3,200	1	0.167	0	533	-533
Remove Screening for SDOH measure (Patient Screening)	2	1	3,200	64,477	2,149	0	6,877,522	-6,877,522
Remove Screening for SDOH measure (Reporting)	10	1	3,200	1	0.167	0	533	-533
Remove Screen Positive for SDOH measure	10	1	3,200	1	0.167	0	533	-533
Modify Excessive Radiation	10	1	640	1	0.167	107	2,133	-2,027

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1109 for the CY 2028 Reporting Period							
eCQM (Data Submission)								
Modify Excessive Radiation eCQM (Login and Run Software)	15	1	640	1	0.25	160	800	-640
	Total Change in Information Collection Burden Hours: -6,924,988							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (**-6,924,988**) = **-$178,884,367**							

TABLE 96: SUMMARY OF PROPOSED HOSPITAL OQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/CY 2026 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-1317 for the CY 2024 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting periods per year**	**Number of HOPDs reporting**	**Average number records per HOPDs per period**	**Annual burden (hours) per HOPD**	**Proposed annual burden (hours) across HOPDs**	**Previously finalized annual burden (hours) across HOPDs**	**Net difference in annual burden hours**
Remove COVID Vaccination Among HCP measure	0.75	12	3,200	1	9	0	28,800	-28,800
	Total Change in Information Collection Burden Hours: -28,800							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-28,800) = **-$1,687,680**							

*For purposes of this table, we state the maximum possible burden across all HOPDs.

B. ICRs for the Rural Emergency Hospital Quality Reporting (REHQR) Program

1. Background

In sections XIV. and XVI. of this proposed rule, we discuss the proposed changes to requirements for the REHQR Program. The REHQR Program is generally aligned with the CMS quality reporting program for HOPDs, known as the Hospital OQR Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94530 through 94533) for detailed discussions of the previously finalized REHQR Program ICRs, which have been submitted for OMB approval under OMB control number 0938-1454 (expiration date April 30, 2027).

In this proposed rule, we propose to: (1) remove the HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination; (2) remove the Screening for SDOH measure beginning with the CY 2025 reporting period; (3) remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period; and (4) adopt the Emergency Care Access & Timeliness eCQM beginning with the CY 2027 reporting period/CY 2029 program determination as an optional measure. In section XIV.D. of this proposed rule, we also propose to update our Extraordinary Circumstances Exception (ECE) Policy for the REHQR Program. This proposed update would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

In the CY 2025 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the REHQR Program by utilizing the BLS mean hourly wage rate for Medical Records Specialists (89 FR 94530). Specifically, we used the industry-specific wage for Medical Records Specialists working in "general medical and surgical hospitals," as this categorization aligns the closest with the REHQR Program care setting. The most recent data from BLS' May 2024 National Occupational Employment and Wage Estimates reflects a median hourly wage of $27.53 per hour for Medical Records Specialists working in "general medical and surgical hospitals" (SOC 29-2072).[330] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median 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 ($27.53 × 2 = $55.06) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified,

[330] U.S. Bureau of Labor Statistics. (2025). Occupational Outlook Handbook, Medical Records Specialists. Available at *https://data.bls.gov/oes/#/industry/622100. Accessed: June 24, 2025.*

we will calculate cost burden to REHs using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this rule for the REHQR Program.

In the CY 2025 OPPS/ASC final rule with comment period, our burden estimates were based on the 33 acute care and critical access hospital conversions to REH status as of September 27, 2024 (89 FR 94530). For this proposed rule, based on the actual number of acute care and critical access hospital conversions to REH status as of April 11, 2025, we estimate that 38 REHs will report data to the REHQR Program during the CY 2026 reporting period unless otherwise noted. While the exact number of REHs required to submit data may vary due to status changes to and from an REH, as reiterated in section XVI. of this proposed rule, REHs are required by statute to submit quality data. Therefore, for purposes of estimating burden, we assume that all 38 REHs will submit data under the REHQR Program for the CY 2026 reporting period and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the HCHE Measure Beginning with the CY 2025 Reporting Period/CY 2027 Program Determination

As discussed in section XIV.C.2. of this proposed rule, we propose to remove the HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination. The information collection burden associated with this measure is currently approved under OMB control number 0938-1454. The currently approved information collection burden estimate for this measure assumes REHs spend approximately 10 minutes (0.167 hours) annually to report measure data. Therefore, for all participating REHs, we estimate removal of this measure would decrease burden by approximately 6 hours (0.167 hours x 38 REHs) at a savings of $349 (6 hours x $55.06/hour).

3. Information Collection Burden Estimate for the Proposed Removal of the Screening for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screening for SDOH measure beginning with the CY 2025 reporting period. 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 have previously estimated 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.

We determine the cost for patients (or their representative) to complete the screening using a post-tax wage of $25.63/hour based on assumptions from the report ''Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices,'' which identifies an approach for valuing time when individuals undertake administrative and other tasks on their own time.[331] 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.[332] 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,[333] 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, would occur outside the scope of their employment.

Under OMB control number 0938-1454, we estimate 11,798 patients annually will be screened per REH when reporting on the measure becomes mandatory. For voluntary reporting in the CY 2025 reporting period, we estimate that 50 percent of REHs will survey 50 percent of patients. Therefore, for all participating REHs with regard to patient screening, we estimate removal of this measure would decrease burden for voluntary reporting for the CY 2025

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[331] Office of the Assistant Secretary for Planning and Evaluation. (2017). Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. Accessed: June 24, 2025.*

[332] Bureau of Labor and Statistics. (2025). Usual Weekly Earnings of Wage and Salary Workers, Fourth Quarter 2025. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf. Accessed: March 3, 2025.*

[333] Guzman, G. & Kollatr, M. (2024). Income in the United States: 2023. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf. Accessed: June 24, 2025.*

reporting period by 3,699 hours for 112,081 patients (0.033 hours x 11,798 patients x 50 percent response rate x 19 REHs) at a savings of $94,797 (3,699 hours x $25.63/hour). For mandatory reporting beginning with the CY 2026 reporting period, we estimate a decrease in burden of 14,795 hours (448,324 patients x 0.033 hours per patient) at a savings of $379,188 (14,795 hours x $25.63/hour). With regard to measure reporting, we estimate a decrease in burden of 3 hours (38 REHs × 50 percent of REHs x 0.167 hours per REH) at a savings of $175 (3 hours × $55.06/hour) for voluntary reporting for the CY 2025 reporting period and 6 hours annually (38 REHs × 0.167 hours) at a savings of $349 (6 hours x $55.06/hour) for mandatory reporting beginning with the CY 2026 reporting period.

4. Information Collection Burden Estimate for the Proposed Removal of the Screen Positive Rate for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period. For this measure, REHs are required to report on an annual basis the number of patients who screen positive for one or more of the five SDOH domains divided by the total number of patients screened (reported as five separate rates). We previously estimated each REH requires 10 minutes (0.167 hours) annually to report this measure. Therefore, we estimate the removal of this measure would decrease burden by 3 hours (38 REHs x 50 percent of REHs x 0.167 hours) at a savings of $175 (3 hours x $55.06/hour) for voluntary reporting for the CY 2025reporting period and 6 hours (38 REHs x 0.167 hours) at a savings of $349 (6 hours x $55.06/hour) annually for mandatory reporting beginning with the CY 2026 reporting period.

5. Information Collection Burden Estimate for the Proposed Adoption of the Emergency Care Access & Timeliness eCQM Beginning with the CY 2027 Reporting Period/CY 2029 Program Determination

As discussed in section XVI.B.1. of this proposed rule, we propose to adopt the Emergency Care Access & Timeliness eCQM beginning with the CY 2027 reporting period/CY

2029 program determination. We refer readers to the discussion of information collection burden associated with the proposal to adopt a similar measure for the Hospital OQR Program in section XXIII.A.6. of this proposed rule. Because this would be the first eCQM adopted in the REHQR Program, we also propose that REHs be provided with the option of reporting either the Median Time for Discharged ED Patients measure or the Emergency Care Access & Timeliness eCQM to meet program requirements. We assume a Medical Records Specialist would require 10 minutes (0.167 hours) to submit the data required per quarter for each REH, therefore, for each REH that elects to report the Emergency Care Access & Timeliness eCQM, we estimate an annual burden of 40 minutes (0.67 hours; 10 minutes x 4 quarters) annually at a cost of $36.92 (0.67 hours x $55.06/hour). Because we are currently unable to estimate the number of REHs that would elect to report the Emergency Care Access & Timeliness eCQM instead of the Median Time for Discharged ED Patients measure, we propose to base our estimate of total burden for the REHQR Program solely on the time to report the Median Time for Discharged ED Patients measure. For reporting the Median Time for Discharged ED Patients measure, we have previously estimated that a Medical Records Specialist would require 12.2 hours per REH annually or 464 hours (12.2 hours x 38 REHs) at a cost of $25,526 (464 hours x $55.06/hour) across all REHs.

6. Summary of Information Collection Burden Estimates for the REHQR Program

Tables 97 through 99 summarizes the information collection burden changes for the REHQR Program. We estimate that the proposals in this proposed rule would result in a decrease of 14,813 hours at a savings of $380,235 for 38 REHs annually from the CY 2025 reporting period through the CY 2027 reporting period. We will submit these information collection estimates to OMB for approval under OMB control number 0938-1454. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis in section XXVI. of this proposed rule).

We invite public comments on the information collection requirements and whether our estimated burden is a reasonable estimate.

TABLE 97: SUMMARY OF PROPOSED REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Remove HCHE measure	10	1	38	1	0.167	0	6	-6
Remove Screening for SDOH measure (Patient Screening)	2	1	19	5,899	196.6	0	3,699	-3,699
Remove Screening for SDOH measure (Reporting)	10	1	19	1	0.167	0	6	-3
Remove Screen Positive for SDOH measure	10	1	19	1	0.167	0	6	-3
	Total Change in Information Collection Burden Hours: -3,711							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-3,711) = **-$95,496**							

TABLE 98: SUMMARY OF PROPOSED REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Remove HCHE measure	10	1	38	1	0.167	0	6	-6
Remove Screening for SDOH measure	2	1	38	11,798	393.3	0	14,795	-14,795

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
(Patient Screening)								
Remove Screening for SDOH measure (Reporting)	10	1	38	1	0.167	0	6	-6
Remove Screen Positive for SDOH measure	10	1	38	1	0.167	0	6	-6
	Total Change in Information Collection Burden Hours: -14,813							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-14,813) = **-$380,235**							

TABLE 99: SUMMARY OF PROPOSED REHQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PROGRAM DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
Adopt Emergency Care Access & Timeliness eCQM	10	4	*	1	0.67	*	*	*
Remove HCHE measure	10	1	38	1	0.167	0	6	-6
Remove Screening for SDOH measure (Patient Screening)	2	1	38	11,798	393.3	0	14,795	-14,795
Remove Screening for SDOH measure (Reporting)	10	1	38	1	0.167	0	6	-6
Remove Screen Positive for	10	1	38	1	0.167	0	6	-6

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1454 for the CY 2027 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of REHs reporting**	**Average number records per REH per quarter**	**Annual burden (hours) per REH**	**Proposed annual burden (hours) across REHs**	**Previously finalized annual burden (hours) across REHs**	**Net difference in annual burden hours**
SDOH measure								
	Total Change in Information Collection Burden Hours: -14,813							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-14,813) = **-$380,235**							

* We do not account for any additional burden associated with this measure as REHs may elect to report the more burdensome Median Time for Discharged ED Patients measure.

C. ICRs for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

1. Background

In sections XIV. and XVII. of this proposed rule, we discuss the proposed requirements for the ASCQR Program. We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94533 through 94537) for detail regarding the previously finalized ASCQR Program ICRs which are currently approved under OMB control number 0938-1270 (expiration date July 31, 2027).

In this proposed rule, we propose to: (1) remove the COVID-19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) remove the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) remove the Screening for SDOH measure beginning with the CY 2025 reporting period; (4) remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period; and (5) adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance measure (Information Transfer PRO-PM) beginning with voluntary reporting for the CY 2027 and CY 2028 reporting periods, followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination.

In section XIV.D. of this proposed rule, we also propose to update our Extraordinary Circumstances Exception (ECE) Policy for the ASCQR Program. This proposed update would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

In the CY 2025 OPPS/ASC final rule with comment period, we calculated reporting burden estimates for the ASCQR Program by utilizing the BLS mean hourly wage rate for Medical Records Specialists (89 FR 94534). Specifically, we used the industry-specific wage for Medical Records Specialists working in the "general medical and surgical hospitals" industry, as this categorization aligns the closest with the ASCQR Program care setting. The most recent data from BLS' May 2024 National Occupational Employment and Wage Estimates reflects a median hourly wage of $27.53 per hour for Medical Records Specialists working in "general medical and surgical hospitals" (SOC 29-2072).[334] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median 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, doubling the hourly wage rate ($27.53 × 2 = $55.06) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to ASCs using a wage plus benefits estimate of $55.06 per hour throughout the discussion in this section of this rule for the ASCQR Program.

Based on the most recent analysis of the CY 2025 payment determination data, we found that, of the 6,012 ASCs that were actively billing Medicare, 4,271 were required to participate in the ASCQR Program. Of the 1,741 ASCs not required to participate in the program, 319 ASCs

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[334] U.S. Bureau of Labor Statistics. (2025). Occupational Outlook Handbook, Medical Records Specialists. Available at: *https://data.bls.gov/oes/#/industry/622100.* Accessed: April 8, 2025.

did so and met full requirements. On this basis, we estimate that 4,590 ASCs (4,271 + 319) would submit data for the ASCQR Program for the CY 2026 reporting period/CY 2028 payment determination and future years.

2. Information Collection Burden Estimate for the Proposed Removal of the COVID–19 Vaccination Coverage Among HCP Measure Beginning with CY 2024 Reporting Period/CY 2026 Payment Determination

As discussed in section XIV.C.1. of this proposed rule, we propose to remove the COVID–19 Vaccination Coverage Among HCP measure beginning with the CY 2024 reporting period/CY 2026 payment determination. The information collection burden associated with this measure is currently approved under OMB control number 0920-1317.

To report this measure, ASCs have the option to manually enter data directly into CDC's NHSN web-based application or to upload a CSV file. CDC estimates that each ASC requires between 40 minutes (0.67 hours) to upload a CSV file and 45 minutes (0.75 hours) monthly to enter the data manually. CDC assumes that manual data entry would be completed by a Microbiologist with a wage rate of $58.60/hour and uploading of a CSV file would be completed by an Information Technologist with a wage rate of $56.50/hour. Therefore, we estimate that this proposal would result in a decrease in burden of between 36,720 hours (0.67 hours x 12 months x 4,590 ASCs) at a savings of $2,074,680 (36,720 hours x $56.50/hour) and 41,310 hours (0.75 hours x 12 months x 4,590 ASCs) at a savings of $2,420,766 (41,310 hours x $58.60/hour) annually across all 4,590 ASCs under OMB control number 0920-1317.

3. Information Collection Burden Estimate for the Proposed Removal of the FCHE Measure Beginning with the CY 2025 Reporting Period/CY 2027 Payment Determination

As discussed in section XIV.C.2. of this proposed rule, we propose to remove the FCHE measure beginning with the CY 2025 reporting period/CY 2027 payment determination. The information collection burden associated with this measure is currently approved under OMB control number 0938-1270.

The currently approved information collection burden estimate for this measure assumes ASCs spend approximately 10 minutes (0.167 hours) annually to report measure data. Therefore, for all participating ASCs, we estimate removal of this measure would decrease burden by approximately 765 hours (0.167 hours x 4,590 ASCs) at a savings of $42,121 (765 hours x $55.06/hour).

4. Information Collection Burden Estimate for the Proposed Removal of the Screening for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screening for SDOH measure beginning with the CY 2025 reporting period. There are two components to this measure's burden calculation: patient screening for five health related social needs domains and ASC submission of aggregated ASC-level measure data. We previously estimated each patient requires 2 minutes (0.033 hours) to complete the screening and each ASC requires 10 minutes (0.167 hours) annually to report this measure. We determine the cost for patients (or their representative) to complete the screening using a post-tax wage of $25.63/hour based on assumptions from 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 administrative and other tasks on their own time.[335] 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.[336] 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,[337] resulting in the post-tax hourly wage rate of $25.63/hour. Unlike

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[335] Office of the Assistant Secretary for Planning and Evaluation. (2017). Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. Accessed: June 24, 2025.*

[336] Bureau of Labor and Statistics. (2025). Usual Weekly Earnings of Wage and Salary Workers, Fourth Quarter 2025. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf. Accessed: March 3, 2025.*

[337] Guzman, G. & Kollatr, M. (2024). Income in the United States: 2023. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf. Accessed: June 24, 2025.*

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, would occur outside the scope of their employment.

Under OMB control number 0938-1270, we estimate an average of 4,765 patients per ASC annually will be screened once the measure becomes mandatory. Therefore, consistent with the burden estimates for this measure under OMB control number 0938-1270, for all participating ASCs with regard to patient screening, we estimate removal of this measure would decrease burden for voluntary reporting for the CY 2025 reporting period by approximately 182,262 hours for 5,467,838 patients (0.033 hours x 4,765 patients x 50 percent response rate x 4,590 ASCs x 50 percent of ASCs) at a savings of $4,671,375 (182,262 hours x $25.63/hour). Beginning with the mandatory reporting for the CY 2026 reporting period, we estimate a decrease in burden of approximately 729,045 hours for 21,871,350 patients (4,765 patients x 4,590 ASCs x 0.033 hours per patient) at a savings of $18,685,423 (729,045 hours x $25.63/hour). With regard to measure reporting, we estimate the removal of this measure would decrease burden for voluntary reporting for the CY 2025 reporting period by 383 hours (4,590 ASCs × 50 percent of ASCs × 0.167 hours per ASC) at a savings of $21,088 (383 hours × $55.06/hour) and 765 hours annually (0.167 hours x 4,590 ASCs) at a savings of $42,121 (765 hours x $55.06/hour) for mandatory reporting beginning with the CY 2026 reporting period.

5. Information Collection Burden Estimate for the Proposed Removal of the Screen Positive Rate for SDOH Measure Beginning with the CY 2025 Reporting Period

In section XIV.C.3. of this proposed rule, we propose to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period. For this measure, ASCs are required to report on an annual basis the number of patients who screen positive for one or more of the five SDOH domains divided by the total number of patients screened (reported as five separate rates). We previously estimated each ASC requires 10 minutes (0.167 hours) annually to report this measure. Therefore, consistent with the burden estimates for this measure under

OMB control number 0938-1270, we estimate the removal of this measure would decrease burden for voluntary reporting for the CY 2025 reporting period by 383 hours (4,590 ASCs × 50 percent of ASCs × 0.167 hours per ASC) at a savings of $21,088 (383 hours × $55.06/hour) and 765 hours annually (0.167 hours x 4,590 ASCs) at a savings of $42,121 (765 hours x $55.06/hour) for mandatory reporting beginning with the CY 2026 reporting period.

6. Information Collection Burden for the Proposed Adoption of the Information Transfer PRO-PM Beginning with Voluntary Reporting for the CY 2027 and CY 2028 Reporting Periods Followed by Mandatory Reporting Beginning with the CY 2029 Reporting Period/CY 2031 Payment Determination

As discussed in section XVII.B.1. of this proposed rule, we propose to adopt the Information Transfer PRO-PM with voluntary reporting for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination. In the CY 2025 OPPS/ASC final rule with comment period, we finalized a similar measure for the Hospital OQR Program (89 FR 94406 through 94413) and discussed our estimates for information collection burden (89 FR 94525); the associated information collection burden is approved under OMB control number 0938-1109 (expiration date January 31, 2026).

The Information Transfer PRO–PM would use patient reported outcome (PRO) data regarding recovery instructions, collected by ASCs through a nine-item survey instrument administered to patients post-operatively. The modes of PRO data collection can include completion of the post-operative surveys electronically. In section XVII.C.1.b, we propose that, for ASCs that anticipate receiving more than 200 completed surveys, these ASCs would have the option to either: (1) survey and report data on their entire eligible Information Transfer PRO–PM patient population, or (2) randomly sample their eligible Information Transfer PRO–PM patient population to collect and report data from 200 completed surveys. As submission rates among facilities may vary, we conservatively estimate that, for voluntary reporting for the CY 2027 and

CY 2028 reporting periods, 50 percent of ASCs (or their third-party vendors) would obtain responses from 30 percent of patients and, beginning with mandatory reporting for the CY 2029 reporting period, ASCs (or their third-party vendors) would obtain responses from 30 percent of patients. To provide an estimate of patient volume for the purposes of calculating the information collection burden associated with this measure, we utilized data derived from the ASC Quality Collaborative (ASCQC) related to ASC patient fall benchmarking data as this metric applies to all patients rather than a subset. Since we expect that ASCs reporting data to the ASCQC will tend to be larger facilities with larger patient populations than non-reporting ASCs, we conservatively estimate that each year approximately 22,326,000 patients (10,433,448 admissions[338] ÷ 2,145 ASCs reporting) × 4,590 ASCs) with an average of 4,864 patients per ASC (22,326,000 admissions ÷ 4,590 ASCs) would be eligible to be screened annually when reporting on the measure becomes mandatory.

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/hr 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.[339] 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/hr.[340] 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

[338] ASC Quality Collaboration. ASC Quality Collaboration Quality Report. Available at *https://ascquality.org/benchmarking/ . Accessed: March 3, 2025.*
[339] Office of the Assistant Secretary for Planning and Evaluation. (2017). Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices. Available at *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework. Accessed: June, 24, 2025.*
[340] Bureau of Labor and Statistics. (2025). Usual Weekly Earnings of Wage and Salary Workers, Fourth Quarter 2025. Available at *https://www.bls.gov/news.release/pdf/wkyeng.pdf. Accessed: March 3, 2025.*

income,[341] resulting in the post-tax hourly wage rate of $25.63/hr. 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, would occur outside the scope of their employment.

We estimate each patient would require an average of 5 minutes (0.083 hours) to complete the survey. For voluntary reporting for the CY 2027 and CY 2028 reporting periods, we estimate a total burden for patients of 279,075 hours (22,326,000 patients × 30 percent response rate × 50 percent of ASCs × 0.083 hours per patient surveyed) at a cost of $7,152,692 (279,075 hours × $25.63/hour). For mandatory reporting beginning with the CY 2029 reporting period, we estimate an annual total burden for patients of 558,150 hours (22,326,000 patients × 30 percent response rate x 0.083 hours per patient) at a cost of $14,305,385 (558,150 hours × $25.63/hour) or $3,117 per ASC ($14,305,385 ÷ 4,590 ASCs).

Measure data would be submitted via the HQR system annually. Similar to the currently approved burden estimate for other web-based measures reported via the HQR system for the ASCQR Program, we estimate a burden of 10 minutes (0.167 hours) per ASC to report measure data. For voluntary reporting for the CY 2027 and CY 2028 reporting periods, we estimate an annual burden for participating ASCs of 383 hours (4,590 HOPDs × 50 percent of ASCs × 0.167 hours) at a cost of $21,088 (383 hours × $55.06/hour). For mandatory reporting beginning with the CY 2029 reporting period, we estimate an annual burden for all ASCs of 765 hours (4,590 ASCs × 0.167 hours) at a cost of $42,121 (765 hours × $55.06/hour).

7. Summary of Information Collection Burden Estimates for the ASCQR Program

Tables 100 through 104 summarizes the information collection burden changes for under OMB control number 0938-1270 (expiration date July 31, 2027). We estimate that the proposals in this proposed rule would result in an overall decrease in information collection burden of

[341] Guzman, G. & Kollatr, M. (2024). Income in the United States: 2023. Available at *https://www2.census.gov/library/publications/2024/demo/p60-282.pdf. Accessed: June, 24, 2025.*

172,425 hours at a savings of $4,464,280 annually for all 4,590 program-eligible ASCs from the CY 2025 reporting period/CY 2027 payment determination through the CY 2029 reporting period/CY 2031 payment determination. We also estimate that the proposals in this proposed rule would result in a decrease in information collection burden of between 36,720 hours at a savings of $2,074,680 and 41,310 hours at a savings of $2,420,766 under OMB control number 0920-1317. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938-1270. With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section XXVI.A. of this proposed rule).

We invite public comments on the information collection requirements and whether our estimated burden is a reasonable estimate.

TABLE 100: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/CY 2027 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2025 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Remove FCHE measure	10	1	4,590	1	0.167	0	765	-765
Remove Screening for SDOH measure (Patient Screening)	2	1	2,295	2,383	79.4	0	182,262	-182,262
Remove Screening for SDOH measure (Reporting)	10	1	2,295	1	0.167	0	383	-383
Remove Screen Positive for SDOH measure	10	1	2,295	1	0.167	0	383	-383
	Total Change in Information Collection Burden Hours: -183,793							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-183,793) = **-$4,755,672**							

TABLE 101: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2026 REPORTING PERIOD/CY 2028 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2026 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Remove FCHE measure	10	1	4,590	1	0.167	0	765	-765
Remove Screening for SDOH measure (Patient Screening)	2	1	4,590	4,765	158.8	0	729,045	-729,045
Remove Screening for SDOH measure (Reporting)	10	1	4,590	1	0.167	0	765	-765
Remove Screen Positive for SDOH measure	10	1	4,590	1	0.167	0	765	-765
	Total Change in Information Collection Burden Hours: -731,340							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-731,340) = **-$18,811,786**							

TABLE 102: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2027 REPORTING PERIOD/CY 2029 PAYMENT DETERMINATION AND CY 2028 REPORTING PERIOD/CY 2030 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 and CY 2028 Reporting Periods							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Adopt Information Transfer PRO-PM (Patient Screening)	5	1	2,295	2,432	202.7	279,075	0	+279,075

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2027 and CY 2028 Reporting Periods							
Adopt Information Transfer PRO-PM (Reporting)	10	1	2,295	1	0.167	383	0	+383
Remove FCHE measure	10	1	4,590	1	0.167	0	765	-765
Remove Screening for SDOH measure (Patient Screening)	2	1	4,590	4,765	158.8	0	729,045	-729,045
Remove Screening for SDOH measure (Reporting)	10	1	4,590	1	0.167	0	765	-765
Remove Screen Positive for SDOH measure	10	1	4,590	1	0.167	0	765	-765
	Total Change in Information Collection Burden Hours: -451,882							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-451,882) = **-$11,638,006**							

TABLE 103: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2029 REPORTING PERIOD

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2029 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting quarters per year**	**Number of ASCs reporting**	**Average number records per ASC per quarter**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Adopt Information Transfer PRO-PM (Patient Screening)	5	1	4,590	4,864	405.3	558,150	0	+558,150
Adopt Information Transfer PRO-PM (Reporting)	10	1	4,590	1	0.167	765	0	+765
Remove FCHE measure	10	1	4,590	1	0.167	0	765	-765
Remove Screening for SDOH measure	2	1	4,590	4,765	158.8	0	729,045	-729,045

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1270 for the CY 2029 Reporting Period							
(Patient Screening)								
Remove Screening for SDOH measure (Reporting)	10	1	4,590	1	0.167	0	765	-765
Remove Screen Positive for SDOH measure	10	1	4,590	1	0.167	0	765	-765
	Total Change in Information Collection Burden Hours: -172,425							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-172,425) = **-$4,464,280**							

TABLE 104: SUMMARY OF PROPOSED ASCQR PROGRAM INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/CY 2026 PAYMENT DETERMINATION

	Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0920-1317 for the CY 2024 Reporting Period							
Activity	**Estimated time per record (minutes)**	**Number of reporting periods per year**	**Number of ASCs reporting**	**Average number records per ASCs per period**	**Annual burden (hours) per ASC**	**Proposed annual burden (hours) across ASCs**	**Previously finalized annual burden (hours) across ASCs**	**Net difference in annual burden hours**
Remove COVID Vaccination Among HCP measure	0.75	12	4,590	1	9	0	41,310	-41,310
	Total Change in Information Collection Burden Hours: -41,310							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (-41,310) = **-$2,420,766**							

*For purposes of this table, we state the maximum possible burden across all ASCs

D. Summary of Information Collection Burden Estimates for the Overall Hospital Quality Star Rating

The Overall Hospital Quality Star Rating uses measures that are publicly reported on Hospital Compare or its successor websites under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Hospital Quality Star Rating, including requesting withholding of measures from public reporting, is already captured in the respective hospital programs' ICRs and represents no increased information collection burden to hospitals.

Therefore, as the Overall Hospital Quality Star Rating utilizes output data from CMS hospital quality and payment programs, there is no additional information collection burden. The burden is accounted for under OMB control numbers 0938-1109, 0938-1022, 0938-1352, 0920-0666, 0938-0981, 0938-1240 and 0938-1197.

E. ICRs for Payer-Specific Negotiated Charges Data Collection

Section XX. of this proposed rule discusses the proposed collection of market-based payment rate information by MS-DRG on the Medicare cost report for cost reporting periods ending on or after January 1, 2026. Hospitals would report the median payer-specific negotiated charge by MS-DRG for payers that are Medicare Advantage Organization (MAOs). We propose to collect this market-based information on new worksheet Supplemental to Form CMS-2552-10, Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet. The required cost report reporting changes to accomplish this collection will be described in more detail in a new Information Collection Request, which is currently under development. However, upon completion of the ICR, we will publish the required 60-day and 30-day notices to solicit public comments in accordance with the requirements of the PRA.

As described further in section XX.C.3. of this proposed rule, for the purposes of reporting the data on the cost report, we propose that hospitals would report the median of the payer-specific negotiated charges for an MS-DRG that the hospital has disclosed for all of its

MAOs on the most recent version of the MRF that the hospital is required to disclose under the hospital price transparency regulations. We believe reporting this market-based information would result in less burden for hospitals given that hospitals are required to make public their payer-specific negotiated charges for the same service packages under the requirements we finalized in the Hospital Price Transparency final rule, which became effective January 1, 2021. We refer readers to the Hospital Price Transparency final rule for the full burden assessment analysis for the requirements set forth within that final rule (84 FR 65524). We also refer readers to section XIX. of this proposed rule, where we propose to amend the hospital price transparency regulations at 45 CFR 180 to require that, beginning January 1, 2026, hospitals would report a new data element, the "median allowed amount," instead of the "estimated allowed amount" reported at present, and that the median allowed amount would be defined as the median of the total allowed amounts that the hospital has historically received from a third-party payer (including MAOs) for an item or service. We refer readers to section XIX. in this proposed rule for more information regarding the specific proposal. For purposes of the market-based rate information we propose to collect on the Medicare cost report, in determining the median of the payer-specific negotiated charges to report on its cost report, if the proposal to amend the regulations at 45 CFR 180 is finalized, the "median allowed amount" would be used for instances in which the payer-specific negotiated charge reported on the MRF is based on a percentage or algorithm. Otherwise, the "estimated allowed amount" (as defined under current regulations) would be used in determining the median of the payer-specific negotiated charges for instances in which the payer-specific negotiated charge is based on a percentage or algorithm. We believe that because hospitals would already be required to publicly report the payer-specific negotiated charge information that they would use to calculate these medians, the additional calculation and reporting of the median payer-specific negotiated charge would result in less burden for hospitals than if hospitals did not already have this information compiled to disclose on the MRF under the hospital price transparency requirements. For additional details on hospital

price transparency requirements, including MRF requirements and the proposed modifications to the hospital price transparency requirements, we refer readers to section XIX. of this proposed rule and *https://www.cms.gov/priorities/key-initiatives/hospital-price-transparency/hospitals*.

Burden hours estimate the time (number of hours) required for each IPPS hospital to complete ongoing data gathering and recordkeeping tasks, search existing data resources, review instructions, and complete the Supplemental to Form CMS-2552-10, Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet. The most recent data from the System for Tracking Audit and Reimbursement, an internal CMS data system maintained by the Office of Financial Management (OFM), reports that 3,038 hospitals, the current number of Medicare certified IPPS hospitals, file Form CMS-2552-10 annually.

In section XX.C.2. of this proposed rule, we propose that subsection (d) hospitals in the 50 states and DC, as defined at section 1886(d)(1)(B) of the Act, and subsection (d) Puerto Rico hospitals, as defined under section 1886(d)(9)(A) of the Act, would be required to report the median payer-specific negotiated charge information. Hospitals that do not negotiate payment rates and only receive non-negotiated payments for service would be exempted from this definition. We note that this proposed data collection requirement would apply to a smaller subset of hospitals as compared to the public reporting requirements under the hospital price transparency regulations. Under our proposal, hospitals that would be exempted from this policy include, Critical Access Hospitals (CAHs), hospitals in Maryland, which are currently paid under the Maryland Total Cost of Care Model, during the performance period of that Model, hospitals operated by an Indian Health Program as defined in section 4(12) of the Indian Health Care Improvement Act, and Federally owned and operated facilities, and non-subsection (d) hospitals. We also note that rural emergency hospitals would not be subject to this proposed data collection requirement given that they do not provide inpatient services. Based on this proposal, we

estimate that 3,038 hospitals (which excludes hospitals described earlier as being exempted from this proposal) would be required to comply with this market-based data collection requirement.

Based on our understanding of the resources necessary to report this information, we estimate an average annual burden per hospital of 20 hours (5 hours for recordkeeping and 15 hours for reporting) for the Supplemental to Form CMS-2552-10: Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet. This estimate includes effort that would be necessary to crosswalk inpatient discharges to an MS-DRG, specifically if a hospital is not familiar with the MS-DRG classification system, for use in calculating the median payer-specific negotiated charges. The burden is minimized because the median payer-specific negotiated charge data that we propose to collect on the Supplemental to Form CMS-2552-10: Weighted Median MAO Payer-Specific Negotiated Charge Data Worksheet is based on payer-specific data that would already be maintained by the hospital, the data from the MRF that hospitals are required to disclose under the hospital price transparency regulations at 45 CFR Part 180. We believe that since hospitals assign the underlying ICD-10-CM principal diagnosis, and any other secondary diagnosis codes and ICD-10-PCS procedure codes, which determine how patients are assigned to an MS-DRG, hospitals are able to associate those items and services to MS-DRGs for each discharge. Additionally, hospitals that are not as familiar with MS-DRGs have access to the most current publicly available version of the CMS Grouper used to group ICD-10 codes to MS-DRGs, and are able to use this software to uniformly group inpatient items and services to MS-DRGs, either initially by proactively using the same Grouper version used by CMS, or retrospectively after an inpatient hospital stay, but prior to submitting this information on the hospital cost report.

We estimate the total annual burden hours as follows: 3,038 hospitals times 20 hours per hospital equals 60,760 annual burden hours.

The 5 hours for recordkeeping include hours for bookkeeping, accounting and auditing clerks; the 15 hours for reporting include accounting and audit professionals' activities. We

believe the basic median calculation would be captured within the recordkeeping portion of this assessment.

Based on the most recent Bureau of Labor Statistics (BLS) in its 2024 Occupation Outlook Handbook, the mean hourly wage for Category 43-3031 (bookkeeping, accounting and auditing clerks) is $25.01 (*https://www.bls.gov/oes/current/oes433031.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $50.02 ($25.01 + $25.01) and multiplied it by 5 hours, to determine the annual recordkeeping costs per hospital to be $250.10 ($50.02 x 5 hours).

The mean hourly wage for Category 13-2011 (accounting and audit professionals) is $44.96 (*www.bls.gov/oes/current/oes132011.htm*). We added 100 percent of the mean hourly wage to account for fringe and overhead benefits, which calculates to $89.92 ($44.96 + $44.96) and multiplied it by 15 hours, to determine the annual reporting costs per hospital to be $1,348.80 ($89.92 x 15 hours). We have calculated the total annual cost per hospital of $1,598.90 by adding the recordkeeping costs of $250.10 plus the reporting costs of $1,348.80 (Table 105). We estimated the total annual cost to be $4,857,458.20 ($1,598.90 x 3,038 IPPS hospitals) (Table 106).

TABLE 105: ESTIMATED ANNUAL COST PER HOSPITAL

Average Hourly Rate Analysis: May 2025	Hours Per Response	BLS Cost Per Hour	Cost Per Hour with Overhead and Fringes	Cost Per Response	Average Hourly Rate
Reporting	15	44.96	89.92	1348.80	
Record Keeping	5	25.01	50.02	250.10	
Third Party Disclosure					
Total	20			1598.90	N/A

TABLE 106: ESTIMATED TOTAL ANNUAL COST

	Currently Approved			Total Requested			Increase/(Decrease) Over Currently Approved	
Respondent Costs	Number of Providers	Per Provider	Total Hours	Number of Providers	Per Provider	Total Hours	Number of Providers	Total
Hours required for CR preparation	3,038	-	-	3,038	20	60,760	-	60,760

Cost for CR preparation						$4,857,458.20		$4,857,458.20

Further instructions for the reporting and complying with this proposed market-based data collection requirement on the Medicare cost report will be discussed in a forthcoming ICR request.

F. ICRs for Medicare OPPS Drug Acquisition Cost Survey

a. Background

In section V.C. of this proposed rule, we discuss our intent to conduct a survey of hospitals' drug acquisition costs. Section 1833(t)(14)(A)(iii) of the Act required the Secretary to set payment rates for specified covered outpatient drugs (SCODs)[342] beginning in 2006 at the amount the Secretary determined to be the average acquisition cost for the drug for that year, at least when certain hospital acquisition cost survey data is available. To collect the cost survey data for the Secretary to use for 2006 payment rates, section 1833(t)(14)(D)(i)(I) of the Act required the Comptroller General of the United States to conduct a survey in each of 2004 and 2005 to determine the hospital acquisition cost for each SCOD. To inform payment rates in later years, section 1833(t)(14)(D)(ii) requires the Secretary periodically to conduct surveys of hospital acquisition costs for each SCOD.

The GAO conducted the required surveys in 2004 and 2005, and, in reporting the results in 2006, recommended that the Secretary thereafter validate, "on an occasional basis—possibly every 5 or 10 years—average sales price (ASP)data that manufacturers report to CMS for developing SCOD payment rates."[343] CMS has not, however, conducted its own survey of the acquisition costs for each SCOD for all hospitals paid under the OPPS. Accordingly, under section 1833(t)(14)(D)(ii) of the Act, we will be conducting a survey, with the survey submission window opening by early CY 2026, of the acquisition costs for each separately payable drug

[342] For the definition of a SCOD, see section 1833(t)(14)(B) of the Act at *https://www.ssa.gov/OP_Home/ssact/title18/1833.htm.*
[343] *https://www.gao.gov/assets/gao-06-372.pdf.*

acquired by all hospitals paid under the OPPS. We intend for the survey to be completed in time for the survey results to be used to inform policy making beginning with the CY 2027 OPPS/ASC proposed rule.

Additionally, on April 18, 2025, President Trump signed Executive Order (E.O.) 14273, "Lowering Drug Prices by Once Again Putting Americans First."[344] Section 5 of the E.O., "Appropriately Accounting for Acquisition Costs of Drugs in Medicare," directs the Secretary of HHS to publish in the **Federal Register** a plan to conduct a survey under section 1833(t)(14)(D)(ii) of the Act so he can determine the hospital acquisition cost for covered outpatient drugs at hospital outpatient departments.

b. OPPS Drug Acquisition Cost Survey Description and Burden Calculation

From January 1, 2026, through March 31, 2026, we intend to survey hospitals paid under the OPPS for their drug acquisition costs, including for SCODs, and drugs and biologicals CMS historically treats as SCODs. The survey is designed to impose the least amount of burden on hospitals as possible while ensuring we capture the required data to inform payment rates as required by statute. As part of this data collection, we will survey hospitals only about drugs that are separately paid under the OPPS and will ask hospitals to report the total acquisition cost, net of all rebates and discounts, of each drug by National Drug Code (NDC) purchased during the 1-year timeframe of July 1, 2024, through June 30, 2025. We are asking hospitals to incorporate all rebates and discounts in their acquisition cost for each NDC, including discounts directly applicable to an individual NDC, but also those discounts that are not necessarily linked to a single NDC, but could be a discount linked to a certain invoice, or discounts linked to purchases made over a certain time period, such as prompt pay discounts, wholesaler discounts, or other discounts. We understand that certain discounts may depend on whether an eligible patient receives the drug. That is true, for example, for drugs acquired through the 340B program. We are therefore asking for hospitals to separately list their acquisition costs for drug NDCs acquired

[344] *https://www.govinfo.gov/content/pkg/FR-2025-04-18/pdf/2025-06837.pdf.*

through the 340B program and those drug NDCs acquired outside of the 340B program in order to ensure that all of the discounts are accurately captured and represent the hospital's acquisition costs. We welcome comments on whether other common drug discount programs have a similar structure or should otherwise also be separately noted.

There are approximately 700 drug HCPCS codes that will be subject to the survey, with most HCPCS codes having multiple NDCs per HCPCS code. With the proposed PRA package, we will publish a draft list of the NDCs that will be included in the survey, if finalized, so hospitals will have ample opportunity to review and prepare to report their acquisition costs for those NDCs. We note there may be slight adjustments to this NDC list, but we expect the final list will be similar to the draft list. We recognize that hospitals may not have acquired all drugs on this list, and hospitals are not expected to provide data for NDCs for which they do not have acquisition cost data. We are collecting acquisition cost data by NDC as we understand most hospitals acquire drugs from wholesalers and manufacturers based on NDCs rather than other identifiers, such as HCPCS billing codes. We expect this method will likely reduce hospital burden, as hospitals can simply report the cost at which they acquired the drug without significant calculations. Additionally, we have designed the survey so that only the total cost and the total units of the drug acquired need to be reported. This means that only two fields of information are required per NDC: total net acquisition cost – non-340B and total units purchased -non-340B. If the same drug NDC is purchased multiple times throughout the given timeframe, only the total cost of all of the drug acquired during the given timeframe plus the total number of units purchased is needed. As we previously discussed, for each NDC, we are asking hospitals to report the total acquisition cost, net of all rebates and discounts, which includes all discounts attributable to each specific NDC as well as those discounts attributable to multiple NDCs. For those discounts received for drugs acquired through the 340B Program, since those discounts may be dependent on whether a 340B eligible patient receives the drug, we are asking for hospitals to separately list their acquisition costs for those drug NDCs acquired through the

340B program and those drug NDCs acquired outside of the 340B program. This means for 340B covered entity hospitals that acquire NDCs through the 340B program, they are to submit up to four fields of information for each NDC depending on their acquisition patterns: total net acquisition cost – non-340B, total units purchased – non-340B, total net acquisition cost 340B, total units purchased 340B.

We will assume the burden of performing any additional calculations. We believe this collection of information is based on common information that the hospital already has in its records from its drug purchase history.

This survey will apply to all hospitals paid under the OPPS, which for purposes of our burden calculations we estimate to be 3,500 hospitals. Based on our understanding of hospital practices, we have estimated the total time for each hospital to respond to this survey to be 73.5 hours, which includes time required to review instructions, gather data (including potentially from hospital wholesalers), perform basic addition calculations, and enter data. As previously mentioned, we will take every practical step to streamline the data collection for each hospital.

We estimated 73.5 hours to complete the survey by aggregating time from the four roles that are most likely to be responsible. These roles are described below:

- A **Top Executive** (11-1000) will likely review the survey request and designate a Submitter prior to survey distribution.
- A **Lawyer** (23-1011) will likely review the survey request, the survey, and requirements for compliance.
- A **Pharmacy Technician** (29-1051) will likely register for the module and apply to fill out the survey. Once the survey is distributed, the Pharmacy Technician will review the survey. Then, the Pharmacy Technician will request data from suppliers, and/or pull data from internal systems, ensure data are in the appropriate format, manually enter data OR upload data into system, review data, make corrections as needed, and certify data.

- A **Pharmacist** (29-2052) will likely review the survey request and data that are pulled by the Pharmacy Technician.

TABLE 107: Estimated Cost for the OPPS Drug Acquisition Cost Survey

Role:	Estimated Hours per Hospital / Survey Response	BLS Cost per Hour ($)	Cost Per Hour with Overhead & Fringes ($)	Cost per Response ($)
Top Executives (11-1000)	0.5	116.99	233.98	116.99
Lawyers (23-1011)	1	108.36	216.72	216.72
Pharmacist (29-1051)	1	70.94	141.88	141.88
Pharmacy Technicians (29-2052)	71	25.2	50.4	3,578.40
			Total Estimated Annual Cost Per Response:	$4,053.93
			Total Estimated Cost Across all Survey Responses:	$4,053.93 * 3,500 hospitals = $14,188,965

As described in Table 107, we estimate the total burden hours as follows: 3,500 hospitals times 73.5 hours per hospital equals 257,250 hours. We used data from the Occupational Employment and Wage Statistics (*Hospital-Specific Wages*) for all salary estimates. In this regard, the previous table presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage for providers that are responsible for completing the survey. We added 100 percent of the mean hourly wage to account for fringe and overhead benefits.

G. ICRs for Hospital Price Transparency

In a final rule published in November 2019 (84 FR 65524) (herein referred to as the CY 2020 HPT final rule), we adopted requirements for hospitals to make public their standard charges in two ways: (1) as a comprehensive machine-readable file (MRF); and (2) in a consumer-friendly format. We codified these requirements at 45 CFR 180.50 and 180.60, respectively.

The proposed changes to the information collection request will be submitted to OMB for review under control number 0938-1369 (CMS-10707). The previously approved requirements

and burden associated with 0938-1369 lapsed due to administrative oversight. Specifically, CMS failed to submit the revisions to 0938-1369 that pertained to the 2024 hospital price transparency requirements in the CY 2024 OPPS/ASC final rule (88 FR 81540). Therefore, we have included the finalized burden mentioned in the CY 2024 OPPS/ASC final rule and the new proposed 2026 OPPS rule in the request for reinstatement.

In the CY 2020 HPT final rule, we originally estimated the number of hospitals to be 6,002. We finalized an initial one-time burden of 150 hours and cost of $11,898.60 per hospital, resulting in a total national burden of 900,300 hours (150 hours × 6,002 hospitals) and $71,415,397 ($11,898.60 × 6,002 hospitals) for hospitals to build processes and make required system updates to make their standard charge information publicly available: (1) as a comprehensive MRF and (2) in a consumer-friendly format. Additionally, we estimated an ongoing annual burden of 46 hours per hospital with a cost of $3,610.88 per hospital, resulting in a total national burden of 276,092 hours (46 hours × 6,002 hospitals) and total cost of $21,672,502 ($3,610.88 × 6,002 hospitals), to make required annual updates to the hospitals' standard charge information. For a detailed discussion of the cost estimates for the requirements related to hospitals making their standard charge information publicly available, we refer readers to our discussion in the collection of information section in the CY 2020 HPT final rule (84 FR 65591 through 65596).

In the CY 2024 OPPS/ASC final rule (88 FR 82080 through 82114), we finalized revisions to the regulations at 45 CFR 180.50 related to making public hospital standard charges in an MRF. First, we finalized adding data elements to be included in the hospital's MRF and to require hospitals to conform to a CMS template layout. Second, to enhance automated access to the MRF, we finalized that hospitals include a .txt file in the root folder of the public website it selects to host its MRF in the form and manner specified by CMS that includes a standardized set of fields, and a link in the footer on its website that is labeled "Hospital Price Transparency" and links directly to the publicly available web page that hosts the link to the MRF.

As explained in the CY 2024 OPPS/ASC final rule, we increased the number of hospitals that we believed to be subject to these requirements from 6,002 to 7,098, which, in turn, increased the estimated national burden. The reason for this increase is because in the CY 2020 HPT final rule (84 FR 65591), we relied on data from the American Hospital Association (AHA).[345] For the collection of information estimates in the CY 2024 OPPS/ASC final rule we used updated hospital numbers based on the publicly available dataset from the Homeland Infrastructure Foundation-Level Data (HIFLD)[346] hospital dataset. The HIFLD dataset compiles a directory of hospital facilities based on data acquired directly from state hospital licensure information and federal sources and validates this data annually. Thus, we stated our belief that the HIFLD dataset is more comprehensive than the AHA Directory. To estimate the number of hospitals subject to these requirements in the CY 2024 OPPS/ASC proposed rule, we leveraged the HIFLD hospital dataset to identify 8,013 total hospitals. We then subtracted 379 hospitals HIFLD identified as "closed" as well as hospitals that are deemed under the regulation to have met requirements (see 45 CFR 180.30) which included 339 federally owned non-military and military hospitals, and 197 state, local, and district run forensic hospitals. We therefore estimated that the CY 2024 OPPS/ASC final rule would apply to 7,098 hospitals operating within the U.S that meet the HPT regulation's definition of "hospital" at 45 CFR 180.20.

In the CY 2024 OPPS/ASC final rule (88 FR 82151) we estimated the total initial one-time burden to implement the CMS standard template and conform to the data dictionary to be 120 hours (5 hours for a Lawyer + 5 hours for a General and Operations Manager + 80 hours for a Business Operations Specialist + 30 hours for a Network and Computer System Administrator) per hospital with a cost of $10,587.10 ($787.40 for a Lawyer + $590.70 for a General and Operations Manager + $6,406.40 for a Business Operations Specialist + $2,802.60 for a Network

[345] American Hospital Association. Fast Facts on U.S. Hospitals, 2019. Available at *https://www.aha.org/statistics/fast-facts-us-hospitals*.

[346] Homeland Infrastructure Foundation-Level Data hospital dataset accessed on May 3, 2023, located at *https://hifld-geoplatform.hub.arcgis.com/maps/9e318142490c4884bf74932af437c6c2/about.*

and Computer System Administrator) per hospital. The initial one-time national burden was calculated to be $75,147,235.80 dollars ($10,587.10 per hospital × 7,098 hospitals). We still believe this estimate to be an accurate estimate of the one-time burden for a new hospital to implement the CMS standard template and conform to the data dictionary. However, CMS is not presently aware of any new hospitals that are beginning operations. We find it challenging to determine the number of new hospitals that are opened each year because distinguishing brand-new hospitals from expansions, new locations, or mergers is inherently arduous. Many hospitals open satellite facilities or rebrand existing ones under similar names, creating ambiguity in identifying independent entities. Additionally, there is no standardized or centralized database that categorizes hospitals based on their origin, and regulatory processes often overlap for new openings, expansions, and mergers, making it difficult to rely on licensing data alone. Complex ownership structures within healthcare systems further blur the lines between new hospitals and extensions of existing networks. Marketing strategies and naming conventions can also mislead public perception, as hospitals often promote new locations as "new" regardless of their operational independence. Finally, data inconsistencies and delays in reporting further complicate efforts to verify whether a hospital is truly new. Because we find it difficult to determine a new hospital, we will still account for the original one-time burden to implement the CMS standard template that we calculated in the CY 2024 OPPS/ASC final rule, but we will no longer account for this one-time burden moving forward.

Additionally, we finalized an estimated ongoing annual national burden of 383,292 hours (54 hours × 7,098 hospitals) and an annual national cost of $32,370,571 dollars ($4,560.52 per respondent × 7,098 hospitals), which represented a $10,698,069 ($32,370,571−$21,672,502) increase over our previous estimated ongoing national annual burden for subsequent years for hospitals to update their standard charge information in the CMS standard template and conform to the data dictionary.

We still believe these hourly estimates are accurate estimates of the ongoing annual burden for hospitals to update their standard charge information in the CMS standard template and conform to the data dictionary. In this proposed rule, we are updating the number of hospitals estimated to be subject to the HPT requirements, providing updated estimates for hospitals to implement new proposed data elements, and updating wage rates for the annual ongoing estimates.

For this proposed rule, we updated the number of hospitals estimated to be subject to the HPT requirements using the same methodology as we did in the CY 2024 OPPS/ASC final rule. There were 8,340 hospitals most recently identified in the HIFLD hospital dataset. We subtracted 374 hospitals HIFLD identified as "closed" as well as hospitals that are deemed under the regulation to have met requirements which included 352 Federally owned non-military and military hospitals, and 198 state, local, and district run forensic hospitals. We therefore estimate that, for this proposed rule, 7,416 hospitals would meet the HPT regulation's definition of "hospital" at 45 CFR 180.2.

We estimated the hourly cost for each labor category used in this analysis by referencing the Bureau of Labor Statistics report on Occupational Employment and Wages (May 2024).[347] We included labor categories for General and Operations Managers, Business Operations Specialists, and Network and Computer Systems Administrators for this proposed rule as we believe these labor categories are associated with the one-time and annual burden related to the implementation of hospital price transparency policies. (See Table 108.)

TABLE 108: OCCUPATION TITLES AND WAGE RATES

Occupational Title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
General and Operations Managers	BLS 11-1021	$64.00	$64.00	$128.00
Business Operations Specialists	BLS 13-1000	$43.76	$43.76	$87.52

[347] U.S. Bureau of Labor Statistics, May 2024 National Occupational Employment and Wage Estimates United States, Occupational Employment and Wage Statistics. Accessed at *https://www.bls.gov/oes/tables.htm.*

Network and Computer Systems Administrators	BLS 15-1244	$48.65	$48.65	$97.30

As discussed in section XIX. of this proposed rule, the "estimated allowed amount" (defined at § 180.20) means the average dollar amount that the hospital has historically received from a third-party payer for an item or service. While we believe that the estimated allowed amount provides useful additional context and enhances transparency and comparability of hospital standard charges, we acknowledge that these average dollar amounts do not necessarily apply to any particular individual, nor do they necessarily represent the actual dollar amount an individual would pay for an item or service. Therefore, we propose to require hospitals to report four new data elements when the standard charge is based on a percentage or algorithm – the median allowed amount (which would replace the estimated allowed amount data element), the tenth percentile allowed amount, the ninetieth percentile allowed amount, and the count of allowed amounts. We also propose to require that hospitals use electronic data interchange (EDI) 835 electronic remittance advice (ERA) transaction data to calculate and encode these values, and we propose to require that hospitals abide by specific instructions regarding the methodology, including the lookback period, that should be used to calculate the median, tenth and ninetieth percentile allowed amounts. We believe that the median, tenth and ninetieth percentile allowed amounts would provide greater context and clarity with respect to the payer-specific negotiated charge, would be a better consumer benchmark than the estimated allowed amount, and better enable price estimator tools to develop and estimate an individual's personalized out-of-pocket cost, enabling MRF users to more easily compare such standard charges across hospitals.

We also propose that beginning January 1, 2026, hospitals must attest in their MRF that they have included all applicable standard charge information in accordance with the requirements of 45 CFR 180.50, and the information encoded is true, accurate, and complete as of the date in the file, and the hospital has included all payer-specific negotiated charges in

dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the MRF, or are not knowable in advance, the hospital would attest that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula. Additionally, we propose that, beginning January 1, 2026, the hospital must encode within the MRF the name of the chief executive officer, president, or senior official designated to oversee the encoding of true, accurate and complete data in the MRF. We believe these proposed requirements would provide the necessary reassurance that hospitals have provided in their MRFs meaningful, accurate information to users of the MRF about their standard charges for health care items and services.

We also propose adding a standard identifier, specifically the National Provider Identifiers (NPIs) to the MRFs. We believe that adding a standard identifier to the file would advance the comparability of the HPT data with other healthcare data, including health plan transparency data from the Transparency in Coverage (TiC) MRFs.

We believe that, by now, hospitals have largely developed standardized processes and procedures for encoding the existing estimated allowed amount and general data elements, like hospital license number, in the MRF and that modifying their existing processes to include the four new data elements related to the proposed allowed amounts and hospital NPI would not entail a significant amount of additional work for hospitals. Furthermore, hospitals are required to encode the affirmation statement in the MRF currently, therefore we believe the additional burden related to the proposed attestation statement is the requirement for hospitals to encode the name of the senior official making the attestation.

We believe hospitals would incur an initial one-time cost to update their processes and systems to (1) identify and collect the newly proposed data elements, and (2) encode the standard

charge information for the newly proposed data elements in the CMS standard template. To implement the proposed requirements, we estimate that it would take a Business Operations Specialist (BLS 13-1000), on average, 4 hours (at a cost of $87.52 per hour) to develop and update the necessary processes and procedures and develop the requirements to implement the proposed data elements and a General and Operations Managers (BLS 11-1021), on average, 1 hour (at a cost of $128.00 per hour) to review the updates.

Therefore, we believe the one-time burden estimate to be 37,080 hours for all hospitals (5 hours × 7,416 hospitals) at a cost of $3,545,441.28 (7,416 hospitals × [($87.52 × 4 hours) + ($128.00 × 1 hour)]); see Table 109. We believe the benefits to users of the MRF of having this additional information would justify the initial one-time burden to hospitals to update their processes and systems to identify and collect the newly proposed data elements and encode the standard charge information for the newly proposed data elements in the CMS standard template.

TABLE 109: SUMMARY OF ONE-TIME BURDEN FOR THE INFORMATION COLLECTIONS

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180.50	0938-1369	7,416	7,416	5	37,080	$3,545,441.28

For the annual burden estimate we rely on our previous assumptions related to labor categories and number of hours as we did in the CY 2024 OPPS/ASC final rule (88 FR 82153). As we previously indicated, we estimate it will take a General and Operations manager 2 hours, per hospital, to review and determine updates in compliance with requirements. We estimate the ongoing time for a Business Operations Specialist to be 40 hours per hospital, to identify and gather the required data elements on an annual basis. We believe that it will take a Computer System Administrator 12 hours to maintain and post the MRF in a manner that conforms to the CMS standard template, which brings the total burden per hospital to 54 hours. Therefore, we estimate a total annual burden of 400,464 hours for all hospitals (7,416 hospitals × 54 hours) at a

cost of $36,519,350.40 (7,416 hospitals × [($128/hour × 2 hours) + ($87.52/hour × 40 hours) + ($97.30/hour × 12 hours)]); see Table 110.

TABLE 110: SUMMARY OF ANNUAL BURDEN FOR THE INFORMATION OF COLLECTIONS

Regulation section	OMB control no.	Number of respondents	Number of responses	Burden per response (hours)	Total annual burden (hours)	Total labor cost of reporting ($)
§ 180	0938-1369	7,416	7,416	54	400,464	$36,519,350.40

XXIII. Files Available to the Public via the Internet

The Addenda to the OPPS/ASC proposed rules and final rules with comment period are published and available via the Internet on the CMS website. In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59154), for CY 2019, we changed the format of the OPPS Addenda A, B, and C by adding a column titled "Copayment Capped at the Inpatient Deductible of $1,364.00" where we flag, through use of an asterisk, those items and services with a copayment that is equal to or greater than the inpatient hospital deductible amount for any given year (the copayment amount for a procedure performed in a year cannot exceed the amount of the inpatient hospital deductible established under section 1813(b) of the Act for that year). In the CY 2022 OPPS/ASC final rule with comment period (85 FR 86266), we updated the format of the OPPS Addenda A, B, and C by adding a column titled "Drug Pass-Through Expiration during Calendar Year" where we flagged, through the use of an asterisk, each drug for which pass-through payment was expiring during the calendar year on a date other than December 31. For CY 2026 and subsequent years, we propose to retain these columns that are updated to reflect the drug codes for which pass-through payment is expiring in the applicable year.

In the CY 2023 OPPS/ASC final rule with comment period (87 FR 72250) for CY 2023, we changed the format of the OPPS Addenda A, B, and C by adding a column titled "Drug Pass-Through Expiration during Calendar Year" to include devices, so that the column reads: "Drug and Device Pass-Through Expiration during Calendar Year" where we flagged, through

the use of an asterisk, each drug and device for which pass-through payment was expiring during the calendar year on a date other than December 31.

For CY 2024, we deleted the column titled "Copayment Capped at the Inpatient Deductible" and instead added a new column for "Adjusted Beneficiary Copayment" to identify any copayment adjustment due to either the inpatient deductible amount copayment cap or the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA). We also added another column for notes. The "Note" column contains multiple messages including, but not limited to, inflation-adjusted copayment of a Part B rebatable drug, the copayment for a code capped at the inpatient deductible, or 8 percent of the reference product add-on applied for a biosimilar.

In addition, for CY 2024, we updated the format of the OPPS Addenda A, B, and C by adding another column for "IRA Coinsurance Percentage" to identify the percentage for the inflation-adjusted copayment of a Part B rebatable drug per section 1833(t)(8)(F) and section 1833(i)(9) of the Act, as added by section 11101 of the Inflation Reduction Act (IRA).

For CY 2026 and subsequent years, we propose to keep the same format for the addenda A, B, and C, and we do not propose any additional changes for CY 2026.

To view the Addenda to this proposed rule pertaining to CY 2026 payments under the OPPS, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient/regulations-notices*; select "CMS-1834-P" from the list of regulations. All OPPS Addenda to this proposed rule are contained in the zipped folder titled "2026 NPRM OPPS Addenda" in the related links section at the bottom of the page. To view the Addenda to this proposed rule pertaining to CY 2026 payments under the ASC payment system, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/ambulatory-surgical-center-asc/asc-regulations-and-notices.* ; select "CMS-1834-P"

from the list of regulations. The ASC Addenda to this proposed rule are contained in a zipped folder titled "2026 NPRM Addendum AA, BB, DD1, DD2, EE, and FF" in the related links section at the bottom of the page.

If you comment on these information collections, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the "ADDRESSES" section of this proposed rule.

Comments must be received by the date and time specified in the "DATES" section of this rule.

XXIV. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble; and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

XXV. Economic Analyses

A. Statement of Need

This proposed rule is necessary to make updates to the Medicare hospital OPPS rates. It is also necessary to make changes to the payment policies and rates for outpatient services furnished by hospitals and CMHCs in CY 2026. We are required under section 1833(t)(3)(C)(ii) of the Act to update annually the OPPS conversion factor used to determine the payment rates for APCs. We also are required under section 1833(t)(9)(A) of the Act to review, not less often than annually, and revise the groups, the relative payment weights, and the wage and other adjustments described in section 1833(t)(2) of the Act. We must review the clinical integrity of payment groups and relative payment weights at least annually. We propose to revise the APC relative payment weights using claims data for services furnished on and after January 1, 2024,

through and including December 31, 2024, and processed through June 30, 2025, and updated HCRIS cost report information.

This proposed rule is also necessary to make updates to the ASC payment rates for CY 2026, enabling CMS to make changes to payment policies and payment rates for covered surgical procedures and covered ancillary services that are performed in ASCs in CY 2026. Because ASC payment rates are based on the OPPS relative payment weights for most of the procedures performed in ASCs, the ASC payment rates are updated annually to reflect annual changes to the OPPS relative payment weights. In addition, we are required under section 1833(i)(1) of the Act to review and update the list of surgical procedures that can be performed in an ASC, not less frequently than every 2 years.

In the CY 2019 OPPS/ASC final rule with comment period (83 FR 59075 through 59079), we finalized a policy to update the ASC payment system rates using the hospital market basket update instead of the CPI-U for CY 2019 through 2023. In the CY 2024 OPPS/ASC final rule with comment period, we finalized a policy to extend the 5-year interim period by an additional 2 years, through CY 2024 and CY 2025, to enable us to more accurately analyze whether the application of the hospital market basket update to the ASC payment system resulted in a migration of services from the hospital setting to the ASC setting (88 FR 81960). As discussed in section XIII. of this proposed rule, we propose to extend our utilization of the hospital market basket update as the update factor for the ASC payment system for one additional year (through CY 2026). The ASC impacts discussed below reflect our application of the hospital market basket update for CY 2026.

In addition, this proposed rule is necessary to make policy changes under rural emergency hospitals (REHs), ASCs reporting data under the Hospital OQR, REHQR, and ASCQR Programs, respectively. The primary objective of these quality reporting programs is to promote higher quality, more efficient health care for Medicare beneficiaries by collection and reporting on quality-of-care metrics. This information is made available to consumers, both to

empower Medicare beneficiaries and inform decision making, as well as to incentivize healthcare facilities to make continued improvements. This rule is also necessary to modify the methodology for the Overall Hospital Quality Star Ratings to emphasize and align the importance of patient safety across CMS programs. The Overall Hospital Quality Star Ratings information is publicly available.

Also, this proposed rule is necessary to enhance clarity and standardization in hospital disclosure of standard charges. The Hospital Price Transparency regulations requiring public release of hospital standard charge information are a necessary and important first step in ensuring transparency in prices of healthcare services for consumers.

B. Overall Impact of Provisions of This Proposed Rule

We have examined the impacts of this 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; and 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, the Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) has determined this rulemaking is significant per section 3(f)(1). Accordingly, we have prepared a Regulatory Impact Analysis that to the best of our ability presents the costs and benefits of the rulemaking. Therefore, OMB has reviewed these proposed regulations, and the Departments have provided the following assessment of their impact.

We estimate that the total increase in Federal Government expenditures under the OPPS for CY 2026, compared to CY 2025, due to the changes to the OPPS in this proposed rule, would be approximately $1.61 billion. Taking into account our estimated changes in enrollment, utilization, and case-mix for CY 2026 we estimate that the OPPS expenditures, including beneficiary cost-sharing, for CY 2026 would be approximately $100.0 billion, which is approximately $8.1 billion higher than estimated OPPS expenditures in CY 2025. Table 112 of this proposed rule displays the distributional impact of the CY 2026 changes in OPPS payment to various groups of hospitals and for CMHCs.

We note that under our proposed CY 2026 policy, drugs and biologicals are generally paid at ASP plus 6 percent, WAC plus 6 percent, or 95 percent of AWP, as applicable.

We estimate that the proposed update to the conversion factor will increase total OPPS payments by 2.4 percent in CY 2026. The proposed changes to the APC relative payment weights, the proposed changes to the wage indexes, the proposed continuation of a payment adjustment for rural SCHs, including EACHs, and the proposed payment adjustment for cancer hospitals would not increase total OPPS payments because these changes to the OPPS are budget neutral. However, these updates would change the distribution of payments within the budget neutral system. We estimate that the total change in payments between CY 2025 and CY 2026,

considering all budget-neutral payment adjustments, changes in estimated total outlier payments, the application of the frontier State wage adjustment, the proposed payment adjustment for drug administration services furnished at excepted off campus PBDs, in addition to the application of the OPD fee schedule increase factor after all adjustments required by sections 1833(t)(3)(F), 1833(t)(3)(G), and 1833(t)(17) of the Act will increase total estimated OPPS payments by 1.9 percent. We note that, as previously discussed in section V.B.7 of this proposed rule, we propose to reduce payments for non-drug items and services for hospitals for whom the annual reduction to payment amounts under § 419.32(b)(1)(iv)(B)(12) applies by 2 percentage points in CY 2026. We estimate that this proposed reduction would reduce OPPS spending by $1.1 billion in CY 2026.

We estimate the total increase (from changes to the ASC provisions in this proposed rule, as well as from enrollment, utilization, and case-mix changes) in Medicare expenditures (not including beneficiary cost-sharing) under the ASC payment system for CY 2026 compared to CY 2025, to be approximately $480 million. Tables 113 and 114 of this proposed rule display the redistributive impact of the CY 2026 changes regarding ASC payments, grouped by specialty area and then grouped by procedures with the greatest ASC expenditures, respectively.

C. Detailed Economic Analyses

1. Estimated Effects of OPPS Changes in this Proposed Rule With Comment Period

a. Limitations of Our Analysis

The distributional impacts presented here are the projected effects of the proposed CY 2026 policy changes on various hospital groups. We post our hospital-specific estimated payments for CY 2026 on the CMS website with the other supporting documentation for this proposed rule. To view the hospital-specific estimates, we refer readers to the CMS website at *https://www.cms.gov/medicare/payment/prospective-payment-systems/hospital-outpatient.* On the website, select "Regulations and Notices" from the left side of the page and then select "CMS-1834-P" from the list of regulations and notices. The hospital-specific file layout and the

hospital-specific file are listed with the other supporting documentation for this proposed rule. We show hospital-specific data only for hospitals whose claims were used for modeling the impacts shown in Table 112 of this proposed rule. We do not show hospital-specific impacts for hospitals whose claims we were unable to use. We refer readers to section II.A. of this proposed rule for a discussion of the hospitals whose claims we do not use for ratesetting or impact purposes.

We estimate the effects of the individual policy changes by estimating payments per service, while holding all other payment policies constant. We use the best data available but do not attempt to predict behavioral responses to our policy changes in order to isolate the effects associated with specific policies or updates, but any policy that changes payment could have a behavioral response. In addition, we have not made any adjustments for future changes in variables, such as service volume, service-mix, or number of encounters.

b. Estimated Effects of the Proposal to Control Unnecessary Increases in the Volume of Outpatient Services Furnished in Excepted Off-Campus Provider Based Departments (PBDs)

In section X.A. of this proposed rule, we discuss our CY 2026 proposal to control for unnecessary increases in the volume of outpatient services by paying for drug administration services furnished at an off-campus PBD at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off- campus PBD (the PFS payment rate). Specifically, we propose to pay for HCPCS codes billed with modifier ‘‘PO’’ and assigned to and paid through drug administration APCs 5691 through 5694 at an amount equal to the site-specific PFS payment rate for nonexcepted items and services furnished by a nonexcepted off-campus PBD (the PFS payment rate). For a discussion of the PFS relativity adjuster that used to pay for all drug administration services provided at all off-campus PBDs, we refer readers to the CY 2018 PFS final rule with comment period discussion (82 FR 53023 through 53024), as well as the CY 2019 PFS proposed rule.

To develop an estimated impact of this proposal, we began with CY 2024 outpatient claims data used, for claim lines with HCPCS codes assigned for payment through drug administration APCs 5691 through 5694 that contained modifier ‘‘PO’’ because the presence of this modifier indicates that such claims were billed for services furnished by an off-campus department of a hospital paid under the OPPS. We then simulated payment for the remaining claim lines as if they were paid at the PFS- equivalent rate, removing a portion of the payment associated with rural Sole Community Hospitals based on our proposed exception for those hospitals. An estimate of the proposed policy that includes the effects of estimated changes in enrollment, utilization, and case-mix based on the FY 2026 Mid-Session review budget approximates the estimated decrease in total payments at $280 million, with Medicare OPPS payments decreasing by $210 million and beneficiary copayments decreasing by $70 million in CY 2026.

This estimate is utilized for the accounting statement displayed in Table 115 of this proposed rule because the impact of this proposed CY 2026 policy, which is not budget neutral, is combined with the impact of the OPD update, which is also not budget neutral, to estimate changes in Medicare spending under the OPPS as a result of the changes proposed in this rule.

We note our estimates may differ from the actual effect of the proposed policy due to offsetting factors, such as changes in provider behavior. We note that by removing this payment differential that may influence site-of-service decision-making, we anticipate an associated decrease in the volume of drug administration services provided in the excepted off-campus PBD setting. We remind readers that this estimate could change in the final rule based on a number of factors such as the availability of updated data, changes in the final payment policy, and/or the method of assessing the payment impact in the final rule. As discussed in more detail in section X.A. of this proposed rule, we are seeking public comment on both our proposed payment policy for drug administration services furnished at off-campus provider-based departments as well as how to apply methods for controlling overutilization of services more broadly.

TABLE 111: ESTIMATED EFFECT OF PROPOSED CHANGES TO DRUG ADMINISTRATION SERVICES WHEN FURNISHED AT EXCEPTED OFF-CAMPUS PROVIDERS (IN $ MILLIONS)

CY	2026	2027	2028	2029	2030	2031	2032	2033	2034	2035	2026 - 2035
Part B Trust Fund benefits	(280)	(780)	(860)	(950)	(1,050)	(1,150)	(1,250)	(1,390)	(1,520)	(1,650)	(10,880)
Premium offset	70	200	210	240	270	290	310	350	380	410	2,730
Net Part B Trust Fund impact	(210)	(580)	(650)	(710)	(780)	(860)	(940)	(1,040)	(1,140)	(1,240)	(8,150)
Beneficiary cost-sharing	(70)	(200)	(210)	(240)	(270)	(290)	(320)	(360)	(390)	(420)	(2,770)

c. Estimated Effects of OPPS Changes on Hospitals

Table 112 shows the estimated impact of the proposed rule on hospitals. Historically, the first line of the impact table, which estimates the change in payments to all facilities, has always included cancer and children's hospitals, which are held harmless to their pre-Balanced Budget Act (BBA) amount. We also include CMHCs in the first line that includes all providers. We include a second line for all hospitals, excluding permanently held harmless hospitals and CMHCs.

We present separate impacts for CMHCs in Table 112, and we discuss them separately below, because CMHCs are paid only for partial hospitalization and intensive outpatient program services under the OPPS and are a different provider type from hospitals. In the CY 2025 OPPS/ASC final rule with comment period (89 FR 94269 through 94270), we finalized paying CMHCs for partial hospitalization services and intensive outpatient services under APCs 5851 through 5854. For CY 2026, we propose to maintain the same APC structure and revise our methodology for calculating APC payment rates. Specifically, we propose to apply the 40 percent Medicare Physician Fee Schedule (MPFS) Relativity Adjuster to calculate PHP and IOP payment rates for CMHCs.

The estimated increase in the total payments made under the OPPS is determined largely by the increase to the conversion factor under the statutory methodology. The distributional impacts presented do not include assumptions about changes in volume and service-mix. The

conversion factor is updated annually by the OPD fee schedule increase factor, as discussed in detail in section II.B. of this proposed rule.

Section 1833(t)(3)(C)(iv) of the Act provides that the OPD fee schedule increase factor is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act, which we refer to as the IPPS market basket percentage increase. The proposed IPPS market basket percentage increase applicable to the OPD fee schedule for CY 2026 is 3.2 percent. Section 1833(t)(3)(F)(i) of the Act reduces that 3.2 percent by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act, which is a proposed 0.8 percentage point for CY 2026 (which is also the productivity adjustment for FY 2026 in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18257)) resulting in the proposed CY 2026 OPD fee schedule increase factor of 2.4 percent. We are using the OPD fee schedule increase factor of 2.4 percent in the calculation of the proposed CY 2026 OPPS conversion factor. Section 10324 of the Affordable Care Act, as amended by HCERA, further authorized additional expenditures outside budget neutrality for hospitals in certain frontier States that have a wage index less than 1.0000. The amounts attributable to this frontier State wage index adjustment are incorporated in the estimates in Table 112 of this proposed rule.

To illustrate the impact of the CY 2026 changes, our analysis begins with a baseline simulation model that uses the CY 2025 relative payment weights, the CY 2025 final OPPS wage indexes that include reclassifications, and the final CY 2025 conversion factor. Table 112 shows the estimated redistribution of the increase or decrease in payments for CY 2026 over CY 2025 payments to hospitals and CMHCs as a result of the following factors: the impact of the APC reconfiguration and recalibration changes between CY 2025 and CY 2026 (Column 2); the wage indexes and the provider adjustments (Column 3); the combined impact of all of the changes described in the preceding columns plus the 2.4 percent OPD fee schedule increase factor update to the conversion factor (Column 4); the additional estimated impact for the proposed payment adjustment for drug administration furnished at excepted off campus PBDs

(Column 5); the estimated impact taking into account all payments for CY 2026 relative to all payments for CY 2025, including the impact of changes in estimated outlier payments and changes to the pass-through payment estimate (Column 6).

We did not model an explicit budget neutrality adjustment for the rural adjustment for SCHs because we propose to maintain the current adjustment percentage for CY 2026. Because the proposed updates to the conversion factor (including the update of the OPD fee schedule increase factor), the estimated cost of the rural adjustment, and the estimated cost of projected pass-through payment for CY 2026 are applied uniformly across services, observed redistributions of payments in the impact table for hospitals largely depend on the mix of services furnished by a hospital (for example, how the APCs for the hospital's most frequently furnished services would change), and the impact of the wage index changes on the hospital. However, total payments made under this system and the extent to which this proposed rule would redistribute money during implementation also will depend on changes in volume, practice patterns, and the mix of services billed between CY 2025 and CY 2026 by various groups of hospitals, which CMS cannot forecast.

Overall, we estimate that the proposed rates for CY 2026 would increase Medicare OPPS payments by an estimated 1.9 percent. Removing payments to cancer and children's hospitals because their payments are held harmless to the pre-OPPS ratio between payment and cost and removing payments to CMHCs results in an estimated 2.0 percent increase in Medicare payments to all other hospitals. These estimated payments would not significantly impact other providers. We note that providers not considered "new providers" for purposes of the 340b remedy offset would receive an adjustment to their OPPS payment rates.

Column 1: Total Number of Hospitals

The first line in Column 1 in Table 112 shows the total number of facilities (3,496), including designated cancer and children's hospitals and CMHCs, for which we were able to use CY 2024 hospital outpatient and CMHC claims data to model CY 2025 and CY 2026 payments,

by classes of hospitals, for CMHCs and for dedicated cancer hospitals. We excluded all hospitals and CMHCs for which we could not plausibly estimate CY 2025 or CY 2026 payment and entities that are not paid under the OPPS. The latter entities include CAHs, IHS and tribal hospitals, and hospitals located in Guam, the U.S. Virgin Islands, Northern Mariana Islands, American Samoa, and the State of Maryland. This process is discussed in greater detail in section II.A. of this proposed rule. At this time, we are unable to calculate a DSH variable for hospitals that are not also paid under the IPPS because DSH payments are only made to hospitals paid under the IPPS. Hospitals for which we do not have a DSH variable are grouped separately and generally include freestanding psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals. We show the total number of OPPS hospitals (3,398), excluding the hold harmless cancer and children's hospitals and CMHCs, on the second line of the table. We excluded cancer and children's hospitals because section 1833(t)(7)(D) of the Act permanently holds harmless cancer hospitals and children's hospitals to their "pre-BBA amount" as specified under the terms of the statute, and therefore, we removed them from our impact analyses. We show the isolated impact on the 31 CMHCs at the bottom of the impact table (Table 112) and discuss that impact separately below.

Column 2: APC Recalibration – All Changes

Column 2 shows the estimated effect of APC recalibration. Column 2 also reflects any changes in multiple procedure discount patterns or conditional packaging that occur as a result of the changes in the relative magnitude of payment weights. As a result of APC recalibration, we estimate that urban hospitals would experience a 0.1 increase, with the impact ranging from no change to an increase of 0.2, depending on the number of beds. Rural hospitals will experience a decrease of 0.4 percent overall. Major teaching hospitals would experience an estimated decrease of 0.1 percent.

Column 3: Wage Indexes and the Effect of the Provider Adjustments

Column 3 demonstrates the combined budget neutral impact of the APC recalibration, the updates for the wage indexes with the FY 2026 IPPS post-reclassification wage indexes, the rural adjustment, the frontier adjustment, and the cancer hospital payment adjustment. We modeled the independent effect of the budget neutrality adjustments and the OPD fee schedule increase factor by using the relative payment weights and wage indexes for each year and using a CY 2025 conversion factor that included the OPD fee schedule increase and a budget neutrality adjustment for differences in wage indexes.

Column 3 reflects the independent effects of the updated wage indexes, including the application of budget neutrality for the rural floor policy on a nationwide basis, as well as the proposed CY 2026 changes in wage index policy, discussed in section II.C. of this proposed rule. We did not model a budget neutrality adjustment for the rural adjustment for SCHs because we propose to continue the rural payment adjustment of 7.1 percent to rural SCHs for CY 2026, as described in section II.E. of this proposed rule. We modeled a budget neutrality adjustment for the proposed cancer hospital payment adjustment because the proposed payment-to-cost ratio target for the cancer hospital payment adjustment in CY 2025 is 0.87, which is the same PCR target adopted in the CY 2025 OPPS/ASC final rule with comment period (89 FR 93979). We note that, in accordance with section 16002 of the 21st Century Cures Act, we propose to apply a budget neutrality factor calculated as if the cancer hospital adjustment target payment-to-cost ratio was 0.88, not the 0.87 target payment-to-cost ratio we propose in section II.F. of this proposed rule with comment period.

We modeled the independent effect of updating the wage indexes by varying only the wage indexes, holding APC relative payment weights, service-mix, and the rural adjustment constant and using the CY 2026 scaled weights and a CY 2025 conversion factor that included a budget neutrality adjustment for the effect of the changes to the wage indexes between CY 2025 and CY 2026.

Column 4: All Budget Neutrality Changes Combined with the Market Basket Update

Column 4 demonstrates the combined impact of all the proposed changes previously described and the update to the conversion factor of 2.4 percent. Overall, these changes would increase payments to urban hospitals by 2.6 percent and to rural hospitals by 2.5 percent. Rural sole community hospitals would receive an estimated increase of 2.7 percent while other rural hospitals would receive an estimated increase of 2.1 percent.

Column 5—Proposed Off-Campus PBD Drug Administration Payment Policy

Column 5 displays the estimated effect of our proposed CY 2026 policy to pay for drug administration services assigned to APCs 5691 through 5694 when billed with modifier ‘‘PO’’ at a PFS-equivalent rate. We note that the numbers provided in this column isolate the estimated effect of this proposed policy adjustment relative to the numerator of Column 4. Therefore, the numbers reported in Column 5 show how much of the difference between the estimates in Column 4 and the estimates in Column 6 are a result of the proposed off-campus PBD visits policy.

Column 6: All Changes with Outlier – Proposed CY 2026 Update

Column 6 depicts the full impact of the proposed CY 2026 policies on each hospital group by including the effect of all changes for CY 2026 and comparing them to all estimated payments in CY 2025. Column 6 shows the combined budget neutral effects of Columns 2 and 3; the effect of the proposed off-campus provider-based department drug administration policy; the OPD fee schedule increase; the impact of estimated OPPS outlier payments, as discussed in section II.G of proposed rule; the Hospital OQR Program payment reduction for the small number of hospitals in our impact model that failed to meet the reporting requirements (discussed in section XV. of this proposed rule); and other rule adjustments to the CY 2026 OPPS payments.

Of those hospitals that failed to meet the Hospital OQR Program reporting requirements for the full CY 2025 update (and assumed, for modeling purposes, to be the same number for

CY 2026), we included 79 hospitals in our model because they had both CY 2024 claims data and recent cost report data. We estimate that the cumulative effect of all changes for CY 2026 would increase payments to all facilities by 1.9 percent for CY 2026. We modeled the independent effect of all changes in Column 6 using the final relative payment weights for CY 2025 and the proposed relative payment weights for CY 2026. We used the final conversion factor for CY 2025 of $89.169 and a CY 2026 conversion factor of $91.747 discussed in section II.B. of this proposed rule.

Column 6 contains simulated outlier payments for each year. We used the 1-year charge inflation factor used in the FY 2026 IPPS/LTCH PPS final rule (90 FR 18434) of 5.4 percent (1.05440) to increase charges on the CY 2024 claims, and we used the overall CCR in the April 2025 Outpatient Provider-Specific File (OPSF) to estimate outlier payments for CY 2025. Using the CY 2024 claims and a 5.4 percent charge inflation factor, we currently estimate that outlier payments for CY 2025, using a multiple threshold of 1.75 and a fixed-dollar threshold of $7,750, would be approximately 0.92 percent of total payments. The estimated current outlier payments of 0.92 percent are incorporated in the comparison in Column 5. We used the same set of claims and a charge inflation factor of 11.2 percent (1.1118) and the CCRs in the April 2025 OPSF, with an adjustment of 0.970113 (90 FR 18435), to reflect relative changes in cost and charge inflation between CY 2025 and CY 2026, to model the proposed CY 2026 outliers at 1.0 percent of estimated total payments using a multiple threshold of 1.75 and a fixed dollar threshold of $6,450. The charge inflation and CCR inflation factors are discussed in detail in the FY 2026 IPPS/LTCH PPS proposed rule (90 FR 18434 through 18435).

Overall, we estimate that facilities would experience an increase of 1.9 percent under this proposed rule in CY 2026 relative to total spending in CY 2025. This projected increase (shown in Column 6) of Table 112 of this proposed rule reflects the proposed 2.4 percent OPD fee schedule increase factor, adding the 0.08 difference in estimated outlier payments between CY 2025 (0.92 percent) and CY 2026 (1.0 percent), minus 0.22 percent for the change in the

pass-through payment estimate between CY 2025 and CY 2026. We estimate that the combined effect of all changes for CY 2026 would increase payments to urban hospitals by 2.0 percent. Overall, we estimate that rural hospitals would experience a 2.0 percent increase as a result of the combined effects of all the changes for CY 2026.

Among hospitals, by teaching status, we estimate that the impacts resulting from the combined effects of all changes include an increase of 1.7 percent for major teaching hospitals and an increase of 2.2 percent for nonteaching hospitals. Minor teaching hospitals would experience an estimated increase of 2.2 percent.

In our analysis, we also have categorized hospitals by type of ownership. Based on this analysis, we estimate that voluntary hospitals would experience an increase of 2.0 percent, proprietary hospitals would experience an increase of 2.6 percent, and governmental hospitals would experience an increase of 2.0 percent.

Reduction for Providers Subject to the 340B Remedy Offset

In column 7 we have included additional information to account for estimated changes in the CY 2026 OPPS for providers subject to the 340B Remedy Offset.

TABLE 112: ESTIMATED IMPACT OF THE PROPOSED CY 2026 CHANGES FOR SERVICES PROVIDED IN THE HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Proposed Payment Adjustment for Drug Admin at Off Campus Providers**	**All Changes with Outlier Proposed CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
ALL PROVIDERS *		3,496	0.0	0.1	2.5	-0.3	**1.9**	-1.9
ALL HOSPITALS		3,398	0.1	0.1	2.6	-0.3	**2.0**	-1.9
	(excludes hospitals held harmless and CMHCs)							

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Proposed Payment Adjustment for Drug Admin at Off Campus Providers**	**All Changes with Outlier Proposed CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
URBAN HOSPITALS	2,710	0.1	0.1	2.6	-0.3	**2.0**	-1.9
LARGE URBAN (GT 1 MILL.)	1,274	0.1	-0.2	2.3	-0.3	**1.9**	-1.9
OTHER URBAN (LE 1 MILL.)	1,436	0.1	0.3	2.8	-0.2	**2.2**	-1.9
RURAL HOSPITALS	688	-0.4	0.4	2.5	-0.1	**2.0**	-1.9
SOLE COMMUNITY	337	-0.4	0.7	2.7	0.0	**2.2**	-1.9
OTHER RURAL	351	-0.4	0.0	2.1	-0.2	**1.5**	-1.9
BEDS (URBAN)							
0 - 99 BEDS	931	0.1	0.4	2.9	-0.2	**2.3**	-1.8
100-199 BEDS	742	0.2	0.0	2.6	-0.1	**2.2**	-1.9
200-299 BEDS	417	0.2	-0.1	2.5	-0.1	**2.1**	-1.9
300-499 BEDS	384	0.2	0.0	2.7	-0.3	**2.1**	-1.9
500 + BEDS	236	0.0	0.1	2.5	-0.4	**1.8**	-1.9
BEDS (RURAL)							
0 - 49 BEDS	330	-0.6	0.6	2.4	0.0	**1.9**	-1.9
50- 100 BEDS	198	-0.4	0.5	2.5	-0.1	**1.9**	-1.9
101- 149 BEDS	88	-0.4	0.3	2.3	0.0	**2.0**	-2.0
150- 199 BEDS	41	-0.2	0.3	2.5	-0.3	**1.7**	-1.9
200 + BEDS	31	-0.2	0.4	2.6	-0.1	**2.3**	-2.0
REGION (URBAN)							
NEW ENGLAND	121	-0.1	-1.1	1.2	-0.4	**0.7**	-1.9
MIDDLE ATLANTIC	290	-0.1	-0.1	2.2	-0.3	**1.8**	-1.9
SOUTH ATLANTIC	443	0.2	-0.3	2.3	-0.2	**1.9**	-1.9
EAST NORTH CENT.	415	0.0	-0.3	2.1	-0.4	**1.5**	-1.9
EAST SOUTH CENT.	171	0.0	-0.3	2.1	-0.3	**1.6**	-1.9
WEST NORTH CENT.	178	0.1	2.4	4.9	-0.3	**3.6**	-1.9
WEST SOUTH CENT.	441	0.3	0.0	2.8	-0.1	**2.5**	-1.9
MOUNTAIN	224	0.3	1.0	3.7	-0.2	**2.8**	-1.9
PACIFIC	379	0.2	0.2	2.8	-0.3	**2.4**	-1.9
PUERTO RICO	48	-0.3	-3.3	-1.3	0.0	**-1.5**	-1.8

	(1)	(2)	(3)	(4)	(5)	(6)	(7)
	Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Proposed Payment Adjustment for Drug Admin at Off Campus Providers**	**All Changes with Outlier Proposed CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
REGION (RURAL)							
NEW ENGLAND	20	-0.1	1.5	3.8	0.0	**3.7**	-1.9
MIDDLE ATLANTIC	49	-0.4	-0.2	1.8	-0.1	**1.5**	-1.9
SOUTH ATLANTIC	109	-0.5	-0.1	1.8	-0.2	**1.4**	-2.0
EAST NORTH CENT.	113	-0.4	-0.5	1.5	-0.2	**1.1**	-1.9
EAST SOUTH CENT.	131	-0.5	-0.9	0.9	-0.1	**0.6**	-2.0
WEST NORTH CENT.	74	-0.2	2.5	4.7	0.0	**3.7**	-1.9
WEST SOUTH CENT.	125	-0.3	-0.2	1.9	0.0	**1.7**	-1.9
MOUNTAIN	41	-0.4	2.7	4.8	0.0	**3.1**	-1.9
PACIFIC	24	-0.7	0.6	2.3	0.0	**2.2**	-1.9
PUERTO RICO	2	-0.4	-1.8	0.1	0.0	**-0.1**	-2.0
TEACHING STATUS							
NON-TEACHING	2,051	0.0	0.2	2.6	-0.1	**2.2**	-1.9
MINOR	896	0.2	0.2	2.8	-0.2	**2.2**	-1.9
MAJOR	451	-0.1	0.0	2.3	-0.4	**1.7**	-1.9
DSH PATIENT PERCENT							
0	6	2.1	-1.7	2.9	0.0	**1.8**	-1.5
GT 0 - 0.10	224	0.4	0.0	2.7	-0.1	**2.2**	-1.9
0.10 - 0.16	217	0.3	-0.2	2.5	-0.1	**2.1**	-1.9
0.16 - 0.23	528	0.3	0.1	2.8	-0.1	**2.4**	-1.9
0.23 - 0.35	1,128	0.0	0.3	2.7	-0.2	**2.2**	-1.9
GE 0.35	870	-0.2	0.0	2.2	-0.4	**1.7**	-1.9
DSH NOT AVAILABLE **	425	3.5	-0.5	5.5	0.0	**5.3**	-1.8
URBAN TEACHING/DSH							
TEACHING & DSH	1,183	0.1	0.1	2.6	-0.3	**2.0**	-1.9
NO TEACHING/DSH	1,122	0.1	0.1	2.6	-0.1	**2.2**	-1.9
NO TEACHING/NO DSH	6	2.1	-1.7	2.9	0.0	**1.8**	-1.5
DSH NOT AVAILABLE2	399	3.6	-0.5	5.6	0.0	**5.4**	-1.8

		(1)	(2)	(3)	(4)	(5)	(6)	(7)
		Number of Hospitals	**APC Recalibration (all changes)**	**New Wage Index and Provider Adjustments**	**All Budget Neutral Changes (combined cols 2 & 3) with Market Basket Update**	**Proposed Payment Adjustment for Drug Admin at Off Campus Providers**	**All Changes with Outlier Proposed CY 2026 Update**	***Reduction for Providers Subject to the 340B Remedy Offset***
TYPE OF OWNERSHIP								
	VOLUNTARY	1,966	0.0	0.1	2.5	-0.3	**2.0**	-1.9
	PROPRIETARY	1,015	0.8	-0.2	3.0	0.0	**2.6**	-1.9
	GOVERNMENT	417	-0.1	0.2	2.5	-0.3	**2.0**	-1.9
CMHCs		31	-0.6	-1.0	0.8	0.0	**0.6**	-0.3

Column (1) shows total hospitals and/or CMHCs.

Column (2) includes all proposed CY 2026 OPPS policies and compares those to the CY 2025 OPPS.

Column (3) shows the budget neutral impact of updating the wage index by applying the FY 2026 hospital inpatient wage index. The rural SCH adjustment proposes to continue our current policy of 7.1 percent so the budget neutrality factor is 1. The proposed budget neutrality adjustment for the cancer hospital adjustment is 1.0000 because the proposed CY 2026 target payment-to-cost ratio is the same as the CY 2025 PCR target.

Column (4) shows the impact of all budget neutrality adjustments and the addition of the proposed 2.4 percent OPD fee schedule update factor (3.2 percent reduced by 0.8 percentage points for the productivity adjustment).

Column (5) shows the separate impact of the proposed payment adjustment for drug administration services furnished at excepted off campus providers.

Column (6) shows the additional adjustments to the conversion factor resulting from a change in the pass-through estimate and adding estimated outlier payments. Note that previous years included the frontier adjustment in this column, but we have included the frontier adjustment to Column 3 in this table.

The column for the 340B Providers shows the separate impact of applying the 2.0 percentage point reduction to the OPPS conversion factor update as part of the 340B Remedy Offset.

These 3,496 providers include children and cancer hospitals, which are held harmless to pre-BBA amounts, and CMHCs.

We estimate that 3,270 providers would be subject to the reduction to payments that result from the 340B remedy offset.

** Complete DSH numbers are not available for providers that are not paid under IPPS, including rehabilitation, psychiatric, and long-term care hospitals.

d. Estimated Effects of OPPS Changes on CMHCs

The last line of Table 112 demonstrates the isolated impact on CMHCs, which furnished only partial hospitalization and intensive outpatient program services under the OPPS during CY 2024. As discussed in section VIII.C. of this proposed rule, we propose for CY 2026 to continue paying CMHCs using APCs 5851 through 5854. We modeled the impact of this APC policy, assuming CMHCs will continue to provide the same PHP and IOP care as seen in the CY 2024 claims used for ratesetting in the proposed rule. We did not exclude days with one or two

services from our modeling for CY 2026, because our proposed rule policy would pay the per diem rate for APC 5853 for such days in CY 2026. As a result of the proposed PHP APC changes for CMHCs, we estimate that CMHCs would experience a 0.6 percent decrease in CY 2026 payments relative to their CY 2025 payments (shown in Column 2). For a detailed discussion of our proposed PHP and IOP policies, please see section VIII. of this proposed rule.

Column 3 shows the estimated impact of adopting the proposed FY 2026 wage index values, which result in an estimated decrease of 1.0 percent to CMHCs.

Column 4 shows that combining the OPD fee schedule increase factor, along with the proposed changes in APC policy for CY 2026 and the proposed FY 2026 wage index updates, would result in an estimated increase of 0.8 percent.

e. Estimated Effect of OPPS Changes on Beneficiaries

For services for which the beneficiary pays a copayment of 20 percent of the payment rate, the beneficiary's payment would increase for services for which the OPPS payments would rise and decrease for services for which the OPPS payments would fall. For further discussion of the calculation of the national unadjusted copayments and minimum unadjusted copayments, we refer readers to section II.H of this proposed rule. In all cases, section 1833(t)(8)(C)(i) of the Act limits beneficiary liability for copayment for a procedure performed in a year to the hospital inpatient deductible for the applicable year.

We estimate that the aggregate beneficiary coinsurance percentage would be approximately 18 percent for all services paid under the OPPS in CY 2026. The estimated aggregate beneficiary coinsurance reflects general system adjustments. We note that the individual payments, and therefore copayments, associated with services may differ based on the setting in which they are furnished. However, at the aggregate system level, we do not currently observe significant impact on beneficiary coinsurance as a result of those policies.

f. Estimated Effects of OPPS Changes on Other Providers

The relative payment weights and payment amounts established under the OPPS affect the payments made to ASCs, as discussed in section XIII. of this proposed rule. Hospitals, CMHCs, and ASCs would be affected by the changes in this proposed rule. Additionally, the payment policies we established for IOP services affect RHCs and FQHCs. These providers of IOP are not paid under the OPPS and are not included in the impact analysis shown in Table 112. However, the proposed payment amount for OPPS APC 5861 would affect payments to RHCs and FQHCs since under sections 1834(o)(5)(A) and 1834(y)(3)(A) of the Act payment for IOP services in these settings is required to be equal to the payment determined for IOP services in the hospital outpatient department.

g. Estimated Effects of OPPS Changes on the Medicare and Medicaid Programs

The effect of the update on the Medicare program is expected to be an increase of $1.61 billion in program payments for OPPS services furnished in CY 2026. The effect on the Medicaid program is expected to be limited to copayments that Medicaid may make on behalf of Medicaid recipients who are also Medicare beneficiaries. We estimate that the changes in this proposed rule would increase these Medicaid beneficiary payments by approximately $130 million in CY 2026. Currently, there are approximately 11.5 million dual-eligible beneficiaries, which represent approximately 40 percent of Medicare Part B fee-for-service beneficiaries. The impact on Medicaid was determined by taking 40 percent of the beneficiary cost-sharing impact. The national average split of Medicaid payments is 58 percent Federal payments and 42 percent State payments. Therefore, for the estimated $130 million Medicaid increase, approximately $75 million would be from the Federal Government and $55 million will be from State governments.

h. Alternative OPPS Policies Considered

Alternatives to the OPPS changes we proposed and the reasons for our selected alternatives are discussed throughout this proposed rule.

Alternatives Considered for the Proposed Payment Policy for Skin Substitute Products

We considered several alternatives to our proposal to group skin substitute products based on FDA regulatory category. For example, we considered grouping skin substitute products based on their composition (for example, whether they are non-synthetic or synthetic) or by graft type (e.g. allograft or xenograft). We also considered grouping all products together to set a single payment rate or creating new categories reflecting product cost, similar to our current payment policy. All of these alternatives considered would be implemented in a budget neutral manner and would involve unpackaging the current costs of skin substitute products from the application procedures, resulting in separate payments for skin substitute products under the OPPS and ASC.

2. Estimated Effects of CY 2026 ASC Payment System Changes

Most ASC payment rates are calculated by multiplying the ASC conversion factor by the ASC relative payment weight. As discussed fully in section XIII. of this proposed rule, we are setting the CY 2026 ASC relative payment weights by scaling the proposed CY 2026 OPPS relative payment weights by the proposed CY 2026 ASC scalar of 0.842. The estimated effects of the updated relative payment weights on payment rates are varied and are reflected in the estimated payments displayed in Tables 113 and 114.

Beginning in CY 2011, section 3401 of the Affordable Care Act requires that the annual update to the ASC payment system after application of any quality reporting reduction be reduced by a productivity adjustment. In CY 2019, we adopted a policy for the annual update to the ASC payment system to be the hospital market basket update for CY 2019 through CY 2023. In the CY 2024 OPPS/ASC final rule with comment period, we extended this 5-year interim period an additional 2 years through CYs 2024 and 2025. As discussed in further detail in section XIII. of this proposed rule, we propose to extend our utilization of the hospital market basket update as the update factor to the ASC payment system one additional year (through CY 2026). Section 1886(b)(3)(B)(xi)(II) of the Act defines the productivity adjustment to be 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). For ASCs that fail to meet their quality reporting requirements, the CY 2026 payment determinations would be based on the application of a 2.0 percentage point reduction to the hospital market basket update for CY 2026. We calculated the proposed CY 2026 ASC conversion factor by adjusting the CY 2025 ASC conversion factor by 0.9999 to account for changes in the pre-floor and pre-reclassified hospital wage indexes between CY 2025 and CY 2026, which includes our policy to limit wage index declines of greater than 5 percent, and by applying the CY 2026 hospital market basket update factor of 2.4 percent (which is equal to the proposed inpatient hospital market basket percentage increase of 3.2 percent reduced by a proposed productivity adjustment of 0.8 percentage point). The proposed CY 2026 ASC conversion factor is $56.207 for ASCs that successfully meet the quality reporting requirements.

a. Limitations of Our Analysis

Presented here are the projected effects of the proposed changes for CY 2026 on Medicare payment to ASCs. A key limitation of our analysis is our inability to predict changes in ASC service-mix between CY 2024 and CY 2026 with precision. We believe the net effect on Medicare expenditures resulting from the proposed CY 2026 changes would be small in the aggregate for all ASCs. However, such changes may have differential effects across surgical specialty groups, as ASCs continue to adjust to the payment rates based on the policies of the revised ASC payment system. We are unable to accurately project such changes at a disaggregated level. Clearly, individual ASCs would experience changes in payment that differ from the aggregated estimated impacts presented below.

b. Estimated Effects of ASC Payment System Policies on ASCs

Some ASCs are multispecialty facilities that perform a wide range of surgical procedures from excision of lesions to hernia repair to cataract extraction; others focus on a single specialty and perform only a limited range of surgical procedures, such as ophthalmology, digestive

system, or orthopedic procedures. The combined effect of the proposed update to the payments on an individual ASC would depend on a number of factors, including, but not limited to, the mix of services the ASC provides, the volume of specific services provided by the ASC, the percentage of its patients who are Medicare beneficiaries, and the extent to which an ASC provides different services in the coming year. The following discussion includes tables that display estimates of the impact of the proposed CY 2026 updates to the ASC payment system on Medicare payments to ASCs, assuming the same mix of services, as reflected in our CY 2024 claims data. Table 113 depicts the estimated aggregate percent change in payment by surgical specialty or ancillary items and services group by comparing estimated CY 2025 payments to estimated CY 2026 payments, and Table 114 shows a comparison of estimated CY 2025 payments to estimated CY 2026 payments for items and procedures that we estimate would receive the most Medicare payment in CY 2025.

In Table 113, we have aggregated the surgical HCPCS codes by specialty group, grouped all HCPCS codes for covered ancillary items and services into a single group, and then estimated the effect on aggregated payment for surgical specialty and ancillary items and services groups. The groups are sorted for display in descending order by estimated Medicare program payment to ASCs. The following is an explanation of the information presented in Table 113.

● Column 1—Surgical Specialty or Ancillary Items and Services Group indicates the surgical specialty into which ASC procedures are grouped and the ancillary items and services group, which includes all HCPCS codes for covered ancillary items and services. To group surgical procedures by surgical specialty, we used the CPT code range definitions and Level II HCPCS codes and Category III CPT codes, as appropriate, to account for all surgical procedures to which the Medicare program payments are attributed.

● Column 2—Estimated CY 2025 ASC Payments were calculated using CY 2024 ASC utilization data (the most recent full year of ASC utilization) and CY 2025 ASC payment rates.

The surgical specialty groups are displayed in descending order based on estimated CY 2025 ASC payments.

● Column 3—Estimated CY 2026 Percent Change is the aggregate percentage increase or decrease in Medicare program payment to ASCs for each surgical specialty or ancillary items and services group that is attributable to proposed updates to ASC payment rates for CY 2026 compared to CY 2025.

As shown in Table 113, for the six specialty groups that account for the most ASC utilization and spending, we estimate that the proposed update to ASC payment rates for CY 2026 would result in a 2 decrease in aggregate payment amounts for eye and ocular adnexa procedures, a 1 percent increase in aggregate payment amounts for musculoskeletal system procedures, a 3 percent increase in aggregate payment amounts for nervous system procedures, a 3 percent increase in aggregate payment amounts for digestive system procedures, a 12 percent increase in aggregate payment amounts for cardiovascular system procedures, and an 18 percent increase in aggregate payment amounts for genitourinary system procedures. We note that these changes can be a result of different factors, including updated data, payment weight changes, and changes in policy. In general, spending in each of these categories of services is increasing due to the 2.4 percent payment rate update. After the payment rate update is accounted for, aggregate payment increases or decreases for a category of services can be higher or lower than a 2.4 percent increase, depending on if payment weights in the OPPS APCs that correspond to the applicable services increased or decreased or if the most recent data show an increase or a decrease in the volume of services performed in an ASC for a category. For example, we estimate a 2 percent decrease in eye surgical procedure payments. The decrease in expenditures for eye surgical procedures is largely a result of a relative decline in the OPPS relative weights for the Level 1 Intraocular Procedures APC which is attributable to the relative decline in hospital geometric mean costs for procedures assigned to this APC. The large increase in cardiovascular and genitourinary procedures is a result of higher APC level assignment in the

OPPS of newer peripheral vascular procedures and prostate biopsy procedure codes compared to prior vascular and prostate biopsy procedure codes. For estimated changes for selected procedures, we refer readers to Table 113.

TABLE 113: ESTIMATED IMPACT OF THE CY 2026 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE CY 2025 MEDICARE PROGRAM PAYMENTS BY SURGICAL SPECIALTY OR ANCILLARY ITEMS AND SERVICES GROUP

Surgical Specialty Group (1)	Estimated CY 2025 ASC Payments (in Millions) (2)	Estimated CY 2026 Percent Change (3)
Total	$7,738	2
Eye	$2,081	-2
Musculoskeletal	$1,747	1
Nervous System	$1,588	3
Gastrointestinal	$1,065	3
Cardiovascular	$487	12
Genitourinary	$314	18

Table 114 shows the estimated impact of the updates to the revised ASC payment system on aggregate ASC payments for selected surgical procedures during CY 2026. The table displays 30 of the procedures receiving the greatest estimated CY 2025 aggregate Medicare payments to ASCs. The HCPCS codes are sorted in descending order by estimated CY 2025 program payment.

● Column 1–CPT/HCPCS code.

● Column 2–Short Descriptor of the HCPCS code.

● Column 3–Estimated CY 2025 ASC Payments were calculated using CY 2024 ASC utilization (the most recent full year of ASC utilization) and the CY 2025 ASC payment rates. The estimated CY 2025 payments are expressed in millions of dollars.

● Column 4–Estimated CY 2026 Percent Change reflects the percent differences between the estimated ASC payment for CY 2025 and the estimated payment for CY 2026 based on the proposed update.

TABLE 114: ESTIMATED IMPACT OF THE PROPOSED CY 2026 UPDATE TO THE ASC PAYMENT SYSTEM ON AGGREGATE PAYMENTS FOR SELECTED PROCEDURES

CPT/HCPCS Code (1)	Short Descriptor (2)	Estimated CY 2025 ASC Payment (in millions) (3)	Estimated CY 2026 Percent Change (4)
66984	Xcapsl ctrc rmvl w/o ecp	$1,371	-5
27447	Total knee arthroplasty	$428	2
63685	Ins/rplc spi npg/rcvr pocket	$385	5
45385	Colonoscopy w/lesion removal	$265	4
45380	Colonoscopy and biopsy	$261	4
63650	Implant neuroelectrodes	$223	0
27130	Total hip arthroplasty	$215	3
43239	Egd biopsy single/multiple	$182	-1
23472	Reconstruct shoulder joint	$150	-4
64590	Ins/rpl prph sac/gstr npg/r	$146	-16
66991	Xcapsl ctrc rmvl insj 1+	$134	6
64483	Njx aa&/strd tfrm epi l/s 1	$112	1
66982	Xcapsl ctrc rmvl cplx wo ecp	$102	-5
64635	Destroy lumb/sac facet jnt	$99	3
29827	Sho arthrs srg rt8tr cuf rpr	$89	5
36902	Intro cath dialysis circuit	$85	4
64561	Implant neuroelectrodes	$80	0
64493	Inj paravert f jnt l/s 1 lev	$76	1
G0105	Colorectal scrn; hi risk ind	$68	5
66821	After cataract laser surgery	$65	1
64555	Implant neuroelectrodes	$57	0
64628	Trml dstrj ios bvn 1st 2 l/s	$51	4
G0121	Colon ca scrn not hi rsk ind	$50	5
65820	Relieve inner eye pressure	$50	7
0627T	Perq njx algc fluor lmbr 1st	$48	6
62323	Njx interlaminar lmbr/sac	$44	4
27279	Arthrd si jt perq/min nvas	$44	-4
15823	Revision of upper eyelid	$40	16
64721	Carpal tunnel surgery	$40	3
C9740	Cysto impl 4 or more	$36	5

c. Estimated Effects of ASC Payment System Policies on Beneficiaries

We estimate that the CY 2026 update to the ASC payment system will be generally positive (that is, result in lower cost-sharing) for beneficiaries with respect to the procedures we are propose to add to the ASC CPL for CY 2026. First, other than certain preventive services where coinsurance and the Part B deductible are waived to comply with sections 1833(a)(1) and (b) of the Act, the ASC coinsurance rate for all procedures is 20 percent. This contrasts with procedures performed in HOPDs under the OPPS, where the beneficiary is responsible for copayments that range from 20 percent to 40 percent of the procedure payment (other than for certain preventive services), although the majority of HOPD procedures have a 20-percent

copayment. Second, in almost all cases, the ASC payment rates under the ASC payment system are lower than payment rates for the same procedures under the OPPS. Therefore, the beneficiary coinsurance amount under the ASC payment system will usually be less than the OPPS copayment amount for the same services. (The only exceptions will be if the ASC coinsurance amount exceeds the hospital inpatient deductible since the statute requires that OPPS copayment amounts not exceed the hospital inpatient deductible. Therefore, in limited circumstances, the ASC coinsurance amount may exceed the hospital inpatient deductible and, therefore, the OPPS copayment amount for similar services.) Beneficiary coinsurance for services migrating from physicians' offices to ASCs may decrease or increase under the ASC payment system, depending on the particular service and the relative payment amounts under the MPFS compared to the ASC. While the ASC payment system bases most of its payment rates on hospital cost data used to set OPPS relative payment weights, services that are performed a majority of the time in a physician office are generally paid the lesser of the ASC amount according to the standard ASC ratesetting methodology or at the nonfacility practice expense-based amount payable under the PFS. For those additional procedures that we propose to designate as office-based in CY 2026, the beneficiary coinsurance amount under the ASC payment system generally will be no greater than the beneficiary coinsurance under the PFS because the coinsurance under both payment systems generally is 20 percent (except for certain preventive services where the coinsurance is waived under both payment systems).

Accounting Statements and Tables for OPPS and ASC Payment System

As required by OMB Circular A-4 (available on the Office of Management and Budget website at *https://trumpwhitehouse.archives.gov/sites/whitehouse.gov/files/omb/circulars/A4/a-4.pdf*), we have prepared accounting statements to illustrate the impacts of the OPPS and ASC changes in this proposed rule with comment period. The first accounting statement, Table 115, illustrates the classification of expenditures for the CY 2026 estimated hospital OPPS incurred benefit impacts associated with the proposed CY 2026 OPD fee schedule increase and the

proposed policy for drug administration services furnished at excepted off-campus PBDs. The second accounting statement, Table 116, illustrates the classification of expenditures associated with the 2.4 percent CY 2026 update to the ASC payment system, based on the provisions of the proposed rule and the baseline spending estimates for ASCs. Both tables classify most estimated impacts as transfers.

TABLE 115: ACCOUNTING STATEMENT: CY 2026 ESTIMATED HOSPITAL OPPS TRANSFERS FROM CY 2025 TO CY 2026 ASSOCIATED WITH THE CY 2026 HOSPITAL OUTPATIENT OPD FEE SCHEDULE INCREASE

Category	Transfers
Annualized Monetized Transfers	$1.61 billion
From Whom to Whom	Federal Government to outpatient hospitals and other providers who receive payment under the hospital OPPS

TABLE 116: ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED TRANSFERS FROM CY 2025 TO CY 2026 AS A RESULT OF THE CY 2026 UPDATE TO THE ASC PAYMENT SYSTEM

Category	Transfers
Annualized Monetized Transfers	$160 million
From Whom to Whom	Federal Government to Medicare Providers and Suppliers
Total	$160 million

TABLE 117: ESTIMATED ONE-TIME COSTS IN CY 2026 FOR HOSPITAL PRICE TRANSPARENCY

Category	Costs
Burden	$3.545 million

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

3. Effects of Changes in Requirements for the Hospital Outpatient Quality Reporting (OQR) Program

a. Background

We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94561 and 94562) for the previously estimated effects of changes to the Hospital OQR Program for the CY 2025 reporting period and subsequent years. Of the 3,014 hospital outpatient departments (HOPDs) that met eligibility requirements for the CY 2025 payment

determination for the Hospital OQR Program, we determined that 42 HOPDs did not meet the program requirements to receive the full annual Outpatient Department (OPD) fee schedule increase factor while an additional 54 HOPDs elected not to participate.

b. Impact of CY 2026 OPPS/ASC Proposed Rule Policies

In this proposed rule, we propose: (1) to remove the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) to remove the Hospital Commitment to Health Equity (HCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) to remove the Screening for Social Drivers of Health (SDOH) measure beginning with the CY 2025 reporting period; (4) to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period; (5) to adopt the Emergency Care Access & Timeliness electronic clinical quality measure (eCQM) with voluntary reporting for the CY 2027 reporting period followed by mandatory reporting beginning with the CY 2028 reporting period/CY 2030 payment determination; (6) to remove the Median Time from Emergency Department (ED) Arrival to ED Departure for Discharged ED Patients (Median Time for Discharged ED Patients) measure beginning with the CY 2028 reporting period/CY 2030 payment determination; (7) to remove the Left Without Being Seen (LWBS) measure beginning with the CY 2028 reporting period/CY 2030 payment determination; and (8) to modify the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Outpatient) eCQM (Excessive Radiation eCQM) from mandatory reporting beginning with the CY 2027 reporting period to continue voluntary reporting in the CY 2027 reporting period and subsequent years.

In section XV.D. of this proposed rule, we also propose to update our Extraordinary Circumstances Exception (ECE) policy for the Hospital OQR Program. This proposed update would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the

same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

We refer readers to section "XXII.A. Collection of Information" of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the Hospital OQR Program for the estimated 3,200 program-eligible HOPDs. As shown in summary tables in section XXII.A.10, we estimate a total information collection and reporting burden decrease of 6,924,988 hours at a savings of $178,884,367 annually associated with our proposals for the CY 2028 reporting period/CY 2030 payment determination and subsequent years compared to our currently approved information collection burden estimates under OMB control number 0938-1109 (expiration date January 31, 2026). We also estimate a decrease of between 25,600 hours at a savings of $1,446,400 and 28,800 hours at a savings of $1,687,680 in information collection burden associated with the proposal to remove the COVID–19 Vaccination Coverage Among HCP measure compared to the currently approved information collection burden estimates and under OMB control number 0920-1317 (expiration date January 31, 2028).

In section XV.B.1. of this proposed rule, we proposed to adopt the Emergency Care Access & Timeliness eCQM. Similar to the effects associated with the ST-Segment Elevation Myocardial Infarction (STEMI) eCQM finalized in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63984 and 63985), we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' electronic health record (EHR) systems for the eCQMs used in the Hospital OQR Program.

In section XV.B.2. of this proposed rule, we proposed to remove the Median Time from ED Arrival to ED Departure for Discharged ED Patients and LWBS measures if the proposed Emergency Care Access & Timeliness eCQM is adopted. Because these measures would be

replaced by the Emergency Care Access & Timeliness eCQM, we believe HOPDs will be positively impacted by the decreased effort required to report one eCQM rather than one chart-abstracted measure and one web-based measure.

In section XV.B.3 of this proposed rule, we proposed to modify the reporting requirements for the Excessive Radiation eCQM by maintaining voluntary reporting instead of mandatory reporting of the measure, beginning with the CY 2027 reporting period. In the CY 2024 OPPS/ASC final rule with comment period, we finalized that for the Excessive Radiation eCQM, HOPDs may incur costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in hospitals' electronic health record (EHR) systems. We also finalized that HOPDs would be required to create a secure account through the measure developer's website and link their EHR and PACS data to their chosen vendor's translation software for CMS Measure Compliance. We estimated this one-time activity would require no more than 1 hour to complete (88 FR 82167). In section XXII.A.9., we estimate that 20 percent of HOPDs would report this measure annually. Because some HOPDs may only elect to report this eCQM for some reporting periods, we are unable to assume that 80 percent of HOPDs would not report this measure in any reporting period. However, for HOPDs who elect not to report this eCQM in any reporting period, the proposed modification would result in a savings of no more than 1 hour and $55 (1 hour x $55.06) as well as any costs that would be associated with implementing and maintaining program requirements specific to this eCQM.

Regarding the remaining proposals, we do not believe these proposals would result in any additional economic impact beyond those discussed in section "XXII.A. Collection of Information'' of this proposed rule.

4. Effects of Proposed Changes in Requirements for the Rural Emergency Hospital Quality Reporting (REHQR) Program

a. Background

We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94562 and 94563) for the previously estimated effects of changes to the REHQR Program for the CY 2025 reporting period and subsequent years. For the CY 2026 reporting period, we have estimated there will be 38 REHs required to report under the REHQR Program based on hospital conversions as of April 11, 2025. We use this number of REHs for our impact analyses knowing that more jurisdictions will pass or amend necessary legislation enabling transitions, acknowledging that the number of conversions could be less than or significantly greater than this estimate with time.

b. Impact of CY 2026 OPPS/ASC Proposed Rule Policies

In this proposed rule, we propose: (1) to remove the HCHE measure beginning with the CY 2025 reporting period/CY 2027 program determination; (2) to remove the Screening for SDOH measure beginning with the CY 2025 reporting period/CY 2027 program determination; (3) to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period/CY 2027 program determination; and (4) to adopt the Emergency Care Access & Timeliness eCQM beginning with the CY 2027 reporting period/CY 2029 program determination as optional in lieu of reporting the chart-abstracted Median Time for Discharged ED Patients. In section XVI.D. of this proposed rule, we also propose to update our ECE policy for the REHQR Program. This proposed update would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

We refer readers to section "XXII.B. Collection of Information" of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the REHQR Program for the estimated 38 REHs. As shown in summary tables in section XXII.B.6., we estimate a total information collection and reporting burden decrease of 14,813 hours at a savings of $380,235 annually

associated with our proposals for the CY 2027 reporting period/CY 2029 program determination and subsequent years compared to our currently approved information collection burden estimates under OMB control number 0938-1454 (expiration date April 30, 2027).

In section XVI.B.1. of this proposed rule, we proposed to adopt the Emergency Care Access & Timeliness eCQM. Similar to the effects associated with the STEMI eCQM finalized for the Hospital OQR Program in the CY 2022 OPPS/ASC final rule with comment period (86 FR 63984 and 63985), we believe that costs associated with adoption of eCQMs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program requirements, such as maintaining measure specifications in REHs' EHR systems for the eCQMs used in the REHQR Program. Because REHs would have the option to report the Emergency Care Access & Timeliness eCQM or the more burdensome Median Time for Discharged ED Patients measure, we believe REHs would be positively impacted by the decreased effort required to report the Emergency Care Access & Timeliness eCQM in the long-term following initial implementation in the EHR.

Regarding the remaining proposals, we do not believe these proposals would result in any additional economic impact beyond those discussed in section "XXII.B. Collection of Information'' of this proposed rule.

5. Effects of Proposed Changes in Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

a. Background

We refer readers to the CY 2025 OPPS/ASC final rule with comment period (89 FR 94563) for the previously estimated effects of changes to the ASCQR Program for the CY 2025 reporting period and subsequent years. Based on the most recent analysis of the CY 2025 payment determination data, we found that, of the 6,012 ambulatory surgical centers (ASCs) that were actively billing Medicare, 4,271 were required to participate in the ASCQR Program. Of the 1,741 ASCs not required to participate in the program, 319 ASCs did so and met full

requirements. On this basis, we estimate that 4,590 ASCs (4,271 + 319) will submit data for the ASCQR Program for the CY 2026 reporting period and subsequent years unless otherwise noted. We note that this estimate is an increase of 115 ASCs from our estimate of 4,475 provided in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94563) due to more recent data analysis regarding numbers of eligible ASCs.

b. Impact of CY 2025 OPPS/ASC Proposed Rule Policies

In this proposed rule, we propose (1) to remove the COVID–19 Vaccination Coverage Among HCP Measure beginning with the CY 2024 reporting period/CY 2026 payment determination; (2) to remove the Facility Commitment to Health Equity (FCHE) measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (3) to remove the Screening for SDOH measure beginning with the CY 2025 reporting period/CY 2027 payment determination; (4) to remove the Screen Positive Rate for SDOH measure beginning with the CY 2025 reporting period/CY 2027 payment determination; and (5) to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance (Information Transfer PRO-PM) measure beginning with voluntary reporting for the CY 2027 and CY 2028 reporting periods followed by mandatory reporting beginning with the CY 2029 reporting period/CY 2031 payment determination.

In section XVII.D. of this proposed rule, we also propose to update our ECE policy for the ASCQR Program. This proposed update would explicitly include extensions as a type of extraordinary circumstances relief option, in addition to exceptions. Because the process for requesting or granting an ECE would remain the same as the current ECE process, these updates would not affect burden associated with the submission of the ECE form.

We refer readers to section "XXII.C. Collection of Information" of this proposed rule for a detailed discussion of the calculations estimating the changes to the information collection and reporting burden for proposed data requirements under the ASCQR Program for the estimated

4,590 program-eligible ASCs. As shown in summary tables in section XXII.C.7., we estimate a total information collection and reporting burden decrease of 172,425 hours at a cost of $4,464,280 annually associated with our proposals for the CY 2029 reporting period/CY 2031 payment determination and subsequent years compared to our currently approved information collection burden estimates under OMB control number 0938-1270 (expiration date July 31, 2027) We also estimate a decrease of between 36,720 hours at a savings of $2,074,680 and 41,310 hours at a savings of $2,420,766 in information collection burden associated with the proposal to remove the COVID–19 Vaccination Among HCP measure compared to the currently approved information collection burden estimates and under OMB control number 0920-1317 (expiration date January 31, 2028).

In section XVII.B.1. of this proposed rule, we proposed to adopt the Information Transfer PRO–PM. Similar to the effects associated with the Information Transfer PRO-PM finalized for the Hospital OQR Program in the CY 2025 OPPS/ASC final rule with comment period (89 FR 94562), for ASCs that are not currently collecting these data and elect to begin doing so as a result of this measure there would be some costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as ASCs may utilize different modes of data collection (collected by facilities or authorized third-party vendors post-discharge through a web-based survey instrument, distributed electronically) and have differing response rates influencing data volume. While we assume the majority of ASCs would report data for this measure directly to CMS, we assume some ASCs may elect to submit measure data via a third-party survey vendor, for which there are associated costs. Under OMB control number 0938–1240 for the Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) Survey (expiration date November 30, 2026), an estimate of approximately $4,000 per hospital is used to account for these costs. Communication interventions have been associated with increased adherence to treatment regimen and improved patient satisfaction, which are positively related to better health outcomes,

such as reduced hospital readmission, mortality, morbidity, or improved quality of life, as well as potentially reducing complaints and malpractice claims.[348] Additional research indicates enhanced readability of discharge instructions is associated with a decrease in the proportion of patients calling after hospital discharge, a decrease in the proportion of hospital readmissions per 100 patients discharged, and a decrease in the proportion of patients calling and readmissions for poor pain control.[349] Therefore, while we are unable to quantify the benefits associated with the measure, we believe the potential improvements in post-operative recovery, patient satisfaction, and quality of life outweigh the estimated burden for patients of $10,389 per ASC.

Regarding the remaining proposals, we do not believe these proposals would result in any additional economic impact beyond those discussed in section "XII.C. Collection of Information'' of this proposed rule.

6. Effects of Requirements for the Overall Hospital Quality Star Ratings

a. Background

In section XVIII. Overall Hospital Quality Star Rating Modification to Emphasize the Safety of Care Measure Group of this proposed rule, we discussed our proposal as it relates to the Overall Hospital Quality Star Rating methodology. The Overall Hospital Quality Star Rating uses measures that are publicly reported on the provider comparison tool on Medicare.gov (*https://www.medicare.gov/care-compare/*) under the public reporting authority of each individual hospital program furnishing measure data. The burden associated with measures included in the Overall Hospital Quality Star Rating, including forms used to request withholding of publicly reported measure data and the Overall Hospital Quality Star Rating (for CAHs), is already captured in respective hospital programs' burden estimates and represents no increased information collection burden to hospitals.

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[348] Becker C, Zumbrunn S, Beck K, et al. (2021). Interventions to Improve Communication at Hospital Discharge and Rates of Readmission: A Systematic Review and Meta-analysis. *JAMA Netw Open.* 4(8):e2119346. doi:10.1001/jamanetworkopen.2021.19346.

[349] Choudhry AJ, Younis M, Ray-Zack MD, et al. (2019). Enhanced readability of discharge summaries decreases provider telephone calls and patient readmissions in the posthospital setting. Surgery. 165(4):789-794. *https://doi.org/10.1016/j.surg.2018.10.014.*

b. Impact of CY 2026 OPPS/ASC Proposed Rule Policies

In this CY 2026 OPPS/ASC proposed rule, we are using the most recent data from the Bureau of Labor Statistics, which reflects a median hourly wage of $24.16 per hour for a Medical Records and Health Information Technician professional.[350] We calculate the cost of overhead, including fringe benefits, at 100 percent of the hourly wage estimate, consistent with the previous year. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer- to-employer and because methods of estimating these costs vary widely from study-to-study. Therefore, we believe that doubling the hourly wage rate ($24.16 x 2 = $48.32) to estimate total cost is a reasonably accurate estimation method. Accordingly, we calculate the cost burden to hospitals using a wage plus benefits estimate of $48.32 per hour. We estimate that the non-information collection burden associated with all non-Veterans Health Administration (VHA) hospitals reviewing their Overall Hospital Quality Star Rating preview report prior to public reporting to be 2 hours per hospital, which includes time to review the report and ask any questions about the calculation necessary to increase comprehension. Estimating that approximately 4,600 hospitals would receive an Overall Hospital Quality Star Rating hospital specific report (HSR), regardless of if they meet the reporting thresholds to be assigned a star rating, we estimate the overall non- information collection burden to be $444,544 annually ($48.32 x 2 hours per preview report x once per year x 4,600 hospitals). For CAHs specifically, which are included in the estimate above, we estimate that 1,300 CAHs would be eligible for an Overall Hospital Quality Star Rating, which represents a burden of $125,632 annually (1,300 CAHs x 2 hours per preview report x once per year x $48.32).

Within this rule, for CY 2026 Overall Hospital Quality Star Rating and subsequent years, we propose to make the following two-stage methodological updates to emphasize the

[350] Bureau of Labor Statistics, U.S. Department of Labor, Occupational Outlook Handbook, Medical Records Specialists, at *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

importance of the Safety of Care measure group to the Overall Hospital Quality Star Rating methodology: (1) implement a 4-star cap for poor performance in the Safety of Care measure group (lowest performing quartile) for the 2026 Star Rating, and (2) implement a blanket 1-star reduction for poor performance in the Safety of Care measure group (lowest performing quartile) for the 2027 Star Rating and thereafter.

To simulate the impact of the proposed Overall Hospital Quality Star Rating methodology, we used the July 2024 refresh of the Overall Hospital Quality Star Rating (the most recent publicly released results as of the writing of this proposal) to describe the overall distribution and reclassification of the Overall Hospital Quality Star Rating across different types of hospitals. The proposed update to the Overall Hospital Quality Star Rating methodology in CY 2026 that will limit hospitals in the lowest quartile of Safety of Care (based on at least three measure scores) to a maximum of 4 out of 5 stars (Stage 1 methodological change) would have resulted in 14 (0.30 percent) hospitals receiving a lower Overall Hospital Quality Star Rating in the July 2024 simulation. While the proposed update to the Overall Hospital Quality Star Rating methodology beginning in CY 2027 that will reduce the Overall Hospital Quality Star Rating of any hospital in the lowest quartile of Safety of Care (based on at least three measure scores) by 1 star, to a minimum 1-star rating (Stage 2 methodological change) would have resulted in 459 (9.90 percent) hospitals receiving a lower Overall Hospital Quality Star Rating.

Utilizing the Stage 1 methodology update, fewer hospitals would have received a different Overall Hospital Quality Star Rating and changes in the Overall Hospital Quality Star Rating are less easily attributed to specific hospital characteristics, as very few hospitals of any type would be affected. In contrast, the Stage 2 methodological update resulted in teaching hospitals, non-safety-net hospitals, VHA hospitals, non-CAHs, large hospitals (100+ beds), and non-specialty hospitals being more likely to receive a lower Overall Hospital Quality Star Rating in the July 2024 simulation. (Table 118).

TABLE 118: IMPACT ASSESSMENT OF PROPOSED METHODOLOGICAL ADJUSTMENTS BY HOSPITAL CHARACTERISTICS, JULY 2024 SIMULATION

Characteristic	N (%)	N Rated (Row %)	N Rated & 3+ Safety measures (%)	N Rated & 3+ measures & Q1 Safety (%)	N Capped* ^ (%) (Stage 1)	N Blanket 1-Star Reduction* (%) (Stage 2)
All hospitals	4,628 (100%)	2,847 (61.5%)	2,475 (53.5%)	595 (12.9%)	14 (0.30%)	459 (9.9%)
Teaching Status						
Teaching	1,284 (27.7%)	1,234 (96.1%)	1,204 (93.8%)	269 (21.0%)	6 (0.47%)	211 (16.4%)
Non-Teaching	3,177 (68.6%)	1,496 (47.1%)	1,185 (37.3%)	293 (9.2%)	4 (0.13%)	222 (7.0%)
Safety-net Status						
Safety-net	1,199 (25.9%)	468 (39.0%)	383 (31.9%)	115 (9.6%)	2 (0.17%)	83 (6.9%)
Non-Safety-net	3,239 (70%)	2,250 (69.5%)	1,999 (61.7%)	445 (13.7%)	8 (0.25%)	348 (10.7%)
Veterans' hospitals						
VHA hospital	136 (2.9%)	113 (83.1%)	82 (60.3%)	33 (24.3%)	4 (2.94%)	26 (19.1%)
Non-VHA	4,490 (97.0%)	2,734 (60.9%)	2,393 (53.3%)	562 (12.5%)	10 (0.22%)	433 (9.6%)
Critical Access Hospitals						
CAH	1,340 (29.0%)	164 (12.2%)	15 (1.1%)	3 (0.2%)	0 (0%)	2 (0.1%)
Non-CAH	3,286 (71.0%)	2,683 (81.6%)	2,460 (74.9%)	592 (18.0%)	14 (0.43%)	457 (13.9%)
Bed Size						
1-99 Beds	2,511 (54.3%)	854 (34.0%)	535 (21.3%)	139 (5.5%)	5 (0.20%)	116 (4.6%)
100+ Beds	1,942 (42.0%)	1,876 (96.6%)	1,854 (95.5%)	423 (21.8%)	5 (0.26%)	317 (16.3%)
Geographic Location						
Urban	2,060 (44.5%)	1,626 (78.9%)	1,559 (75.7%)	362 (17.6%)	4 (0.19%)	280 (13.6%)
Rural	2,399 (51.8%)	1,104 (46.0%)	830 (34.6%)	200 (8.3%)	6 (0.25%)	153 (6.4%)
Specialty status						
Specialty	122 (2.6%)	32 (26.2%)	27 (22.1%)	4 (3.3%)	0 (0%)	3 (2.5%)
Non-Specialty	4,317 (93.3%)	2,686 (62.2%)	2,355 (54.6%)	556 (12.9%)	10 (0.23%)	428 (9.9%)

*Capped is the number and proportion of hospitals impacted by the proposed 4-star cap for rated hospitals reporting three or more safety measures and performing in the lowest quartile of Safety of Care measure group. Star Reduction is the number and proportion of hospitals impacted by the proposed blanket 1-Star reduction for rated hospitals reporting three or more safety measures and performing in the lowest quartile of Safety of Care measure group.

^ Certain hospital characteristics (teaching status, safety net status, bed size, geographic location) are only available for non-VHA hospitals.

7. Effects of a Proposed Market-Based MS-DRG Relative Weight Methodology

In section XX. of the preamble of this proposed rule, we propose to adopt a market-based methodology for determining the MS-DRG relative weights beginning in FY 2029 utilizing the median payer-specific negotiated charge information we are proposing to collect on the cost

report. That is, our proposal to collect on the Medicare cost report the median of the payer-specific negotiated charge that the hospital has negotiated with all of its MAOs, by MS-DRG, effective cost reporting periods ending on or after January 1, 2026.

We note that the estimated total annual burden hours for this proposal are as follows: 3,038 hospitals times 20 hours per hospital equals 60,760 annual burden hours and $4,857,458.20. We refer readers to section XXII.E. of this proposed rule for further analysis of this assessment.

If CMS were to finalize a change to the MS-DRG relative weight methodology, we would apply a budget neutrality factor to ensure that the overall payment impact of any MS-DRG relative weight changes was budget neutral, as required by section 1886(d)(4)(C)(iii) of the Act and consistent with our current practice.

Similar to our discussion in the economic analysis section of the FY 2021 IPPS/LTCH PPS final rule (85 FR 59089 through 59090) regarding the market-based MS-DRG relative weight methodology, if our current proposal is finalized then once we have access to the weighted payer-specific negotiated charge information at the MS-DRG level from the cost reports we would be able to more precisely estimate the payment impact of adopting this market-based MS-DRG relative weight methodology for payments beginning in FY 2029. If our proposal is finalized, we intend to provide these more precise estimates prior to the FY 2029 effective date. However, to explore the potential impacts more generally, we conducted a literature search to compare the payment rates of Medicare FFS, MA organizations, and other commercial payers, which is discussed in section XX.B. of this proposed rule. As discussed in that section, the payer-specific charges negotiated between hospitals and MAOs are generally well-correlated with Medicare IPPS payment rates, although in the future this may change over time for some services. As under the current methodology, the impact of any MS-DRG relative weight changes on an individual hospital would depend on the mix of services provided by that particular hospital.

8. Graduate Medical Education Accreditation

In section XXI. of this proposed rule, we discuss that, effective January 1, 2026, we propose that accreditors may not require as part of accreditation or otherwise encourage institutions to put in place diversity, equity, and inclusion programs that encourage unlawful discrimination on the basis of race or other violations of Federal law. We believe there is no financial impact associated with this proposed change because, as of our proposed effective date, we do not expect that current or future accrediting organizations would continue to or newly require or otherwise encourage institutions to put in place diversity, equity, and inclusion programs that encourage unlawful discrimination on the basis of race or other violations of Federal law.

We also note that the Secretary may recognize other organizations that meet or exceed Medicare's requirements as accreditors to increase the potential for competition in the accreditation space and improve the quality of the accreditation process. We believe there is no financial impact associated with the potential recognition of other accrediting organizations because we do not expect that an increase in competition or an improvement in the quality of the accreditation process would change the total number of approved programs significantly. It would only potentially change the organization that accredits some of those approved programs.

9. Effects of Proposals Relating to Hospital Price Transparency

a. Background

Since the January 1, 2021, effective date of the CY 2020 Hospital Price Transparency (HPT) final rule, hospitals have been required to make their standard charges available to the public. Consistent with Executive Order 14221, and to further advance the goals articulated in previous HPT rulemaking of requiring hospitals to make meaningful price information available to consumers, employers, policymakers, and others to support a more competitive, innovative, and affordable healthcare system, we are proposing several updates to the HPT regulations to enhance the clarity and standardization of hospital disclosure of standard charges. Specifically,

we propose: (1) revisions to 45 CFR 180.20 to add definitions for "tenth (10^{th}) percentile allowed amount," "median allowed amount," and "ninetieth (90^{th}) percentile allowed amount"; (2) revisions to 45 CFR 180.50 to require hospitals, beginning January 1, 2026, to disclose the 10^{th} percentile, median, and 90^{th} percentile allowed amounts in machine-readable files (MRFs) when standard charges are based on percentages or algorithms, as well as the count of allowed amounts, to more accurately reflect the distribution of actual amounts that the hospital has received for an item or service; (3) to require that hospitals use electronic data interchange (EDI) 835 electronic remittance advice (ERA) transaction data to calculate and encode these allowed amount data elements, and to require that hospitals comply with specific instructions regarding the methodology, including the lookback period, that must be used to calculate the 10^{th} percentile, median, and 90^{th} percentile allowed amounts; (4) revisions to § 180.50(a)(3) to replace the affirmation statement in the MRF with an attestation statement that would also contain new specifications (relative to existing affirmation requirements) and to require hospitals to encode the name of the chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data in the MRF; (5) revisions to § 180.50(b)(2)(i)(A) to require hospitals to include their National Provider Identifier(s) (NPIs) in the MRFs to advance the comparability of HPT data with other healthcare data; and (6) revisions to § 180.90 to reduce the amount of a civil monetary penalty (CMP) by 35 percent, in certain circumstances and under certain conditions, when a hospital waives its right to an administrative law judge (ALJ) hearing, to encourage faster resolution and payment of CMPs in exchange for the hospital's acceptance of responsibility for failing to meet HPT requirements. These proposed changes aim to improve price transparency, facilitate efficient enforcement, and empower consumers with actionable information.

b. Overall Estimated Burden on Hospitals Due to HPT Requirements

To analyze the costs of the proposed requirements, we used an updated baseline that assumes the existing requirements (those adopted in the CY 2020 HPT final rule, the CY 2022

OPPS/ASC final rule with comment period and the CY 2024 OPPS/ASC final rule with comment period and still codified at 45 CFR part 180) remain in place over the time horizon of this RIA.

In the CY 2024 OPPS/ASC final rule with comment period, we estimated that the annual burden of the HPT regulations would be 54 hours per hospital with a cost of $4,560.52 per hospital, resulting in a total national annual burden of 383,292 hours and $32,370,571 (88 FR 82171). As described in section "XXII. Collection of Information" of this proposed rule, we still believe these hourly estimates are accurate estimates of the ongoing annual burden for hospitals to update their standard charge information in the CMS standard template and conform to the data dictionary.

For this proposed rule, we updated the number of hospitals estimated to be subject to the HPT requirements using the same methodology as we did in the CY 2024 OPPS/ASC final rule with comment period. There were 8,340 hospitals most recently identified in the HIFLD hospital dataset. We subtracted 374 hospitals HIFLD identified as "closed" as well as hospitals that are deemed under the regulation to have met requirements which included 352 Federally owned non-military and military hospitals, and 198 state, local, and district run forensic hospitals. We therefore estimate that, for this proposed rule, 7,416 hospitals would meet the HPT regulation's definition of "hospital" at 45 CFR 180.20, increasing the national annual burden to 400,464 hours and $36,519,350.40.

We estimate that hospitals will incur an additional one-time cost to update their processes and systems to (1) identify and collect six new data elements and (2) encode the standard charge information for the newly proposed elements in the CMS standard template. This one-time burden estimate, as demonstrated in section "XXII. Collection of Information" of this proposed rule is 37,080 hours for all hospitals (5 hours x 7,416 hospitals) at a cost of $3,545,441.28 (7,416 hospitals x [($87.52 x 4 hours) + ($128.00 x 1 hour)]). We note that hospitals have been required to publicize their standard charges in a standardized template since July 1, 2024, as specified in

the CY 2024 OPPS/ASC final rule with comment period, and therefore expect minimal hospital burden to modify the existing template. In addition, four of the new proposed data elements, the median, 10th percentile, and 90th percentile allowed amounts, as well as the count of allowed amounts, are applicable only in the limited instances when a hospital's payer-specific negotiated charge for an item or service is based on an algorithm or a percentage. The fifth and sixth new data elements, the hospital NPI and the name of name of the chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data in the MRF, would be required at the hospital level, not a separate entry for each item or service. CMS therefore believes this estimate to be an accurate estimate of the one-time burden for a hospital to collect the new data elements and encode them in the CMS standard template.

c. Benefit of Proposals

Although we cannot quantify the benefits of including additional data elements and encoding such data in the CMS required MRF template, we believe any opportunity to provide further context about standard charges, including through the addition of contextual information when the payer-specific negotiated charge is based on a percentage or algorithm, would be helpful to all consumers of the MRF as they analyze the data to identify cost savings and ways to stimulate market competition. We believe strengthening the existing affirmation statement and requiring a senior official to publicly attest to the accuracy and completeness of the data encoded within the file will reduce public confusion related to whether all standard charges for hospital items and services are included within the MRF as dollar amounts, if possible, and the hospital has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula. We also believe the addition of the NPI data element would catalyze more fulsome HPT and Transparency in Coverage (TiC) analysis.

(1) Benefits to Hospitals

Hospitals, either directly or through management or actuarial consultants, are consuming the data released in the MRFs for their own operational purposes. Hospitals consume and analyze MRF data to improve negotiation strategies with employers and third party payers, improve contracting strategies, and demonstrate value in the negotiation process.[351,352] Hospitals also use the MRF data to determine pricing strategies and to identify and hone their competitive advantage,[353] as well as to improve their revenue cycle efficiency.[354] Further, we believe that, for those hospitals that are assessed a CMP, the proposed reduction of the CMP if the hospital elects not to appeal CMS' findings, would offset some of the hospital financial burden, including legal fees and costs associated with challenging the imposition – including requesting and defending a hearing before an Administrative Law Judge (ALJ) and any subsequent appeals.

(2) Benefits to Other Interested Parties

As discussed in the CY 2020 HPT final rule (84 FR 65538), we believe public access to hospital standard charge information can be useful to the public, including patients who need to obtain services from a hospital, consumers of healthcare who wish to view hospital standard charge information prior to selecting a hospital, employers and state governments searching for lower cost options for health care coverage, and other users of the MRF who may develop consumer-friendly price transparency tools or perform price analyses to uncover disparities or drive value-based policy development. Since the effective date of the HPT regulations, innovators have been compiling HPT data sets and making them available for employers, researchers, and journalists to perform cost comparison studies and publish findings.

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[351] Clarify Insights Center. (2023, August 15). *How hospitals can use price transparency data to negotiate better contracts with payers*. Retrieved from *https://clarifyhealth.com/insights/blog/how-hospitals-can-use-price-transparency-data-to-negotiate-better-contracts-with-payers/.*

[352] Gomes, C. (2023, July 31). *Why healthcare providers should harness price transparency data*. Medlyze - Price Transparency Data and Analysis for the Healthcare Industry Insights. Retrieved from *https://www.medlyze.com/blog/why-healthcare-providers-should-harness-the-power-of-price-transparency-data.*

[353] Xiao, F. (2024, October 25). *Is price transparency helping? Here are three ways to tell: Let's explore our biggest indicators of change: competition, pricing, and power*. Turquoise Health Blog. Retrieved from *https://blog.turquoise.health/is-price-transparency-helping-heres-three-ways-to-tell/.*

[354] Healthcare Financial Management Association. (2023, August 28). *Leverage healthcare price transparency data to promote financial sustainability*. Retrieved from *https://www.hfma.org/price-transparency/leverage-healthcare-price-transparency-data-to-promote-financial-sustainability/.*

Feedback from interested parties, specifically innovators and researchers, has illuminated the need to detangle complex hospital contracting methods through the provision of data elements that help define the algorithm or percentage set forth in hospital MRFs. The proposed allowed amount data elements would support a better understanding of the range of payer-specific negotiated charge dispersion, which would further assist employers and consumers to understand a hospital's value as compared to other hospitals, stimulating competition and potentially resulting in price convergence to drive more predictable and consistent health care costs.[355]

With regard to the proposals to strengthen the affirmation statement requirement, beginning January 1, 2026, by replacing it with an attestation in the MRF that would contain new specifications (relative to existing affirmation requirements) and to require hospitals to encode the name of the chief executive officer, president or senior official designated to oversee the encoding of true, accurate and complete data in the MRF, we believe this will provide the necessary reassurance that hospitals have provided in their MRFs meaningful, accurate information to users of the MRF about their standard charges for health care items and services.

With regard to the NPI data element, including identifiers used for financial transactions in the MRF would make it easier for key participants in price negotiations (for example, employers and payers) to programmatically identify hospitals in their internal financial databases, such as claims data, to conduct more in-depth payment and volume analyses to support contract negotiations and potentially reduce healthcare costs for consumers. A standard identifier could also help CMS, researchers, and innovators reduce dependence on manual processes for identifying the hospital and the hospital locations and increase opportunities for automated processes.

d. Limitations of Our Analysis

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355 Xiao, F. (2024, October 25). *Is price transparency helping? Here are three ways to tell.* Turquoise Health. Retrieved from *https://blog.turquoise.health/is-price-transparency-helping-heres-three-ways-to-tell/.*

As stated in the CY2024 OPPS/ASC final rule with comment period (88 FR 82174), it would be difficult for us to conduct a detailed quantitative analysis of the impact of requiring hospitals to make HPT information publicly available, given the lack of studies at the national level on the impact of the HPT regulations. Thus, in assessing the impact of our proposals, we rely on qualitative evidence of, and experiences with, the use of the public HPT data and feedback from consumers of the MRFs as well as our own experiences reviewing the MRFs. Specifically, we have noted through our own reviews that many hospital MRFs lack dollar values when the standard charge for an item or service is based on an algorithm or percentage and have heard from interested parties the limitations of drawing meaningful comparisons without necessary context to help understand the standard charge in dollars for such items or services. We also have received comments from MRF users since the effective date of the 2024 OPPS/ASC final rule with comment period indicating that requiring hospitals to make a good faith effort did not go far enough to convey CMS' intent that all standard charge information available must be encoded in the MRF, with commenters suggesting our requirement to allow a good faith estimate may actually deter hospitals from providing fully complete and accurate standard charge data in their MRF. We also heard users of the MRFs who questioned a hospital's inability to encode dollar amounts for the payer-specific negotiated charge data elements, and whether the complex contracting methodologies used by hospitals and payer organizations could only be expressed through an algorithm or formula, and not a dollar amount. We understand that users of the MRF may find the addition of algorithms make price comparisons among hospitals challenging when only an algorithm is available because the algorithms may not be consumer friendly. We believe that our proposal to require an attestation, as opposed to merely requiring an affirmation statement, may enhance users' confidence that the data encoded is accurate and complete.

In addition, in discussions with innovators and researchers, we have heard that the addition of an NPI as a hospital unique identifier would allow more effective data crosswalking

between hospital HPT MRFs and TiC MRFs, as well as to other CMS datasets that contain hospital quality data. We believe this regulation would provide the additional context needed for consumers of the MRFs to create meaningful dollar comparisons that would ultimately benefit consumers through development of cost comparison tools, increased competition, or improved price negotiations with employers.

e. Alternatives Considered

The proposed revisions to the HPT regulations are designed to further address some of the barriers identified that limit price transparency, with a goal of increasing competition among healthcare providers to bring down costs. Specifically, this proposed rule aims to make meaningful price information via hospital standard charges more readily available to the public by providing additional contextual information, displayed as a dollar value, in those instances where standard charges are based on a percentage or an algorithm, as well as provide needed hospital identifier values to enable innovators and researchers to combine the HPT data with other claims and quality data to further empower consumer decision-making. We considered a number of alternative approaches, including other methodologies and lookback periods for calculating the allowed amount data elements, and whether to display specific counts of allowed amounts or ranges. We discuss these alternatives in section XIX. of this proposed rule. Specifically, we considered EDI 835 ERA transaction data lookback period alternatives of 3 months, 6 months, as well as requiring hospitals to use a rolling 12-month period prior to when the MRF posted. . We sought comment on data sources other than the EDI 835 ERA transaction data to use to derive the allowed amount data elements. We also considered whether hospitals could encode a range of allowed amounts, as opposed to the exact count of allowed amounts, to achieve our objective of providing needed context to the allowed amount data element values.

We considered several alternative options to updating the required affirmation within the MRF, as discussed in section XIX. of this proposed rule. We considered asking the official to submit their MRF attestation directly to CMS, using a CMS developed template that would

provide evidence of the accuracy and completeness of the MRF, and we also considered requiring the hospitals to post a more detailed attestation document that is signed by a senior official on the publicly available website that hosts the MRF. However, we believe these alternatives to be less useful than our proposals as they would either not meet the stated need to alert the public to the hospital's declaration of the accuracy and completeness of the data encoded within the MRF, or the attestation would not "travel" inside the MRF like the affirmation statement.

In addition, we considered different types of hospital identifiers, specifically the Employer identification Number and the CMS Certification Number. Ultimately, however, we determined that the alternatives would either limit the usefulness of hospital standard charge information or increase burden for hospitals without any additional benefit for users of MRF standard charge information.

D. Regulatory Review Cost Estimation

Due to the uncertainty involved with accurately quantifying the number of entities that will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this rule. It is possible that not all commenters reviewed last year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons we believe that the number of past commenters would be a fair estimate of the number of reviewers of this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this proposed rule, and therefore for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule. We seek comments on this assumption.

Using the wage information from the Bureau of Labor Statistics (BLS) for medical and health service managers (Code 11-9111), we estimate that the cost of reviewing this rule is $113.42 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 8 hours for the staff to review half of this proposed rule. For each entity that reviews the rule, the estimated cost is $907.36 (8 hours x $113.42). Therefore, we estimate that the total cost of reviewing this regulation is $3,175,760 ($907.36 x 3,500).

E. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, we estimate that many hospitals and CAHs are considered small businesses either by the Small Business Administration's size standards with total revenues of $41.5 million or less in any single year or by the hospital's not-for-profit status. Most ASCs and most CMHCs are considered small businesses with total revenues of $16.5 million or less in any single year. While we note the limited availability of certain information for OPPS providers, we estimate that approximately 3,000 OPPS providers included in the impact analysis would be considered small entities. As the small entity category would represent the majority of the providers in the table, the individual impact table categories would provide more specific estimated hospital impacts. While the estimated impacts of the proposed rule vary by OPPS provider category, many of those categories will be within the range of 1.5 to 2.5 percent. For details, we refer readers to the Small Business Administration's "Table of Size Standards" at *http://www.sba.gov/content/small-business-size-standards*

Individuals and States are not included in the definition of a small entity. As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We believe that this threshold would not be reached by the requirements in this proposed rule, since as noted earlier in this section, most estimated changes

would be below that range. Therefore, the Secretary has certified that this proposed rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has 100 or fewer beds. We estimate that this proposed rule would increase payments to small rural hospitals by approximately 1.9 percent; therefore, it should have a negligible impact on approximately 528 small rural hospitals. We note that the estimated payment impact for any category of small entity will depend on both the services that they provide as well as the payment policies and/or payment systems that may apply to them. Therefore, the most applicable estimated impact may be based on the specialty, provider type, or payment system.

The analysis above, together with the remainder of this preamble, provides a regulatory flexibility analysis and a regulatory impact analysis.

F. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2025, that threshold is approximately $187 million. This proposed rule would not impose a mandate that will result in the expenditure by State, local, and Tribal Governments, in the aggregate, or by the private sector, of more than $187 million in any 1 year."

G. Federalism

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. We have examined the OPPS and ASC provisions included in this proposed rule in accordance with Executive Order 13132, Federalism, and have determined that they would not have a substantial direct effect on State, local, or tribal governments, preempt State law, or otherwise have a federalism implication. As reflected in Table 111 of this proposed rule, we estimate that OPPS payments to governmental hospitals (including State and local governmental hospitals) would increase by 2.0 percent under this proposed rule. While we do not know the number of ASCs or CMHCs with government ownership, we anticipate that it is small. The analyses we have provided in this section of this proposed rule, in conjunction with the remainder of this document, demonstrate that this rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866, the RFA, and section 1102(b) of the Act.

This proposed rule would affect payments to a substantial number of small rural hospitals and a small number of rural ASCs, as well as other classes of hospitals, CMHCs, and ASCs, and some effects may be significant. However, as noted in section XXV. of this proposed rule, this rule should not have a significant effect on small rural hospitals.

H. E.O. 14192, "Unleashing Prosperity Through Deregulation"

Executive Order 14192, entitled "Unleashing Prosperity Through Deregulation" was issued on January 31, 2025, and requires that "any new incremental costs associated with new regulations shall, to the extent permitted by law, be offset by the elimination of existing costs associated with at least 10 prior regulations." This proposed rule, if finalized as proposed, is expected to be an E.O. 14192 deregulatory action. We estimate that this proposed rule would generate $2.54 million in annualized cost savings at a 7 percent discount rate, discounted relative to year 2024 over a perpetual time horizon.

Mehmet Oz, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 10, 2025.

List of Subjects

42 CFR Part 410

Diseases, Health facilities, Health professions, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 413

Diseases, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 415

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

45 CFR Part 180

Hospital Price Transparency.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

1. The authority citation for part 410 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395m, 1395hh, 1395rr, and 1395ddd.

2. Section 410.27 is amended by revising paragraph (a)(1)(iv)(B)(*1*) to read as follows:

§ 410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

(a) * * *

(1) * * *

(iv) * * *

(B) * * *

(*1*) For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished as specified in §§ 410.47 and 410.49, respectively. The presence of the physician or nonphysician practitioner for the purpose of the supervision of pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services includes virtual presence through audio/video real-time communications technology (excluding audio-only); and

* * * * *

3. Section 410.28 is amended by revising paragraph (e)(2)(iii) to read as follows:

§ 410.28 Hospital or CAH diagnostic services furnished to outpatients: Conditions.

* * * * *

(e) * * *

(2) * * *

(iii) The presence of the physician or nonphysician practitioner under paragraphs (e)(2)(i) and (ii) of this section includes virtual presence through audio/video real-time communications technology (excluding audio-only) for services without a 010 or 090 global surgery indicator.

* * * * *

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

4. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

5. Section 412.3 is amended by revising paragraph (d)(2) to read as follows:

§ 412.3 Admissions.

* * * * *

(d) * * *

(2) An inpatient admission for a surgical procedure specified by Medicare as inpatient only under § 419.22(n) of this chapter is generally appropriate for payment under Medicare Part A regardless of the expected duration of care. Procedures no longer specified as inpatient only under § 419.22(n) of this chapter are appropriate for payment under Medicare Part A in accordance with paragraph (d)(1) or (3) of this section. Claims for services and procedures removed from the inpatient only list under § 419.22 of this chapter on or after January 1, 2021 are exempt from certain medical review activities until the Secretary determines that the service or procedure is more commonly performed in the outpatient setting than the inpatient setting.

* * * * *

6. Section 412.105 is amended by--

a. Revising paragraphs (f)(1)(i)(A), (B), and (C); and

b. Adding paragraph (f)(1)(i) (E).

The revisions and addition read as follows:

§ 412.105 Special treatment: Hospitals that incur indirect costs for graduate medical education programs.

* * * * *

(f) * * *

(1) * * *

(i) * * *

(A) Is approved by one of the national organizations listed in § 415.152 of this chapter, provided that the national organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

(B) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(*1*) The Directory of Graduate Medical Education Programs published by the American Medical Association.

(*2*) The Annual Report and Reference Handbook published by the American Board of Medical Specialties.

Provided that listing in either of those publications, or in successor information sources, does not require the program to promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

(C) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine, provided that the Council or other organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color,

sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

* * * * *

(E) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

* * * * *

7. Section 412.190 is amended by—

a. Revising paragraph (a)(2);

b. Adding paragraph (a)(3);

c. Redesignating paragraph (a)(5) as (6), and paragraph (a)(6) as (5);

d. Revising paragraph (b)(1);

e. Adding paragraph (d)(9); and

f. Revising paragraphs (e) and (f).

The revisions and additions read as follows:

§ 412.190 Overall Hospital Quality Star Rating.

(a) * * *

(2) To update the methodology that will be used to calculate the Overall Hospital Quality Star Ratings to emphasize the contribution of the Safety of Care measure group to the Overall Hospital Quality Star Rating. This change aims to address the issue of hospitals receiving a high Star Rating despite performance in the lowest quartile of the Safety of Care measure group.

(3) The guiding principles of the Overall Hospital Quality Star Rating are as follows. In developing and maintaining the Overall Hospital Quality Star Ratings, we strive to:

(i) Use scientifically valid methods that are inclusive of hospitals and measure information and able to accommodate underlying measure changes;

(ii) Align with Care Compare on Medicare.gov and CMS programs;

(iii) Provide transparency of the methods for calculating the Overall Hospital Quality Star Rating; and

(iv) Be responsive to stakeholder input.

* * * * *

(b) * * *

(1) * * * Measures are selected from those publicly reported on Care Compare on Medicare.gov through certain CMS hospital inpatient and outpatient quality programs:

* * * * *

(d) * * *

(9) *Emphasize Safety of Care*.

(i) Apply a 4-star cap for hospitals in the lowest quartile of the Safety of Care measure group performance in Calendar Year 2026. Any hospital that is assigned 5 stars in step eight but has a lowest quartile Safety of Care score (based on at least three Safety of Care measures) would be reassigned to 4 stars.

(ii) Apply a blanket 1-Star reduction for hospitals in the lowest quartile of Safety of Care measure group performance beginning in Calendar Year 2027 and later years. Any hospital assigned a 2, 3, 4, or 5-star rating in step eight, but with a lowest quartile Safety of Care score (based on at least three Safety of Care measures) would be reduced to 1, 2, 3, or 4 stars, respectively.

(e) *Preview period prior to publication*. CMS provides hospitals the opportunity to preview their Overall Hospital Quality Star Rating prior to publication. Hospitals have at least 30 days to preview their results, and if necessary, can reach out to CMS with questions.

(f) *Suppression of Overall Hospital Quality Star Rating—*

(1) *Subsection (d) hospitals*. CMS may consider suppressing Overall Hospital Quality Star Rating for subsection (d) hospitals only under extenuating circumstances that affect

numerous hospitals (as in, not an individualized or localized issue) as determined by CMS, or when CMS is at fault, including but not limited to when:

(i) There is an Overall Hospital Quality Star Rating calculation error by CMS;

(ii) There is a systemic error at the CMS quality program level that substantively affects the Overall Hospital Quality Star Rating calculation; or;

(iii) If a Public Health Emergency substantially affects the underlying measure data.

(2) *CAHs*.

(i) CAHs may request to withhold their Overall Hospital Quality Star Rating from publication on Care Compare on Medicare.gov so long as the request for withholding is made, at the latest, during the Overall Hospital Quality Star Rating preview period.

(ii) CAHs may request to have their Overall Hospital Quality Star Rating withheld from publication on Care Compare on Medicare.gov, as well as their data from the public input file, so long as the request is made during the CMS quality program-level 30-day confidential preview period for the Care Compare refresh data used to calculate the Overall Hospital Quality Star Ratings.

PART 413—PRINCIPLES OF REASONABLE COST REIMBURSEMENT; PAYMENT FOR END-STAGE RENAL DISEASE SERVICES; PROSPECTIVELY DETERMINED PAYMENT RATES FOR SKILLED NURSING FACILITIES; PAYMENT FOR ACUTE KIDNEY INJURY DIALYSIS

8. The authority citation for part 413 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395d(d), 1395f(b), 1395g, 1395l(a), (i), and (n), 1395m, 1395x(v), 1395x(kkk), 1395hh, 1395rr, 1395tt, and 1395ww.

9. Section 413.20 is amended by revising paragraph (d)(3) to read as follows:

§ 413.20 Financial data and reports.

* * * * *

(d) * * *

(3)(i) The provider must furnish the contractor—

(A) Upon request, copies of patient service charge schedules and changes thereto as they are put into effect; and

(B) Its median payer-specific negotiated charge by MS-DRG for payers that are Medicare Advantage (MA) organizations, as applicable, and changes thereto as they are put into effect.

(ii) The contractor evaluates the charge schedules as specified in paragraph (d)(3)(i) of this section to determine the extent to which they may be used for determining program payment.

* * * * *

10. Section 413.75 is amended in paragraph (b)—

a. By revising the definition of "Approved geriatric program"; and

b. In the definition of "Approved medical residency program" by revising paragraphs (1), (2), and (3), and adding paragraph (5).

The revisions and addition read as follows:

§ 413.75 Direct GME payments: General requirements.

* * * * *

(b) * * *

* * * * *

Approved geriatric program means a fellowship program of one or more years in length that is approved by one of the national organizations listed in § 415.152 of this chapter under that respective organization's criteria for geriatric fellowship programs, provided that the national organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

Approved medical residency program means a program that meets one of the following criteria:

(1) Is approved by one of the national organizations listed in § 415.152 of this chapter, provided that the national organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

(2) May count towards certification of the participant in a specialty or subspecialty listed in the current edition of either of the following publications:

(i) The Directory of Graduate Medical Education Programs published by the American Medical Association, and available from American Medical Association, Department of Directories and Publications, 515 North State Street, Chicago, Illinois 60610; or

(ii) The Annual Report and Reference Handbook published by the American Board of Medical Specialties, and available from American Board of Medical Specialties, One Rotary Center, Suite 805, Evanston, Illinois 60201.

Provided that listing in either of those publications, or in successor information sources, does not require the program to promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

(3) Is approved by the Accreditation Council for Graduate Medical Education (ACGME), or other organization designated by the Secretary, as a fellowship program in geriatric medicine, or other organization designated by the Secretary, provided that the Council or other organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

* * * * *

(5) Is a program that would be accredited except for the accrediting agency's reliance upon an accreditation standard that requires an entity to promote or emphasize diversity, equity,

inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

* * * * *

PART 415— SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

11. The authority citation for part 415 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395h(h).

12. In § 415.152 amend the definition of "Approved graduate medical education (GME) program" by revising paragraph (1) to read as follows:

§ 415.152 Definitions.

* * * * *

Approved graduate medical education (GME) program * * *

(1) A residency program approved by the Accreditation Council for Graduate Medical Education, by the American Osteopathic Association, by the Commission on Dental Accreditation of the American Dental Association, or by the Council on Podiatric Medical Education of the American Podiatric Medical Association, or other organization determined by the Secretary, provided that the applicable organization does not use accreditation criteria that promote or emphasize diversity, equity, inclusion, or awareness based on race, color, sex, sexual orientation or identity, national origin, or any other characteristic which serves as a proxy to achieve the same ends.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

13. The authority citation for part 416 is revised to read as follows:

Authority: 42 U.S.C. 273, 1302, 1320b-8, and 1395hh.

14. Section 416.164 is amended by--

a. Revising paragraphs (a)(5), (b)(5) and (6);

c. Adding paragraph (b)(7).

The revisions and addition read as follows:

§ 416.164 Scope of ASC services.

(a) * * *

(5) Medical and surgical supplies not on pass-through status under subpart G of part 419 of this subchapter and not covered ancillary skin substitute supplies under paragraph (b) of this section;

* * * * *

(b) * * *

(5) Certain radiology services and certain diagnostic tests for which separate payment is allowed under the OPPS;

(6) Non-opioid pain management drugs, biologicals, and medical devices as determined by CMS under § 416.174; and

(7) Groups of skin substitute supply products.

* * * * *

15. Section 416.166 is revised to read as follows:

§ 416.166 Covered surgical procedures.

(a) *Covered surgical procedures.* (1) Effective for services furnished on or after January 1, 2008, through December 31, 2025, covered surgical procedures are those procedures that meet the general standards described in paragraph (b)(1) of this section (whether commonly furnished in an ASC or a physician's office) and are not excluded under paragraph (c) of this section; and

(2) Effective for services furnished on or after January 1, 2026, covered surgical procedures are those procedures that meet the requirements described in paragraph (b)(2) of this section (whether commonly furnished in an ASC or a physician's office).

(b) *Requirements for covered surgical procedures*. (1) *General Standards.* Effective for services furnished on or after January 1, 2008 through December 21, 2025, subject to the exclusions in paragraph (c) of this section, covered surgical procedures are surgical procedures specified by the Secretary and published in the **Federal Register** and/or via the internet on the CMS website that are separately paid under the OPPS, that would not be expected to pose a significant safety risk to a Medicare beneficiary when performed in an ASC, and for which standard medical practice dictates that the beneficiary would not typically be expected to required active medical monitoring and care at midnight following the procedure.

(2) Effective for services furnished on or after January 1, 2026, covered surgical procedures are surgical procedures specified by the Secretary that are published in the **Federal Register** and/or via the internet on the CMS website and that:

(i) Are separately paid under the OPPS; and

(ii) Are not:

(A) Currently designated as requiring inpatient care under § 419.22(n) of this subchapter;

(B) Only able to be reported using a CPT unlisted surgical procedure code; or

(C) Otherwise excluded under § 411.15 of this chapter.

(c) *General exclusions effective January 1, 2008, through December 31, 2025.* Notwithstanding paragraph (b)(1) of this section, covered surgical procedures do not include those surgical procedures that:

(1) Generally result in extensive blood loss;

(2) Require major or prolonged invasion of body cavities;

(3) Directly involve major blood vessels;

(4) Are generally emergent or life-threatening in nature;

(5) Commonly require systemic thrombolytic therapy;

(6) Are designated as requiring inpatient care under § 419.22(n) of this subchapter;

(7) Can only be reported using a CPT unlisted surgical procedure code; or

(8) Are otherwise excluded under § 411.15 of this chapter.

(d) *Physician considerations beginning January 1, 2026.* Physicians consider the following safety factors as to a specific beneficiary when determining whether to perform a covered surgical procedure. The covered procedure:

(1) Is not expected to pose a significant safety risk when performed in an ASC;

(2) Is one of which standard medical practice dictates the beneficiary would not typically be expected to required active medical monitoring and care at midnight following the procedure;

(3) Generally results in extensive blood loss;

(4) Requires major or prolonged invasion of body cavities;

(5) Directly involves major blood vessels;

(6) Is generally emergent or life-threatening in nature; and

(7) commonly requires systemic thrombolytic therapy.

(e) *Additions to the list of ASC covered surgical procedures beginning January 1, 2026.* On or after January 1, 2026, CMS adds surgical procedures to the list of ASC covered procedures as follows:

(1) CMS identifies a surgical procedure that meets the requirements at paragraph (b)(2) of this section.

(2) CMS is notified of a surgical procedure that could meet the requirements at paragraph (b)(2) of this section and CMS confirms that such surgical procedure meets those requirements.

16. Section 416.171 is amended by revising paragraphs (a)(2)(iii) through (viii) to read as follows:

§ 416.171 Determination of payment rates for ASC services.

(a) * * *

(2) * * *

(iii) For CY 2019 through CY 2026, the update is the hospital inpatient market basket percentage increase applicable under section 1886(b)(3)(B)(iii) of the Act.

(iv) For CY 2027 and subsequent years, the update is the Consumer Price Index for All Urban Consumers (U.S. city average) as estimated by the Secretary for the 12-month period ending with the midpoint of the year involved.

(v) For CY 2014 through CY 2018, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(ii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vi) For CY 2019 through CY 2026, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(vii) For CY 2027 and subsequent years, the Consumer Price Index for All Urban Consumers update determined under paragraph (a)(2)(iv) of this section is reduced by 2.0 percentage points for an ASC that fails to meet the standards for reporting of ASC quality measures as established by the Secretary for the corresponding calendar year.

(viii)(A) For CY 2011 through CY 2018, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(ii) of this section, after application of any reduction under paragraph (a)(2)(iv) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(B) For CY 2019 through CY 2026, the hospital inpatient market basket percentage increase determined under paragraph (a)(2)(iii) of this section, after application of any reduction under paragraph (a)(2)(v) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

(C) For CY 2027 and subsequent years, the Consumer Price Index for All Urban Consumers determined under paragraph (a)(2)(iv) of this section, after application of any

reduction under paragraph (a)(2)(vii) of this section, is reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act.

* * * * *

17. Section 416.174 is amended by revising paragraph (c)(1) to read as follows:

§ 416.174 Payment for non-opioid pain management drugs, biologicals, and medical devices.

* * * * *

(c) * * *

(1) For a qualifying medical device as defined in paragraph (b) of this section, the amount of payment is the amount of the hospital's charges for the device, adjusted to cost, that exceeds the portion of the otherwise applicable Medicare OPD fee schedule amount, subject to paragraph (c)(3) of this section.

* * * * *

18. Section 416.310 is amended by revising paragraph (d) to read as follows:

§ 416.310 Data collection and submission requirements under the ASCQR 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 ASC. For purposes of this paragraph (d), an extraordinary circumstance is an event beyond the control of an ASC (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the ASC to comply with one or more applicable reporting requirements with respect to a calendar year.

(2) *Process for requesting an ECE*.

(i) An ASC may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the ASC of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the ASC, the written decision specifies whether the ASC is exempted from one or more reporting requirements or whether CMS has granted the ASC 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 ASCs that have not requested an ECE if CMS determines that—

(i) A systemic problem with a CMS data collection system directly impacted the ability of the ASC to comply with a quality data reporting requirement; or

(ii) An extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (d)(3) specifies whether the affected ASCs are exempted from one or more reporting requirements or whether CMS has granted the ASCs an extension of time to comply with one or more reporting requirements.

* * * * *

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

19. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

20. Section 419.2 is amended by revising paragraph (b)(16) to read as follows:

§ 419.2 Basis of payment.

* * * * *

(b) * * *

(16) Drugs and biologicals that function as supplies when used in a surgical procedure including, but not limited to, products, excluding skin substitutes, that aid wound healing.

* * * * *

21. Section 419.22 is amended by revising paragraph (n) to read as follows:

§ 419.22 Hospital services excluded from payment under the hospital outpatient prospective payment system.

* * * * *

(n) Services and procedures that the Secretary designates as requiring inpatient care. Effective beginning on January 1, 2026, the Secretary shall eliminate the list of services and procedures designated as requiring inpatient care through a 3-year transition, with the list eliminated in its entirety by January 1, 2029.

* * * * *

22. Section 419.23 is removed.

§ 419.23 [Removed].

23. Section 419.32 is amended by revising paragraph (b)(1)(iv)(B)(*12*) to read as follows:

§ 419.32 Calculation of prospective payment rates for hospital outpatient services.

* * * * *

(b) * * *

(1) * * *

(iv) * * *

(B) * * *

(*12*) Beginning in calendar year 2026, a multifactor productivity adjustment (as determined by CMS), and 2.0-percentage point reduction, except that the 2.0-percentage point reduction shall not apply to hospital outpatient items and services furnished by a hospital with a CMS certification number (CCN) effective date of January 2, 2018, or later. This reduction and associated exception to the reduction will be in effect until the estimated payment reduction reaches $7.769 billion, as further described in each calendar year's rule.

* * * * *

24. Section 419.46 is amended by revising paragraph (e) to read as follows:

§ 419.46 Requirements under the Hospital Outpatient Quality Reporting (OQR) Program.

* * * * *

(e) *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 (e), 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 calendar year.

(2) *Process for requesting an ECE*.

(i) A hospital may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the hospital of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the hospital, the written decision specifies whether the hospital is exempted from one or more reporting requirements or whether CMS has granted the hospital an extension of time to comply with one or more reporting requirements.

(3) *Authority to Grant an ECE.* CMS may grant an ECE to one or more hospitals that have not requested an ECE if CMS determines that—

(i) 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

(ii) An extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (e)(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.

* * * * *

25. Section 419.49 is added to read as follows:

§ 419.49 Additional payment for technetium-99m (Tc-99m) derived from domestically produced molybdenum-99 (Mo-99).

(a) General rule. CMS provides for an additional payment (as specified in this section § 419.49) beyond the standard payment to a hospital for a dose of Tc-99m derived from Mo-99, if at least 50 percent of the Mo-99 in the Tc-99m generator that produced the dose was both irradiated and processed in the United States.

(1) Domestically produced Mo-99 refers to Mo-99 that was both irradiated and processed in the United States.

(2) Irradiated refers to the process of bombarding a uranium or molybdenum target with radiation in order to produce Mo-99. Irradiation is typically performed with a nuclear reactor or particle accelerator.

(3) Processed refers to the purification of Mo-99 from irradiated material.

(b) Exclusions. A dose of Tc-99m does not qualify for the add-on payment if more than 50 percent of the Mo-99 in the Tc-99m generator was irradiated or processed outside the United States, even if the Mo-99 has been loaded into a Tc-99m generator in the United States or if the Tc-99m has been eluted at a radiopharmacy in the United States.

(1) Eluted refers to the process by which Tc-99m is chemically separated from Mo-99 within the generator and collected in an elution vial.

(2) [Reserved].

26. Section 419.64 is amended by removing paragraph (a)(4)(iv).

§ 419.64 Transitional pass-through payments: Drugs and biologicals. [Amended]

27. Section 419.95 is amended by revising paragraph (g) and adding paragraph (h) to read as follows:

§ 419.95 Requirements under the Rural Emergency Hospital Quality Reporting (REHQR) Program.

* * * * *

(g) *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 REH. For purposes of this paragraph (g), an extraordinary circumstance is an event beyond the control of an REH (for example, a natural or man-made disaster such as a hurricane, tornado, earthquake, terrorist attack, or bombing) that affected the ability of the REH to comply with one or more applicable reporting requirements with respect to a calendar year.

(2) *Process for requesting an ECE*.

(i) An REH may request an ECE within 30 calendar days of the date that the extraordinary circumstance occurred by submitting the information specified by CMS at QualityNet or a successor website.

(ii) CMS notifies the REH of its decision on the request, in writing, via email. In the event that CMS grants an ECE to the REH, the written decision specifies whether the REH is exempted from one or more reporting requirements or whether CMS has granted the REH 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 REHs that have not requested an ECE if CMS determines that—

(i) A systemic problem with a CMS data collection system directly impacted the ability of the REH to comply with a quality data reporting requirement; or

(ii) An extraordinary circumstance has affected an entire region or locale. Any ECE granted under this paragraph (g)(3) specifies whether the affected REHs are exempted from one or more reporting requirements or whether CMS has granted the REHs an extension of time to comply with one or more reporting requirements.

(h) *Requirements for submission of electronic clinical quality measures (eCQMs) under the REHQR Program*.

When reporting eCQMs under the REHQR Program, REHs must adhere to the following requirements:

(1) REHs must utilize technology certified to the Office of the National Coordinator for Health Information Technology's (ONC's) health information technology (IT) certification criteria, as adopted and updated in 45 CFR 170.315, for reporting eCQMs under the REHQR Program.

(2) REHs must use health IT certified to all eCQMs that are available to report under the REHQR Program.

(3) REHs must use the most recent version of the eCQM electronic measure specifications for the applicable reporting period available on the Electronic Clinical Quality Improvement Resource Center website at *https://ecqi.healthit.gov/*, or another website as designated by CMS.

(4) The requirements set forth in paragraphs (h)(1) through (3) of this section apply only where an REH opts to report an eCQM.

For the reasons set forth in the preamble, the Department of Health and Human Services proposes to amend 45 CFR part 180 as set forth below:

PART 180—HOSPITAL PRICE TRANSPARENCY

28. The authority citation for part 180 continues to read as follows:

Authority: 42 U.S.C. 300gg-18**,** 42 U.S.C. 1302**.**

29. Section 180.20 is amended by adding definitions for "Median allowed amount", "Ninetieth (90th) percentile allowed amount", and "Tenth (10th) percentile allowed amount" in alphabetical order to read as follows.

§ 180.20 Definitions.

* * * * *

Median allowed amount means the median of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer

than the 12 months prior to posting the machine-readable file. Should the calculated median fall between two observed allowed amounts, the median allowed amount is the next highest observed value.

Ninetieth (90th) percentile allowed amount means the 90th percentile of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 90th percentile allowed amount is the next highest observed value.

Tenth (10th) percentile allowed amount means the 10th percentile of the total allowed amounts the hospital has historically received from a third party payer for an item or service for a time period no longer than the 12 months prior to posting the machine-readable file. Should the calculated percentile fall between two observed allowed amounts, the 10th percentile allowed amount is the next highest observed value.

* * * * *

30. Section 180.50 is amended by revising paragraphs (a)(3), (b)(2)(i)(A), and (b)(2)(ii)(C) to read as follows:

§ 180.50 Requirements for making public hospital standard charges for all items and services.

(a) * * *

(3) Each hospital must:

(i) Prior to January 1, 2026, make a good faith effort to ensure that the standard charge information encoded in the machine-readable file is true, accurate, and complete as of the date indicated in the machine-readable file.

(ii) Prior to January 1, 2026, affirm in its machine-readable file that, to the best of its knowledge and belief, the hospital has included all applicable standard charge information in

accordance with the requirements of this section, and that the information encoded is true, accurate, and complete as of the date indicated in the machine-readable file.

(iii) Beginning January 1, 2026, attest in its machine-readable file the following: This hospital has included all applicable standard charge information in accordance with the requirements of 45 CFR 180.50, and the information encoded is true, accurate, and complete as of the date in the file. This hospital has included all payer-specific negotiated charges in dollars that can be expressed as a dollar amount. For payer-specific negotiated charges that cannot be expressed as a dollar amount in the machine-readable file or not knowable in advance, the hospital attests that the payer-specific negotiated charge is based on a contractual algorithm, percentage or formula that precludes the provision of a dollar amount and has provided all necessary information available to the hospital for the public to be able to derive the dollar amount, including, but not limited to, the specific fee schedule or components referenced in such percentage, algorithm or formula.

(iv) Beginning January 1, 2026, encode the name of the hospital chief executive officer, president or senior official designated to oversee the encoding of true, accurate, and complete data as directed in in paragraph (a)(3)(iii) of this section.

(b) * * *

(2) * * *

(i) * * *

(A) Hospital name, license number, location name(s) and address(es) under the single hospital license to which the list of standard charges applies, and beginning January 1, 2026, Type 2 (organizational) National Provider Identifier(s) (NPI). Location name(s) and address(es) must include, at minimum, all inpatient facilities and stand-alone emergency departments; and

* * * * *

(ii) * * *

(C) Whether the standard charge indicated should be interpreted by the user as a dollar amount, or if the standard charge is based on a percentage or algorithm. If the standard charge is based on a percentage or algorithm, the machine-readable file (MRF) must also describe the percentage or algorithm that determines the dollar amount for the item or service, and

(1) Beginning January 1, 2025 through December 31, 2025, calculate and encode an estimated allowed amount in dollars for that item or service; and

(2) Beginning January 1, 2026, calculate and encode the tenth (10^{th}) percentile allowed amount, the median allowed amount, and the ninetieth (90^{th}) percentile allowed amount in dollars for that item or service. Hospitals must also calculate and encode the total number of allowed amount remittances that were used to calculate the 10th percentile allowed amount, median allowed amount, and 90th percentile allowed amount.

* * * * *

31. Section 180.90 is amended by—

a. Adding new paragraph (c)(4);

b. Revising paragraph (d)(1);

c. Redesignating paragraphs (d)(2) and (3) as paragraphs (d)(3) and (4), respectively; and

d. Adding new paragraph (d)(2).

The additions and revision read as follows:

§ 180.90 Civil monetary penalties.

* * * * *

(c) * * *

(4) Except as provided in this paragraph, the amount of a civil monetary penalty is reduced by 35 percent if the hospital submits a written notice to CMS requesting to waive its right to a hearing under § 180.100 within 30-calendar days of the date of the notice of imposition of the civil monetary penalty. A hospital that receives a 35 percent reduction in a civil monetary penalty under this paragraph is not eligible to receive a 35 percent reduction for any civil

monetary penalties imposed pursuant to continuing violations according to § 180.90(f) and also waives its right to appeal under § 180.100 any civil monetary penalties imposed for such continuing violations. A hospital is not eligible to request that CMS reduce the amount of a civil monetary penalty imposed by CMS upon the hospital if –

(i) The hospital does not request to waive its right to a hearing in accordance with this paragraph; or

(ii) CMS imposed the CMP because the hospital failed to make public an MRF as required at § 180.40(a) or failed to make public a consumer-friendly list of standard charges as required at § 180.40(b).

(d) * * *

(1) A hospital that does not meet the criteria to receive a reduction to the civil monetary penalty that had been imposed upon it as set forth in paragraph (c)(4) of this section must pay the civil monetary penalty in full within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

(2) A hospital that meets the criteria to receive a reduction to the civil monetary penalty that had been imposed upon it as set forth in paragraph (c)(4) of this section must pay the civil monetary penalty, as reduced in accordance with paragraph (c)(4) of this section, within 60 calendar days after the date of the notice of imposition of a civil monetary penalty from CMS under paragraph (b) of this section.

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Robert F. Kennedy, Jr.,

Secretary,

Department of Health and Human Services.

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